

3. Plaintiff AUBREY WEAVER, JR. is one of four surviving children of decedent ANNETTE WEAVER and brings this action pursuant to Texas Civil Practice & Remedies Code § 71.004 individually and as representative of the estate of ANNETTE WEAVER, deceased, and for the benefit of all of decedent's surviving children listed below:

| <u>Name</u> | <u>Relationship to Decedent</u> |
|--------------|---------------------------------|
| Terry Vaughn | Adult Child |
| Kerry Vaughn | Adult Child |
| Marci Rogers | Adult Child |

4. 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, P.O. Box 1608, Bloomington, Indiana 47404. Defendant COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., regularly conducts business in the state of Texas.

5. 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 47404. Defendant COOK INCORPORATED regularly conducts business in the state of Texas.

6. 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 47404. Defendant COOK GROUP INC. regularly conducts business in the state of Texas.

7. Defendant COOK MEDICAL LLC is an Indiana Corporation with principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47404. Defendant COOK MEDICAL LLC regularly conducts business in the state of Texas.

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

9. At all times alleged herein, Cook Defendants include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, 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.

10. 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 include the Gunther Tulip Vena Cava Filter and the Celect Vena Cava Filter, which are used for the prevention of recurrent pulmonary embolism via placement in the vena cava.

11. Defendants COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, and COOK GROUP, INC. may be served with process by serving the Texas Secretary of State, 1019 Brazos Street, Austin, Travis County, Texas 78701, as its agent for service because Defendants engage in business in Texas but do not maintain a regular place of business in this state or a designated agent for service of process, and this suit arose from Defendants' business in Texas.

12. Defendant COOK MEDICAL LLC may be served with process through its registered agent, Corporation Service Company d/b/a CSC – Lawyers Incorporating Service Company, at 211 E. 7th Street, Suite 620, Austin, TX 78701-3218.

VENUE

13. Venue is proper in Midland County pursuant to Texas Civil Practice & Remedies Code § 15.002(a)(1), in that all or substantial part of the events or omissions giving rise to the claim occurred in Midland County.

CLAIMS FOR RELIEF

14. Pursuant to Rule 47 of the Texas Rules of Civil Procedure, Plaintiff hereby seeks monetary relief within the jurisdictional limits of the Court over \$1,000,000 and demands judgment for all other relief to which Plaintiff deems himself entitled.

BACKGROUND

The Inferior Vena Cava (IVC) Filter

15. At all times relevant herein, Defendants designed, researched, developed, manufactured, tested, marketed, advertised, promoted, distributed, and sold products such as IVC filters that are sold to and marketed as a temporary/retrievable device to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. One such Defendants' product, the Cook Celect Vena Cava Filter, is introduced into the vena cava via an 8.5 French coaxial introducer sheath system.

16. The Cook Celect Filter Set is collectively referred to herein as the "Cook Filter."

17. Prior to the implantation of the Cook Filter at issue in this claim, Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the Cook Celect Filter under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

18. An IVC filter, like the Cook Filter, is a device designed to filter blood clots (called “thrombi”) that would otherwise 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.

19. 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. PE presents a grave risk to human life and often results in death.

20. An IVC filter, like the Cook Filter, is designed to prevent thromboembolic events by filtering or preventing blood clots/thrombi from traveling to the heart and/or lungs.

21. The Cook Celect Filter is a retrievable filter, and is based on the Gunther Tulip filter.

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

FACTS

23. On May 6, 2011, decedent ANNETTE WEAVER was admitted to Midland Memorial Hospital located in Midland County, Texas. Upon admission, decedent was diagnosed with pulmonary embolism. It was determined that decedent would be implanted with a temporary/retrievable IVC Filter known as a Cook Celect Filter.

24. On May 10, 2011, a Cook Celect Filter was positioned and placed in decedent ANNETTE WEAVER'S inferior vena cava below her lowest renal vein. There were no complications at the time of implantation and decedent was discharged home on May 11, 2011.

25. On August 29, 2012, decedent ANNETTE WEAVER was admitted to Midland Memorial Hospital after chest x-rays indicated a strut of her Cook Celect Filter appeared to have fractured and migrated into her right lung.

26. On August 31, 2012, doctors attempted to remove decedent ANNETTE WEAVER'S Cook Celect Filter, but could not traverse the filter.

27. Shortly after decedent ANNETTE WEAVER'S unsuccessful filter removal, she returned to her hospital room where she developed sudden disorientation and unresponsiveness. Over the next several days, decedent became totally unresponsive. She remained hospitalized in a comatose condition for the next several weeks and was pronounced dead at Midland Memorial Hospital on September 20, 2012.

28. At all times relevant hereto, the Cook Filter was 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 as a temporary/retrievable device.

29. At all times relevant hereto, Defendants knew their Cook Filter was defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

30. The Defendants failed to disclose to physicians, patients, or decedent ANNETTE WEAVER that their Cook Filter was subject to not being removed/retrieved once the risk for pulmonary emboli had 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.

31. At all times relevant hereto, the Defendants continued to promote the Cook Filter as safe and effective even though the clinical trials that had been performed were not adequate to support long or short term efficacy.

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

33. The Cook Filter is constructed of conichrome.

34. The Defendants specifically advertise the conichrome construction of the filter as a frame which “reduces the risk of fracture.”

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

36. At all times relevant hereto the Defendants failed to provide sufficient warnings and instructions that would have put decedent ANNETTE WEAVER and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Filter, including, but not limited to the design’s failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

37. The Cook Filter was designed, manufactured, distributed, sold and/or supplied by the Defendants and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants’ knowledge of the products’ failure and serious adverse events.

38. 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 said products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by decedent ANNETTE WEAVER.

39. As a direct and proximate result of the negligence of the Cook Defendants, decedent ANNETTE WEAVER was required to undergo an additional surgery to attempt to remove her fractured Colect Filter.

40. Decedent ANNETTE WEAVER died on September 20, 2012 as a proximate result of the failure of her Cook Colect Filter and the injuries stemming from the Defendant's negligence and defective product as described herein.

CAUSES OF ACTION

Negligence

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

42. At all times relevant hereto, the 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 decedent ANNETTE WEAVER and to those people receiving the Cook Filter.

43. The injuries and damages sustained by decedent ANNETTE WEAVER were proximately caused by the negligence of Defendants in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Cook Filter.

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

- a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;
- b. Was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device;
- c. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or,
- d. Was designed and manufactured so as to present an unreasonable risk of perforation and damage to the vena cava wall.

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

- a. Unreasonably and carelessly failed to properly warn of the dangers and risks of harm associated with the Cook 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 decedent ANNETTE WEAVER and others similarly situated in that it was prone to fail.

46. Each act or omission of negligence, acting separately or in combination, was a proximate cause of the damages and injuries to decedent ANNETTE WEAVER, resulting in her death.

Strict Liability - Design Defect

47. At the time the Cook Filter was implanted in decedent ANNETTE WEAVER, Defendants were engaged in the business of selling this product.

48. The Cook Filter was defectively designed when sold.

49. The Cook Filter was unreasonably dangerous, taking into consideration the utility of this product and the risks involved in its use.

50. The Cook Filter reached decedent's implanting doctor and ANNETTE WEAVER without substantial change in the condition in which it was sold.

51. The defective and unreasonably dangerous condition of the Cook Filter was a proximate cause of the damages and injuries to decedent ANNETTE WEAVER resulting in her death.

52. Thus, Defendants are strictly liable to Plaintiff.

Strict Liability - Failure to Warn

53. Defendants manufactured, sold, and/or distributed the Cook Filter that was implanted in decedent ANNETTE WEAVER.

54. At all times mentioned herein, the Cook Filter was dangerous and presented a substantial danger to patients who were implanted with them.

55. The risks and dangers associated with the Cook Filter were known or knowable to Defendants at the time of implantation in decedent ANNETTE WEAVER, yet they failed to provide warnings of such risks and dangers to decedent.

56. Ordinary consumers would not have recognized the potential risks and dangers the Cook Filter posed because their uses were specifically promoted to improve the health of

such patients while the nature and prevalence of such risks were either downplayed or not provided to consumers and their physicians.

57. The Cook Filter was used in a way reasonably foreseeable to Defendants, particularly given the educational material or instructions given to physicians by Defendants.

58. Defendants' failure to adequately warn about the risks and dangers associated with the Cook Filter was a proximate cause of the damages and injuries to decedent ANNETTE WEAVER resulting in her death.

59. Thus, Defendants are strictly liable to Plaintiff.

Breach of Implied Warranty

60. Defendants impliedly warranted that the Cook Filter was merchantable and was fit for the ordinary purpose for which it was intended.

61. When the Cook Filter was implanted in decedent ANNETTE WEAVER to treat her medical conditions, this product was being used for the ordinary purpose for which it was intended.

62. Decedent ANNETTE WEAVER, individually and/or by and through her physicians, relied upon Defendants' implied warranty of merchantability in consenting to have the Cook Filter implanted.

63. Defendants breached this implied warranty of merchantability because the Cook Filter implanted in decedent was neither merchantable nor suited for its intended use as warranted.

64. Defendants' breaches of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in decedent's body, placing ANNETTE WEAVER's health and safety in jeopardy.

65. Defendants' breaches of the aforementioned implied warranties were a proximate cause of the damages and injuries to decedent ANNETTE WEAVER resulting in her death.

Breach of Express Warranty

66. Defendants made assurances to the general public, hospitals, and health care professionals that the Cook Filter was safe and reasonably fit for its intended purpose.

67. Decedent ANNETTE WEAVER and/or her healthcare providers chose the Cook Filter based upon Defendants' warranties and representations regarding the safety and fitness of the Cook Filter.

68. Decedent ANNETTE WEAVER, individually, and/or by and through her physicians, reasonably relied upon Defendants' express warranties and guarantees that the Cook Filter was safe, merchantable, and reasonably fit for its intended purpose.

69. Defendants breached these express warranties because the Cook Filter implanted in decedent ANNETTE WEAVER was unreasonably dangerous and defective and not as they had represented.

70. Defendants' breaches of their express warranties resulted in the implantation of unreasonably dangerous and defective products in decedent ANNETTE WEAVER'S body, placing decedent's health and safety in jeopardy.

71. Defendants' breaches of the aforementioned express warranties were a proximate cause of the damages and injuries to decedent ANNETTE WEAVER resulting in her death.

Wrongful Death

72. Plaintiff AUBREY WEAVER, JR. and decedent's surviving children have suffered pecuniary loss from the death of their mother, ANNETTE WEAVER, including losses of care, maintenance, support, services, advice, counsel, and contributions of a pecuniary value

that they would, in reasonable probability, have received from their mother during her lifetime had she lived. They have suffered additional losses by virtue of the destruction of the parent-child relationship, including right to love, affection, solace, comfort, companionship, society, emotional support, and happiness. They have suffered mental depression and anguish, grief, and sorrow as a result of the death of their mother, ANNETTE WEAVER, and are likely to continue to suffer for the foreseeable future. For these losses, Plaintiff seeks damages in a sum within the jurisdictional limits of the Court.

VICARIOUS LIABILITY

73. Whenever in this Petition it is alleged that Defendants did or omitted to do any act, it is meant that Defendants' officers, agents, servants, employees, or representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendants or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, or representatives.

DAMAGES

74. As a direct and proximate result of Defendants' improper acts and/or omissions described herein, decedent ANNETTE WEAVER was caused to suffer severe injuries and damages that resulted in her death, including, but not limited to, the following:

- a. Physical pain and mental anguish;
- b. Disfigurement;
- c. Physical impairment; and
- d. Medical care expenses.

75. As a direct and proximate result of Defendants' conduct as described in this Complaint, Plaintiff AUBREY WEAVER, JR. and decedent's surviving children, suffered and in

the future will suffer the loss of their mother's affection, companionship, services, society and other damages.

76. As a direct and proximate result of Defendants' conduct as described in this Petition, Plaintiff is entitled to and hereby seeks all such compensatory damages, punitive damages, attorney fees, reimbursement for all past health and medical care costs related to the Cook Filter, and any and all other damages allowed by law, in an amount to be determined at trial.

EXEMPLARY DAMAGES

77. Defendants' conduct described herein, when viewed objectively from the standpoint of Defendants at the time of the occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Moreover, Defendants had actual, subjective awareness of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, and welfare of others. Thus, Plaintiff seeks exemplary damages in an amount to be determined by the jury.

JURY TRIAL

78. Plaintiff demands a trial by jury in this cause.

PRAYER

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that Defendants be cited to appear and answer herein and that upon final trial of this cause, Plaintiff recovers:

1. Judgment against Defendants for Plaintiff's damages, both past and future, as set forth above including:
 - a. Loss of affection and companionship of the decedent;
 - b. Loss of pecuniary support from the decedent;
 - c. Mental and emotional anguish and suffering;
 - d. Reasonable and necessary medical expenses of the decedent;
 - e. Physical pain and suffering of the decedent; and
 - f. Disfigurement and physical impairment of the decedent.

2. Exemplary Damages;
3. Post-judgment interest at the legal rate from the date of judgment;
4. Pre-judgment interest as allowed by law;
5. Costs of court; and
6. Any such other and further relief to which Plaintiff may be entitled.

Respectfully submitted,

/s/ D. Douglas Grubbs

D. Douglas Grubbs

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