Ramon Rossi Lopez, SBN 86361
Matthew Ramon Lopez, SBN 263134
LOPEZ McHUGH LLP
100 Bayview Circle, Suite 5600
Newport Beach, CA 92660
Telephone: (949) 737-1501
Facsimile: (949) 737-1504
rlopez@lopezmchugh.com
mlopez@lopezmchugh.com

Julia Reed Zaic, SBN 224671
HEAVISIDE REED ZAIC
213 Broadway Street, Suite 203
Laguna Beach, CA 92651
Telephone: (949) 715-5120
Facsimile: (949) 715-5123
julia@hrzlaw.com

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

JOAN WISEMAN,

Plaintiff,

vs.

COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC. ; COOK INCORPORATED; and COOK GROUP, INC.,

Defendants.

Case No. 8:16-cv-01542

COMPLAINT FOR DAMAGES

1. **STRICT LIABILITY FAILURE TO WARN**
2. **STRICT LIABILITY DESIGN DEFECT**
3. **NEGLIGENCE**
4. **NEGLIGENCE *PER SE***
5. **BREACH OF EXPRESS WARRANTY**
6. **BREACH OF IMPLIED WARRANTY**
7. **VIOLATION OF CALIFORNIA**

LAW PROHIBITING CONSUMER FRAUD AND UNFAIR AND DECEPTIVE TRADE PRACTICES

8. LOSS OF CONSORTUM

9. PUNITIVE DAMAGES

DEMAND FOR JURY TRIAL

Plaintiff Joan Wiseman, by and through her undersigned attorney, brings this action against the Defendants, Cook Medical Incorporated a/k/a Cook Medical Inc., Cook Incorporated, and Cook Group Incorporated. (collectively, the "Defendants") and allege as follows: This is an action for damages relating to Defendants' development, testing, assembling, manufacturing, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "inferior vena cava filter" (hereinafter "IVC filter").

PARTIES

1. Plaintiff Joan Wiseman a citizen of California and resided in and continues to reside in Huntington Beach, California.

2. On or about January 11, 2008, Plaintiff underwent placement of a Cook Celect® IVC Filter at Hoag Memorial Presbyterian Hospital in Newport Beach, California.

3. The Cook Celect® IVC Filter subsequently failed, two limbs fractured and one arm of the filter fractured, embolized and lodged in the right side of her

heart; the filter also migrated and perforated her inferior vena cava walls and protruding into her right kidney. Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, loss of enjoyment of life, disability, scarring, disfigurement and other losses. Plaintiff will require ongoing medical care.

4. Plaintiff was caused to undergo extensive medical care as a result of the failure of the Cook Celect® IVC Filter manufactured by the Cook Defendants. Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, loss of enjoyment of life, disability, scarring, disfigurement and other losses.

5. Defendant Cook Medical Incorporated a/k/a Cook Medical, Inc. is an Indiana Corporation with a principal place of business located at 750 Daniels Way, Bloomington, Indiana 47404. Defendant Cook Medical Incorporated a/k/a Cook Medical, Inc. regularly conducts business in the United States to include the State of Indiana, and is authorized to do so and is a citizen of Indiana.

6. Defendant Cook Incorporated is the parent company of defendant Cook Medical Incorporated a/k/a Cook Medical, Inc. and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana 47402. Defendant Cook Incorporated regularly conducts

business in the United States to include the State Indiana, and is authorized to do so and is a citizen of Indiana.

7. Defendant Cook Group, Inc. is the parent company of Defendant Cook Medical Incorporated and Cook Incorporated and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group Inc. regularly conducts business in the United States to include the State of Indiana, and is authorized to do so and is a citizen of Indiana.

8. Defendant William Cook Europe APS is based in Bjaeverskov, Denmark and regularly conducts business in the United States to include the State Indiana, and is authorized to do so.

9. Hereinafter, each of the above Defendants shall be collectively referred to as "Cook."

10. At all times alleged herein, the Cook defendants include any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

11. Cook develops, manufactures, sells and distributes medical devices for use in various medical applications including endovascular cardiology, and

surgical products throughout the United States and around the world. Cook's products at issue in this matter include the Cook Celect® Vena Cava Filter, the Gunther Tulip® Vena Cava Filter, and Celect Platinum® IVC Filter all of which are used for the prevention of recurrent pulmonary embolism via placement in the vena cava.

STATEMENT OF JURISDICTION

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

13. The Court has personal jurisdiction over the Defendants under 28 U.S.C. §1391, as all Defendants regularly conduct business in the state of California. Further, Defendants are present and doing business within this state and have continuous and systematic contacts in this state. Defendant's activities include: marketing, advertising, promoting, distributing, and receiving substantial compensation and profits from sales and other acts that caused or contributed to the harm giving rise to this action. Defendants also made or caused to be made material omissions and misrepresentations and breaches of warranties in California to Plaintiff.

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VENUE

14. Venue is proper in this Court under 28 U.S.C. § 1391, as a substantial part of the events or omissions giving rise to the claim occurred within this judicial district and the Defendants regularly conduct business in this District.

15. A substantial amount of activity giving rise to the claims occurred in this District, and Defendants may be found within this District. Therefore, venue is proper in this jurisdiction under 28 U.S.C. §1391.

FACTUAL BACKGROUND

16. Defendants design, research, develop, manufacturer, test, market, advertise, promote, distribute, and sell products that are sold to and marketed to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. Defendant's products include, the Cook Celect Vena Cava Filter and the Gunther Tulip Filter (hereinafter "Cook Filters"), which are introduced via a coaxial introducer sheath system.

17. The Cook Filters are collectively referred to herein as the Cook Filters.

18. Defendants sought Food and Drug Administration ("FDA") approval to market the Cook Filter's and/or its components under Section 510(k) of the Medical Device Amendment.

19. Section 510(k) allows marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" process in an amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp*., 376 F.3d 163, 167 (3d Cir.2004):

> A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a premarket notification to the agency in accordance with section 510(k)…A device found to be 'substantially equivalent' to a predicate device is said to be "cleared" by FDA (as opposed to "approved" by the agency under a [premarket approval]). A pre-market notification submitted under 510(k) is thus entirely different from a [pre-market approval] which must include data sufficient to demonstrate that the device is safe and effective. (Emphasis in original).

20. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470,478-79 (1996), the Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] §510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…The §510(k) notification process is by no means comparable to the [premarket approval] process; in contract to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in average of 20

> hours…Section §510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets process quickly.

21. An IVC filter, like the Cook Filter's, is a device designed to filter blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either temporarily or permanently, within the vena cava.

22. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach the lungs they are considered "pulmonary emboli" or PE. An IVC filter, like the Cook IVC Filters, is designed to prevent thromboembolic events by filtering or preventing blood clots/thrombi from traveling to the heart and/or lungs.

23. The Cook Celect® IVC Filter was sold and marketed as a **temporary/retrievable filter**, and is based on the Gunther Tulip® IVC Filter, which is was initially cleared as a permanent filter, and later cleared as a retrievable filter.

24. The Cook Celect® Vena Cava Filter has four (4) anchoring struts for fixation and eight (8) independent secondary struts to improve self-centering and clot trapping.

25. On or about January 11, 2008, Joan Wiseman was diagnosed with an extensive thrombosis at Hoag Hospital Presbyterian in Newport Beach, California. It was determined that she would be implanted with a temporary/retrievable IVC Filter known as the Cook Celect® IVC Filter which was designed, manufactured, marketed, distributed and sold by Cook. The Cook Celect® IVC Filter was implanted into Joan Wiseman on January 11, 2008. There were no complications at the time of implantation.

26. On September 5, 2015, Joan Wiseman received a call from Dr. John Brown with the results from her CT scan informing her that the Cook Celect® IVC Filter was defective and recommended consulting a doctor regarding removal.

27. On October 30, 2015, Joan Wiseman presented at Stanford University Medical Center for a complex IVC filter retrieval of her Cook Celect® IVC Filter. At this time, it was determined that the Cook Celect® IVC Filter had migrated, apex of the filter tilted medially, perforated through her right renal vein into to her right kidney, two of the filter limbs had fracture, and one of the fractured pieces migrated inferiorly into the posterior retroperitoneum, the other fracture arm resides

in the right ventricle of Joan Wiseman's heart. As such, the decision was made to remove the Cook Celect® IVC Filter.

28. The body of the Cook Celect® IVC Filter was removed including one of the two the fractured limbs; still, one fractured arm remains lodged in the right ventricle of Joan Wiseman's heart.

29. On November 18, 2015, another effort at removal of the fractured arm was endeavored by doctors at Stanford University Medical Center and subsequently abandoned due to the complexity of the injury and the inability to retrieve the fractured arm.

30. At all times relevant hereto the Cook Filters were widely advertised and promoted by the Defendants as a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava. At all times relevant hereto, Defendants knew its Cook Filters were defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

31. In a retrospective review of all Cook Gunther Tulip Filters and Cook Celect Filters retrieved between July 2006 and February 2008 was performed. 130 filter retrievals were attempted but in 33 cases, the standard retrieval technique failed. The authors concluded that "unsuccessful retrieval was due to significant endothelialization and caval penetration" and that "hook endothelialization is the

main factor resulting in failed retrieval and continues to be a limitation with these filters." O Doody, et al.; "Assessment of Snared-Loop Technique When Standard Retrieval of Inferior Vena Cava Filters Fail" Cardiovasc Intervent Radiol (Sept 4, 2008 Technical Note).

32. In another retrospective review of 115 patients who underwent Cook Celect IVC Filter insertion between December 2005 and October 2007. While filter insertion was successful in all patients, the authors also concluded that "'[f]ailed retrieval secondary to hook endothelialization continues to be an issue with this filter." O Doody, et al; Journal of Medical Imaging and Radiation Oncology "Initial Experience in 115 patients with the retrievable Cook Celect vena cava filter" 53 (2009) 64-68 (original article).

33. In a review of clinical data related to 73 patients who had Celect IVC Filter implanted between August 2007 and June 2008, the authors found that the Celect IVC Filter was related to a high incidence of caval filter leg penetration. Immediately after fluoroscopy-guided filter deployment in 61 patients, four filters (6.5%) showed significant tilt. Follow-up abdominal CT in 18 patients demonstrated filter related problems in 7 (39%), which included penetration of filter legs in 4 and fracture/migration of filter components in 1.

34. In a study of Gunther Tulip and Celect IVC Filters implanted between July 2007 and May of 2009 reported by Cardiovascular Interventional Radiology

electronically on March 30, 2011and published by journal in April 2012, one hundred percent of the Cook Celect filters and Gunther Tulip filters imaged after 71 days of implant caused some degree of filter perforation of the venal caval wall. Durack JC, et al, Cardiovasc Intervent Radiol "Perforation of the IVC: rule rather than the exception after longer indwelling times for the Gunther Tulip and Celect Retrievable Filters," 2012 Apr.; 35(2):299-308. Epub 2011 Mar 30. Defendants knew or should have known that their IVC filters were more likely than not to perforate the vena cava wall.

35. This same study reported that tilt was seen in forty percent of the implanted Gunther Tulip and Celect IVC Filters. Defendants knew or should have known that their IVC filters were more likely than not tilt.

36. While not inclusive of all medical studies published during the relevant time period, the above references show that the Defendants failed to disclose to physicians, patients or Plaintiff that its Cook Filters **were subject to breakage, tilt, unable to be removed and migration** even though they knew or should have known the same was true**.**

37. At all times relevant hereto, the Defendants continued to promote the Cook Filter as safe and effective even when inadequate clinical trials had been performed to support long or short to safety and/or efficacy.

38. The Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook Filters, as aforesaid.

39. The Defendants failed to disclose to physicians, patients, or Plaintiff that it's Cook Filter was subject to not being removed/retrieved once the risk for pulmonary emboli has passed thus placing patients at risk for injury due to breakage and migration or risk of perforation and damage to the vena cava wall. These patients also require lifetime anticoagulation medication(s) and are at high risk for hemorrhage.

40. The Cook Filters are constructed of conichrome.

41. The Defendants specifically advertise the conichrome construction of the filter as a frame which "reduces the risk of fracture."

42. The failure of the Cook Filters is attributable, in part, to the fact that the Cook Filters suffer from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

43. At all times relevant hereto the Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff(s) and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Filters, including, but not limited to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

44. The Cook Filters were designed, manufactured, distributed, sold and/or supplied by the Defendant, and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendant's knowledge of the products failure and serious adverse events.

45. That at all times relevant hereto, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of the said products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by the Plaintiff.

PLAINTIFF'S CAUSES OF ACTION

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

46. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

47. Cook IVC Filters were defective and unreasonably dangerous when they left the possession of the Defendants in that they contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation,

fracture and migration which are associated with and did cause serious injury and/or death.

48. Information provided by Cook to the medical community and to consumers concerning the safety and efficacy of it IVC Filters did not accurately reflect the serious and potentially fatal adverse events Plaintiff could suffer.

49. At all times relevant hereto, the Cook IVC Filters were dangerous and presented a substantial danger to patients who were implanted with the Cook IVC Filter, and these risks and dangers were known or knowable at the times of distribution and implantation in Plaintiff. Ordinary consumers would not have recognized the potential risks and dangers the Cook IVC Filter posed to patients, because its use was specifically promoted to improve health of such patients.

50. Had adequate warnings and instructions been provided, Plaintiff would not have been implanted with Cook IVC Filters, and would not have been at risk of the harmful injuries described herein. The Defendants failed to provide warnings of such risks and dangers to the Plaintiff and their medical providers as described herein. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused b Cooks' IVC Filters.

51. Defendants knew or had knowledge that the warnings that were given failed to properly warn of the increased risks of serious injury and/or death associated with and/or caused by Cook IVC Filters.

52. Plaintiff, individually and through her implanting physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

53. Defendants had a continuing duty to warn Plaintiff and their physicians of the dangers associated with the subject product.

54. Safer alternatives were available that were effective and without risks posed by Cooks IVC Filters.

55. As a direct and proximate result of the Cook IVC Filter's defects, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff have lost earnings and will continue to lose earnings into the future and have medical bills both past and future related to care because of the Cook IVC Filter's defects.

56. By reason of the foregoing, Defendant is liable to the Plaintiff for damages as a result of its failure to warn and/or adequately warn the Plaintiff and

healthcare professionals about the increased risk of serious injury and death caused by their defective IVC filter.

WHEREFORE, plaintiff Joan Wiseman demands judgment against the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, and Cook Group, Inc. for whatever amount he may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

57. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

58. Defendants have a duty to provide adequate warnings and instructions for its products including its IVC Filters, to use reasonable care to design a product that is not unreasonably dangerous to users.

59. At all times relevant to this action, Defendants designed, tested, manufactured, packaged, labeled, marketed, distributed, promoted and sold its IVC Filters, placing the devices into the stream of commerce.

60. At all times relevant to this action, Cook's IVC Filters were designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by

Defendants in a condition that was defective and unreasonably dangerous to consumers, including Plaintiff.

61. Cook IVC Filters are defective in their design and/or formulation in that they are not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

62. Cook IVC Filters were expected to reach, and did reach, users and/or consumers, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which they were manufactured and sold.

63. Physicians implanted as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommend, promoted, and marketed by the Defendants. Plaintiff received and utilized Cook IVC Filters in a foreseeable manner as normally intended recommend, promoted, and marketed by the Defendants.

64. Cook IVC Filters were and are unreasonably dangerous in that, as designed, it failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

65. Cook IVC Filters were and are unreasonably dangerous and defective in design or formulation for their intended use in that, when they left the hands of the manufacturers and/or supplier, they posed a risk of serious vascular and other

serious injury which could have been reduced or avoided, inter alia, by the adoption of feasible reasonable alternative design. There were safer alternative designs for the like product.

66. Cook IVC Filters were insufficiently tested and caused harmful adverse events that outweighed any potential utility.

67. Cook IVC Filters, as manufactured and supplied, were defective due to inadequate warnings, and/or inadequate clinical trials, testing, and study, and inadequate reporting regarding the results of the clinical trials, testing and study.

68. Cook IVC Filters, as manufactured and supplied, were defective due to its no longer being substantially equivalent to its predicate device with regard to safety and effectiveness.

69. Cook IVC Filters as manufactured and supplied by the defendants are and were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from use and acquired additional knowledge and information confirming the defective and dangerous nature of its IVC Filters, Defendants failed to provide adequate warnings to the medical community and the consumers, to whom Defendant was directly marketing and advertising; and further, Defendant continued to affirmatively promote its IVC Filters as safe and effective and as safe and effective as its predicate device.

70. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the IVC filter's defect.

71. By reason of the foregoing, Defendant is liable to the Plaintiff for damages as a result of its failure to warn and/or adequately warn the Plaintiff and healthcare professionals about the increased risk of serious injury and death caused by their defective IFC filters.

WHEREFORE, the Plaintiff Joan Wiseman demands judgment against the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, and Cook Group, Inc. for whatever amount he may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

THIRD CAUSE OF ACTION

NEGLIGENCE

72. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

73. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including its Cook IVC Filters.

74. At all times relevant hereto, the Cook Defendants were under a duty to act reasonably to design, develop, manufacture, market and sell a product that did not present a risk of harm or injury to the Plaintiff and to those people receiving its Cook IVC Filters.

75. At the time of manufacture and sale of the Cook IVC Filters, the Cook Defendants knew or reasonably should have known the Cook IVC Filter:

a. was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device, as aforesaid;

b. was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device, as aforesaid; and/or

c. was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

d. was designed and manufactured so as to present an unreasonable risk of perforation and damage to the vena caval wall.

76. Despite the aforementioned duty on the party of the Cook Defendants they committed one or more breaches of their duty of reasonable care and were negligent in:

a. unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Cook IVC Filter, specifically its incidents fracture, migration, perforation and other failure;

b. unreasonably and carelessly manufactured a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. unreasonably and carelessly designed a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

d. unreasonably and carelessly designed a product that presented a risk of harm to the Plaintiff and others similarly situated in that it was prone to fail.

77. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the Cook IVC Filters' defects.

78. By reason of the foregoing, Defendant is liable to the Plaintiff for damages as a result of its failure to warn and/or adequately warn the Plaintiff and

healthcare professionals about the increased risk of serious injury and death caused by their defective IVC filters.

WHEREFORE, the Plaintiff Joan Wiseman demands judgment against the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, and Cook Group, Inc. for whatever amount he may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

FOURTH CAUSE OF ACTION

NEGLIGENCE *PER SE*

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

79. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

80. At all times herein mentioned, Defendants had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning and post-sale warning and other communications of the risks and dangers of Cook IVC Filters.

81. By reason of its conduct as alleged herein, Cook violated provisions of statutes and regulations, including but not limited to, the following:

a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§331 and 352, by misbranding its Cook IVC Filters;

b. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 in making statements and/or representations via word, design, device or any combination thereof failing to reveal material facts with respect to the consequences that may result from the use of Cook IVC Filters to which the labeling and advertising relates;

c. Defendants violated the 21 C.F.R. §1.21 in misleading the consumers and patients by concealing material facts in light of representations made regarding safety and efficacy of its Cook IVC Filters;

d. Defendants violated the 21 C.F.R. §801 in mislabeling its Cook IVF Filters as to safety and effectiveness of its products and by failing to update its label to reflect post-marketing evidence that Cook IVC Filters were associated with an increased risk of injuries due to tilting, fracture, migration and perforation;

e. Defendants violated the 21 C.F.R. §803 by not maintaining accurate medical device reports regarding adverse events of tilting, fracture,

migration and perforation and/or misreporting these adverse events maintained via the medical device reporting system;

f. Defendants violated the 21 C.F.R. §807 by failing to notify the FDA and/or the consuming public when its Cook IVC Filters were no longer substantially equivalent with regard to safety and efficacy with regard to post-marketing adverse events and safety signals;

g. Defendants violated the 21 C.F.R. §820 by failing to maintain adequate quality systems regulation including, but not limited to, instituting effective corrective and preventative actions

WHEREFORE, the Plaintiff Joan Wiseman demands judgment against the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, and Cook Group, Inc. for whatever amount he may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

82. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action. Plaintiff, though their medical providers, purchased a Cook IVC Filter from the Cook Defendants.

83. At all times to this cause of action, the Cook Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e, Cook IVC Filters).

84. At the time and place of sale, distribution and supply of the Cook IVC Filter to Plaintiff, the Defendants expressly represented and warranted in their marketing materials, both written and orally, and in the IFUs, that the Cook IVC Filter was safe, well-tolerated, efficacious, and fit for its intended purpose and was of marketable quality, that it did not produce any unwarned-of dangerous side effects, and that it was adequately tested.

85. At the time of Plaintiff's purchase from Defendants, the Cook IVC Filters were not in a merchantable condition and Defendants breached its expressed warranties, in that:

a. It was designed in such a manner so as to be prone to a unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

b. It was designed in such a manner so as to result in a unreasonably high incident of injury to the organs of its purchaser; and

c. It was manufactured in such a manner so that the exterior surface of the Cook Filter was inadequately, improperly and inappropriately designed causing the device to weaken and fail.

86. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the IVC filter's defect.

87. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of its breach express warranty.

WHEREFORE, the Plaintiff Joan Wiseman demands judgment against the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, and Cook Group, Inc. for whatever amount he may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

88. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

89. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold its IVC Filters.

90. At all relevant times, the defendants intended its IVC Filters be used in the manner that Plaintiff in fact used them.

91. Defendant impliedly warranted its IVC Filters to be of merchantable quality, safe and fit for the use for which the Defendants intended them and Plaintiff in fact used.

92. Defendants breached its implied warranties as follows:

a. Defendants failed to provide the warning or instruction and/or an adequate warning or instruction which a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that its Cook IVC Filters would cause harm;

b. Defendants manufactured and/or sold its Cook IVC Filters and said filters did not conform to representations made by the Defendant when it left the Defendant's control;

c. Defendants manufactured and/or sold its Cook IVC Filters which were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the Cook Filter design or formulation exceeded the benefits associated with that design.

These defects existed at the time the product left the Defendant's control; and

d. Defendants manufactured and/or sold its Cook IVC Filters when it deviated in a material way from the design specifications, formulas or performance standards or form otherwise identical units manufactured to the same design specifications, formulas, or performance standards, and these defects existed at the time the product left the Defendant's control.

93. Further, Defendants' marketing of its Cook IVC Filters was false and/or misleading.

94. Plaintiff through her attending physicians relied on these representations in determining which IVC filter to use for implantation in the Plaintiff.

95. Defendants' filters were unfit and unsafe for use by users as it posed an unreasonable and extreme risk of injury to persons using said products, and accordingly Defendants breached their expressed warranties and the implied warranties associated with the product.

96. The foregoing warranty breaches were a substantial factor in causing Plaintiff's injuries and damages as alleged.

97. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the IVC filter's defect.

98. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of its breaches of implied warranty.

WHEREFORE, the Plaintiff Joan Wiseman demands judgment against the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, and Cook Group, Inc. for whatever amount he may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

SEVENTH CAUSE OF ACTION

VIOLATION OF CALIFORNIA LAW PROHIBITING CONSUMER FRAUD AND UNFAIR AND DECEPTIVE TRADE PRACTICES

99. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

100. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of Cook's IVC Filter to Plaintiff.

101. Defendants engaged in unfair, unconscionable, deceptive, fraudulent and misleading acts or practices in violation of all states' consumer protection laws, identified below.

102. Through its false, untrue and misleading promotion of Cook's IVC Filters, Defendants induced Plaintiff to purchase and/or pay for the purchase of Cook's IVC Filters.

103. Defendants misrepresented the alleged benefits and characteristics of Cook's IVC Filters; suppressed, omitted, concealed, and failed to disclose material information concerning known adverse effects of Cook's IVC Filters; misrepresented the quality and efficacy of Cook's IVC Filters as compared to much lower-cost alternatives; misrepresented and advertised that Cook's' IVC Filters was of a particular standard, quality, or grade that it was not; misrepresented Cook's IVC Filters in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiff would have opted for an alternative IVC Filter or method of preventing pulmonary emboli.

104. Defendants' conduct created a likelihood of, and in fact caused, confusion and misunderstanding. Defendants' conduct misled, deceived and damaged Plaintiff, and Defendants' fraudulent, misleading and deceptive conduct

was perpetrated with an intent that Plaintiff rely on said conduct by purchasing and/or paying for purchases of Cook's IVC Filters. Moreover, Defendants knowingly took advantage of Plaintiff who was reasonably unable to protect her interests due to ignorance of the harmful adverse effects of the Cook's IVC Filter.

105. Defendants' conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable and substantially injurious to Plaintiff and offends the public conscience.

106. Plaintiff purchased Cook's IVC Filter primarily for personal, family, or household purposes.

107. As a result of Defendants' violative conduct, Plaintiff purchased and/or paid for purchase of the Cook IVC Filter that was not made for resale.

108. Defendant engaged in unfair competition or deceptive acts or practices in violation of Cal. Civ. Code § 1770, *et seq.* (the "Consumer Legal Remedies Act"), and Cal. Bus. & Prof. Code § 17200 *et seq.* and § 17500 *et seq.*

WHEREFORE, the Plaintiff Joan Wiseman demands judgment against the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, and Cook Group, Inc. for whatever amount he may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

EIGHTH CAUSE OF ACTION

LOSS OF CONSORTIUM

109. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

110. At all times relevant hereto the Plaintiff's spouse ("Spouse Plaintiff") and/or family members ("Family Member Plaintiff") have suffered injuries and losses as a result of the Plaintiff's injuries.

111. For the reasons set forth herein, Spouse Plaintiff and/or Family Member Plaintiff have necessarily paid and have become liable to pay for medical aid, treatment, and medications, and will necessarily incur further expenses of a similar nature in the future as a proximate result of the Defendant's misconduct.

112. For the reasons set forth herein, Spouse Plaintiff and/or Family Member Plaintiff have suffered and will continue to suffer the loss of her loved ones' support, companionship, services, society, love, and affection.

113. For Spouse Plaintiff, Plaintiff alleges her marital relationship has been impaired and depreciated, and the marital association between husband and wife has been altered.

114. Spouse Plaintiff and/or Family Member Plaintiff have suffered great emotional pain and mental anguish.

115. As a direct and proximate result of the Defendants' misconduct, Spouse Plaintiff and/or Family Member Plaintiff have sustained injuries and damages alleged herein and other damages to be proved at trial.

116. By reason of the foregoing, Defendants are liable to Spouse Plaintiff and/or Family Member Plaintiff for damages as a result of its misconduct.

WHEREFORE, the Plaintiff Joan Wiseman demands judgment against the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, and Cook Group, Inc. for whatever amount he may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

NINTH CAUSE OF ACTION

PUNITIVE DAMAGES

117. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

118. At all times material hereto, Defendants knew or should have known that it's Cook IVC Filter were inherently dangerous with respect to the risk of tilt, fracture, migration and/or perforation.

119. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of its Cook IVC Filters.

120. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff's physicians, concerning the safety of its Cook IVC Filter. The Defendant's conduct was willful, wanton, and undertaken with a conscious indifference to the consequences that consumers of their product faced, including Plaintiff.

121. At all times material hereto, Defendants knew and recklessly disregarded the fact that its Cook IVC Filters have an unreasonably high rate of tilt, fracture, migration and/or perforation.

122. Notwithstanding the foregoing, Defendant continued to market its Cook IVC Filters aggressively to consumers, including Plaintiff, without disclosing the aforesaid side effects.

123. Defendants knew of its' IVC Filters' lack of warnings regarding the risk of fracture, migration, and/or perforation, but it intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell its Filters without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious disregard of the foreseeable harm caused by Cook's IVC Filters.

124. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff's physicians of necessary information to enable her to weigh the true risks of using Cook IVC Filters against its benefits.

125. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the safety and rights of consumers including Plaintiff, have suffered and will continue to suffer severe and permanent physical and emotional injuries, as described with particularity, above. Plaintiff has endured and will continue to endure pain, suffering, and loss of enjoyment of life; and have suffered and will continue to suffer economic loss, including incurring significant expenses for medical care and treatment and lost wages.

126. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the safety and rights of consumers including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

PRAYER FOR DAMAGES

The Plaintiff Joan Wiseman demands judgment against the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, and Cook Group, Inc., for whatever amount he may be entitled, including punitive damages

if deemed applicable, together with costs of this action. The jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

DEMAND FOR JURY TRIAL

The Plaintiff respectfully requests a trial by jury in the above case as to all issues.

Date: August 22, 2016

Respectfully Submitted,

LOPEZ McHUGH

By: */s/Matthew R. Lopez*
Ramon Rossi Lopez, Bar No. 86361
Matthew R. Lopez, Bar No. 263134

-And-

Julia Reed Zaic, Bar No. 224671
HEAVISIDE REED ZAIC

Attorneys for Plaintiff