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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

BARBARA GETTMAN, ALFRED HAKIM, DALE HOLDGREVE, HENRY JOHNSON, DETRICE LIVINGSTON, WENDY NOVEL, individually and on behalf of other members of the general public similarly situated,

Plaintiffs,

v.

COOK GROUP, INC.; COOK INCORPORATED; COOK MEDICAL, LLC; AND WILLIAM COOK EUROPE APS,

Defendants.

Case No. _____

CLASS ACTION COMPLAINT

For their Complaint against Cook Group, Inc.; Cook Incorporated; Cook Medical, LLC; and William Cook Europe ApS (collectively "Defendants" or "Cook") Plaintiffs Barbara Gettman, Alfred Hakim, Dale Holdgreve, Henry Johnson, Detrice Livingston and Wendy Novel alleges as follows:

Introduction

1. This is a class action to allow Plaintiffs and Class Members (defined below) to seek and receive appropriate diagnostic services and other declaratory relief that they require as a direct and proximate result of the negligent and wrongful misconduct of Defendants in connection with the development, design, promotion, marketing, and sale of certain inferior vena cava filters.

2. Defendants have designed, marketed, and sold medical devices known as Gunther Tulip Mreye, Gunther Tulip Vena Cava Filter, Cook Celect Vena Cava Filter, and Cook Celect Platinum ("Cook IVC Filters") that were negligently and defectively designed and for which Defendants have failed to provide adequate information and warnings regarding their safety, effectiveness, and failure rates.

3. These Cook IVC Filters are prone to break into parts (fracture) such that struts break away from the device and ultimately can become lodged in a vein, artery, or even an organ, such as the heart or lungs. The filters also tend to break loose from the point of implantation and migrate to other locations in the bloodstream or become lodged in the heart or lungs. The filters also have a significant chance of tilting within the IVC, perforating the vena cava and/or causing the formation of blood clots.

4. Any and all of these adverse events have the potential to cause serious and life threatening medical conditions for patients implanted with the Cook IVC Filters. In so doing, they significantly increase the risks of injury and death for those patients.

5. However, many of these conditions can be asymptomatic in the patient prior to the manifestation of significant and sometimes fatal injuries.

6. Plaintiffs and each and every Class Member will be better off knowing the state of their Cook IVC Filter, including its present condition and position. The notice plan and

diagnostic program described below will arm Plaintiffs, Class Members and their doctors with the knowledge they need to take steps to protect themselves from future harm.

7. The devices at issue have injured Plaintiffs and the Class. These devices are ticking time bombs implanted in unsuspecting patients. The harm suffered by these patients exists as a result of the design defects inherent in the devices such that patients and doctors are unsure of safety of the current state of the device. Each patient is in need of a diagnostic test to determine what is the safest course of medical action to deal with the flawed device.

8. The relief that Plaintiffs seek on their own behalf and on behalf of the Class Members is consistent with the Food and Drug Administration's ("FDA") conclusion, described below, that physicians should consider removal as soon as a patient's transient risk for pulmonary embolism has passed, and will allow Plaintiffs and the healthcare community to effectuate the FDA's guidance. This case presents a simple question: who should pay for the diagnosis and testing that the FDA has stated is needed for the Class?

Parties

9. Plaintiff Barbara Gettman is a resident of the state of Colorado. She was implanted with a Cook Gunther Tulip filter. The filter has not been explanted.

10. Plaintiff Alfred Hakim is a resident of the state of California. He was implanted with a Cook Gunther Tulip filter. The filter has not been explanted.

11. Plaintiff Dale Holdgreve is a resident of the state of Ohio. He was implanted with a Cook Gunther Tulip filter. The filter has not been explanted.

12. Plaintiff Henry Johnson is a resident of the state of Arizona. He was implanted with a Cook Gunther Tulip filter. The filter has not been explanted.

13. Plaintiff Detrice Livingston is a resident of the state of Maryland. She was implanted with a Cook Celect filter. The filter has not been explanted.

14. Plaintiff Wendy Novel is a resident of the state of Pennsylvania. She was implanted with a Cook Gunther Tulip filter. The filter has not been explanted.

15. Defendant Cook Group, Inc. is a citizen of the state of Indiana with a principle place of business at 750 Daniels Way, Bloomington, Indiana 47404 and is authorized to do

business in the state of California and Cook Group, Inc. was doing business in California. Cook Group, Inc. at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Cook IVC Filters.

16. Defendant Cook Incorporated is a citizen of the state of Indiana with a principle place of business at 750 Daniels Way, Bloomington, Indiana 47404 and is authorized to do business in the state of California and Cook Incorporated was doing business in Los Angeles County. Cook Incorporated at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Cook IVC Filters.

17. Defendant Cook Medical LLC is a citizen of the state of Indiana with a principle place of business at 750 Daniels Way, Bloomington, Indiana 47404 and is authorized to do business in the state of California and Cook Medical LLC was doing business in Los Angeles County. Cook Medical LLC at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Cook IVC Filters.

18. Defendant William Cook Europe ApS is based in Bjaeverskov, Denmark with its principal place of business located at Sandet 6, 4632 Bjaeverskov, Denmark and is authorized to do business in the state of California and William Cook Europe ApS was doing business in Los Angeles County. William Cook Europe ApS at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Cook IVC Filters.

Jurisdiction

19. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2), because this is a class action, filed under Rule 23 of the Federal Rules of Civil Procedure; there are hundreds, if not thousands, of proposed Class Members; the aggregate amount in controversy exceeds the jurisdictional amount or $5,000,000.00; and the citizenships of Defendants are diverse from those of Plaintiffs and the Class Members. This Court also has

subject matter jurisdiction over Plaintiffs' and the proposed Classes' claims pursuant to 28 U.S.C. § 1367(a).

20. Venue is proper in this Court pursuant to 28 U.S. C. § 1391, because a Plaintiff resides in this district, and resided in this district at the time of implantation of the IVC filter, and because Defendants regularly conduct business here.

Background

A. IVC FILTERS

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

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

23. 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 inferior vena cava, and into the lungs or heart. 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 present serious risks to human health.

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

25. Even though IVC filters have been on the market for decades and were traditionally permanent implants, the use of these filters was limited primarily to patients who were contraindicated for anticoagulation therapy.

26. In order to increase sales of these devices, Cook began to sell "retrievable" versions of the IVC filter in an effort to expand the market for prophylactic uses among nontraditional patient populations that were temporarily at risk of developing blood clots.

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

28. The Cook IVC Filters were marketed as retrievable filters. The Cook Celect Vena Cava Filters have four anchoring struts for fixation and eight independent secondary struts to help with self-centering and clot trapping.

29. The Gunther Tulip Vena Cava Filters have a top hook and four anchoring struts for fixation and on each strut it has a "flower" formation that is shorter than the strut where a wire piece branches out on each side.

30. Cook engaged in aggressive marketing campaigns for the Cook IVC Filters, despite negative clinical data.

31. Cook bypassed the FDA's more onerous approval process for new devices and obtained "clearance" under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act by claiming the filters were substantially similar in respect to safety, efficacy, design, and materials to previous devices.

32. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the new device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

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

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

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

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

518 U.S. 470, 478-79 (1996) (quoting Adler, The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

34. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse events associated with the [product]. . . and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling . . . ." This obligation extends to post-market monitoring of adverse events/complaints.

35. Cook was aware that Cook IVC Filters were also used extensively off-label, including for purely prophylactic reasons for trauma patients or patients with upcoming surgeries such as bariatric (weight loss) and orthopedic procedures and that the filters were used for permanent and not temporary placement.

36. The Cook IVC Filters are constructed of conichrome. Conichrome construction is specifically advertised as a frame which reduces the risk of fracture.

37. The extreme failure rates of the Cook IVC Filters is attributable, in part, to the fact that they suffer from a design defect causing them to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo* indicating that they pose an ever present and continuing unreasonable risk of harm.

B. Post-Market Performance Revealed The Cook IVC Filters Failed to Perform as Expected

38. Both prior to and once placed on the market, Cook became aware of numerous confirmed events where its filters fractured, migrated, or perforated the inferior vena cava, caused thrombus and clotting, and caused serious injury, including death.

39. Premarket and post-market clinical trials revealed that these filters failed and caused serious risks of harm. In addition, peer-reviewed literature reflected that such filters actually increased the risk of patients developing thromboembolitic events.

40. In a study of Gunther Tulip and Celect IVC filters implanted between July 2007 and May of 2009 reported by Cardiovascular Interventional Radiology on March 30, 2011 and later published in print journal in April of 2012, one hundred percent of the Gunther Tulip and Cook Celect filters imaged after 71 days of showed filter perforation of the vena cava wall. Durack JC, et al, *Cardiovasc Interent Radiol.*, "Perforation of the IVC: rule rather than the exception after longer indewelling times for the Gunther Tulip and Celect Retrievable Filters" 2012 Apr.; 35(2):299-308. Epub 2011 Mar 30. The authors concluded: "Longer indwelling times usually result in vena caval perforation by retrievable Guther Tulip and Celect IVC filters. Although infrequently reported in the clinical literature, clinical sequelea from IVC filter components breaching the vena cava can be significant. We advocate filter retrieval as early as clinically indicated…"

41. The same study found that 40% of all studied filters experienced tilt and all tilter filters demonstrated vena caval perforation.

42. The Cook IVC Filters are prone to an unreasonably high risk of failure and patient injury following placement in the human body.

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

44. The high risk of tilting and perforating the vena cava walls by Cook IVC Filters is well documented. When such tilting occurs, the filters can also perforate the adjacent aorta,

duodenum, small bowel, spine, or ureter, which may lead to retroperitoneal hematomas, small-bowel obstructions, extended periods of severe pain, and/or death.

45. With respect to the initial testing and specifications of the filters at issue, Cook's analysis to evaluate the stresses placed on the devices after implant was inadequate to properly determine their real world performance. In particular, Cook did not adequately consider the stress loading impact of the struts incorporation into the walls of the vena cava sufficient to properly design a filter that would not fail after implantation.

46. The geometric design of these filters and struts encouraged unnecessary stress on the contact point between the wires and sheath of the filters as well as wire to wire contact such that unreasonable failure rates would likely result and this defect would subject the devices to unreasonably high levels of tilt after implantation as well as perforation of the vena cava wall. These implantation malfunctions significantly and unreasonably raise the injury risk for these devices.

47. Cook is and was aware that Cook IVC Filters had substantially higher reported failure rates than other IVC filters for fracture, perforation, migration, and death.

48. Despite knowing that the Cook IVC Filters were substantially more likely than not to fracture, migrate, tilt, and/or cause death, Cook marketed its IVC Filters as being safe and effective.

49. At all times material hereto from the design phase, testing, and manufacture of the Cook IVC Filters, Cook lacked a thorough understanding dynamics of caval anatomy that impacted testing methods.

50. At this time, each of the Cook IVC Filters contain the same or substantially similar defects resulting in the same or substantially similar mechanism of risk to Plaintiffs and the Class Members.

51. The Cook IVC Filters are misbranded and adulterated by virtue of them failing to be the substantial equivalent of their predecessor device, making them subject to corrective action, including recall, in the interest of patient safety.

52. Safer and more efficacious designs existed for this product, as well as reasonable treatment alternatives.

53. Cook marketed and sold these IVC Filters as being retrievable but also represented them as being safe for the life of the patient without retrieval, and particularly that they were safe to remain in vivos as permanent devices despite their extreme failure rate at even low indwell times.

C. FDA WARNING LETTER

54. On August 9, 2010, the FDA issued an advisory to physicians and clinicians responsible for the care of patients with IVC filters. Noting that it had, as of that date, received 921 device adverse event reports involving IVC filters, the FDA stated that it was "concerned that these retrievable IVC filters, intended for short-term placement, are not always removed once a patient's risk for [pulmonary embolism] subsides. It recommended that physicians and clinicians consider removing the filter as soon as protection from PE is no longer needed."

55. On May 6, 2014, the FDA issued an updated safety communication concerning IVC filters. This communication reported that the FDA had developed a quantitative decision analysis designed to assess when "the risk of having an IVC filter in place is expected to outweigh the benefits." The FDA published that decision analysis in the Journal of Vascular Surgery: Venous and Lymphatic Disorders, in October 2013. The FDA's "mathematical model suggested that if the patient's transient risk for pulmonary embolism has passed, the risk/benefit profile begins to favor removal of the IVC filter between 29 and 54 days after implantation."

PROPOSED NOTICE AND DIAGNOSTIC PROGRAM

56. In its May 2014 safety communication concerning IVC filters, the FDA expressed concerns over the continuing presence of implanted IVC filters in patients. To that end, the FDA recommended that:

> physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from pulmonary embolism is no longer needed. The FDA encourages all physicians involved in the treatment and follow-up of patients receiving IVC filters to consider the risks and benefits of filter removal for each patient. A patient should be referred for IVC

> filter removal when the risk/benefit profile favors removal and the procedure is feasible given the patient's health status.[1]

57. Pursuant to the Durack study concerning the Cook IVC Filters all patients in whom a vena cava filter is placed are at risk of at least perforation and more often than not, some injury as a result of their implanted filter.

58. Against this backdrop, and the massive scale of medical literature indicating that the Cook IVC Filters pose long term risks of migration, fracture, perforation, tilting, and ultimately catastrophic injury or death, Plaintiffs seek a monitoring program designed to evaluate whether the risk/benefit profile of every Class Member favors removal of the Cook IVC Filter and, if so, to gather information on the appearance, condition, and location of the IVC filter, including whether it has fractured, migrated, perforated, or tilted, in order to provide a physician with the information necessary to remove the Cook IVC Filter safely.

59. Specifically, Plaintiffs seek a medical monitoring protocol which consists of a notice campaign to all Class Members informing them of the availability and necessity of the medical motoring protocol; imaging of the filter and surrounding structures performed with a non-contrast CT scan of the abdomen in order to provide a detailed and accurate assessment of the current status of the device and critical information as to the safety and difficulty of possible filter removal; and review of the patient data collected by the protocol by an experienced interventional radiologist for every Class Member who still has a Cook IVC Filter installed. The purpose of this monitoring procedure is to then allow the Class Member (or Class Member's care givers) to meet with the Class Member's physician to determine if retrieval is clinically necessary and, if so, to provide the physician with necessary information regarding how best to approach removal of the Cook IVC Filter (the "Medical Monitoring Protocol"). In addition to facilitating the assessment of the condition and removal prospects of the Cook IVC Filter, this monitoring protocol allows specific attention to be paid to the particular defects at issue before removal of the filter is attempted.[2]

[1] http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm396377.htm (last visited 2/3/17.)

60. Dr. Myerburg, writing in the New England Journal of Medicine, noted that with implantation of medical devices that have a demonstrated failure rate leading to death, (1) "tolerance and surveillance strategies should aim to achieve a risk of malfunction that is as close to zero as possible"; (2) that "physicians must know about the performance features of [the] device"; and (3) "patients have a right to obtain product information so that they can make informed decisions."[3] Plaintiffs' proposed Medical Monitoring Protocol aims to reduce complications by aiding in the detection and remediation of any malfunction and also generally provides awareness of the issue so it can be investigated. Without this protocol, many if not most patients implanted with these IVC Filters will not even be aware of the serious risk they are in.

61. Additionally, medical literature notes that "there appears to be no long-term survival benefit from long-term filter implantation…" and "lack of adequate follow-up evaluation for device retrieval may also contribute to inadvertent chronic filter implantation."[4] Dr. Kuo and his co-authors also note that "When IVC filtration is no longer required, we believe prompt filter retrieval is desired if it can be performed with reasonable safety to avoid the risk of complications from long-term implantation." Plaintiffs' proposed Medical Monitoring Protocol is designed to evaluate the risk of long-term implantation in association with the need and possibility of removal by offering Class Members an individual evaluation of their circumstances while educating them on the risks of the IVC Filter currently implanted in their vena cava.

Fraudulent Concealment

62. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Cook when they had a duty to disclose those facts. Defendants have kept Plaintiffs and their physicians ignorant of vital information essential to the pursuit of their claims, without any fault or lack of diligence on Plaintiffs' part, for the

[3] Myerburg R., et al., Life-Threatening Malfunction of Implantable Cardiac Devices. The New England Journal of Medicine 2006; 354:22.

[4] Kuo W., et al., High-risk Retrieval of Adherent and Chronically Implanted IVC Filters; Techniques for Removal and Management of Thrombotic Complications. Journal of Vascular and Interventional Radiology 2009, 20:1548-1556.

purpose of obtaining delay on Plaintiffs' part in filing on their causes of action. Cook's fraudulent concealment did result in such delay.

63. Cook is estopped from relying on the statute of limitations defense because Cook failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Cook IVC Filters.

64. Cook was under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiffs, but instead they concealed them. Cook's conduct, as described in this Complaint, amounts to conduct purposely committed, which Cook must have realized was dangerous, needlessly reckless, without regard to the consequences or the rights and safety of Plaintiffs and Class Members.

Class Action Allegations

65. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a), (b)(2), and (c)(4) as representatives of the classes defined as follows:

66. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, the class representative Plaintiffs, for themselves and on behalf all others similarly situated, seek certification of the classes defined as follows (collectively, the "Classes"):

Arizona Class (represented by Henry Johnson)

All Arizona residents who, between October 31, 2003 and the date of the filing of this complaint, were implanted with a Cook IVC Filter – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the Cook IVC Filter.

California Class (represented by Alfred Hakim)

All California residents who, between October 31, 2003 and the date of the filing of this complaint, were implanted with a Cook IVC Filter – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the Cook IVC Filter.

Colorado Class (represented by Barbara Gettman)

All Colorado residents who, between October 31, 2003 and the date of the filing of this complaint, were implanted with a Cook IVC Filter –

whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the Cook IVC Filter.

Maryland Class (represented by Detrice Livingston)

All Maryland residents who, between October 31, 2003 and the date of the filing of this complaint, were implanted with a Cook IVC Filter – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the Cook IVC Filter.

Ohio Class (represented by Dale Holdgreve)

All Ohio residents who, between October 31, 2003 and the date of their filing of this complaint, were implanted with a Cook IVC Filter – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the Cook IVC Filter.

Pennsylvania Class (represented by Wendy Novel)

All Pennsylvania residents who, between October 31, 2003 and the date of the filing of this complaint, were implanted with a Cook IVC Filter – whose filter has not been explanted, and who has not filed a claim or lawsuit for personal injury relating to the Cook IVC Filter.

Excluded from these classes are Defendants and their subsidiaries and affiliates, as well as the judicial officers and their staff to whom this is assigned or referred, and their immediate family members.

67. The Class Members are so numerous that joinder is impracticable. Thousands of Class Members have been implanted with the Cook IVC Filters and have not filed a claim or lawsuit alleging personal injury relating to the Cook IVC Filters.

68. This case presents numerous questions of law or fact that are common to all Class Members. These questions' answers are central to the validity of Plaintiffs' and Class Members' claims, and their determination is apt to drive the resolution of the claims. These common questions predominate over any individualized issues and include:

a. Whether the Cook IVC Filters have design defects;

b. Whether Cook acted negligently in the design, manufacturing, marketing, and sale of the Cook IVC Filters at issue;

c. Whether Plaintiffs have been exposed to increased or significantly increased risk of injury as a result of the implantation of the Cook IVC Filter at issue;

d. Whether a Court-supervised notice and diagnostic program should be established to mitigate or reduce the risk of injury as a result of the implantation of the Cook IVC Filters at issue; and

e. What a medical monitoring program that is consistent with the standard of care and with contemporary scientific principles would entail.

69. Plaintiffs' claims are typical of the claims of those of Class Members, as they all arise from the same common course of conduct on the part of Defendants.

70. Plaintiffs will fairly and adequate protect the interests of the Classes. Plaintiffs' interests are aligned with and not in conflict with those of Class Members. Plaintiffs and the Classes are represented by counsel with long and deep experience in the prosecution of class actions, including those relating to product defects, including medical devices, medical negligence, personal injury, and medical monitoring. Plaintiffs' counsel is knowledgeable about the applicable law and possesses the resources to fully commit to representing the Classes.

71. Defendants have acted and have refused to act on grounds that apply generally to the Classes, so that final injunctive relief or corresponding declaratory relief, in the form of medical monitoring, is appropriate respecting the Classes as a whole.

72. Questions of law or fact common to Class Members predominate over any questions affecting only individual Class Members.

73. A class action is superior to other available methods for fairly and efficiently adjudicating these claims.

CAUSE OF ACTION
MEDICAL MONITORING
(ON BEHALF OF COLORADO AND PENNSYLVANIA CLASSES)

74. Plaintiffs repeat and incorporate by reference each of the foregoing allegations of this Complaint.

75. Colorado and Pennsylvania recognize medical monitoring as an independent claim for relief.

76. Plaintiffs were exposed to a significantly higher risk of injury and death from Cook's IVC Filters than they would have faced if they had the filters been designed without defect, had Cook given appropriate and adequate warnings regarding the risks of the IVC Filters, or had Plaintiffs received alternative forms of treatment. As a result, Plaintiffs are and will be exposed to a significant risk of injury and death on an ongoing basis as a result of Cook's negligent conduct.

77. Cook was fully aware of yet failed to adequately warn, protect, and educate Plaintiffs concerning these increased risks.

78. Cook had a duty to provide necessary and adequate warnings of the increased risks of these IVC Filters. By such negligent conduct, Cook breached their duties of care to the Plaintiffs and Class Members, and caused significantly increased risk of injury and damages to Plaintiff, giving rise to the need for diagnosis, assessment, and/or monitoring of these IVC Filters.

79. As a proximate result of Cook's negligent conduct, Plaintiffs have experienced and been exposed to significantly increased risks of injury from the IVC Filters (including the devices' migration, tilting, fracturing, and perforation of the vena cava), including hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels, and organs; and death.

80. Diagnostic and/or monitoring procedures exist that comport with contemporary scientific principles and the standard of care and make possible early detection of potential injury to Plaintiffs and Class Members, which would not be possible without such diagnostic and/or monitoring procedures. The proposed Court-supervised diagnostic and/or monitoring program includes, but is not limited to, baseline exams and diagnostic exams. This program is necessary and includes more monitoring than will be typically provided to Class Members in order to detect, prevent, and mitigate injury that may occur if treatment was delayed, and enable prompt treatment of the adverse consequences of the IVC Filters.

81. The program and procedures set forth above are non-routine, and are fundamentally different from and more extensive than the normally prescribed medical treatment and/or diagnostic procedures for those with Cook IVC Filters, including non-defective devices.

82. The diagnostic and/or monitoring procedures proposed by this action are reasonably necessary for all Plaintiffs and Class Members because Plaintiffs and Class Members have been implanted with the IVC Filters, which present significantly increased risks of the same injuries and harm, including possibly death, to Plaintiffs and Class Members by the same mechanisms and modes of failure.

83. As set forth above, the Court-supervised monitoring procedures are reasonably necessary according to contemporary scientific principles to enable Plaintiffs to obtain early detection and diagnosis of the potential injury and increased risk of injury as a result of the implantation of the IVC Filters described above.

84. By monitoring and testing Plaintiffs and Class Members who are at increased risk of injury from the IVC Filters, the risk of Plaintiffs and Class Members suffering injury, disease, and losses as described above may be significantly reduced, as Plaintiffs and Class Members and their physicians will have gained information necessary to choose appropriate interventions and treatments.

85. Plaintiffs therefore seeks an injunction creating a Court-supervised comprehensive medical monitoring fund for Plaintiffs and the Class Members, which would facilitate the early diagnosis and treatment to mitigate future injury to Plaintiffs and Class Members.

86. Accordingly, Cook should be required to establish a Court-supervised and Court-administered trust fund, in an amount to be determined, to pay for the medical monitoring protocol for all Class Members, which includes, among other things: (1) a notice campaign to all Class Members informing them of the availability and necessity of the medical motoring protocol and (2) an imaging procedure to be performed on every Class Member who still has a Cook IVC Filter installed by an interventional radiologist who will then consult with the Class Member's physician within 60 days to determine if retrieval is clinically necessary and, if so, to provide the

physician with necessary information regarding how much force to exert in removing the Cook IVC Filter.

87. Cook's negligent conduct has caused significant increased risk, as described above, that the law of these states recognizes as an injury to legally protected rights, giving rise to claims for injunctive/equitable relief. The distribution of damages to individual Class Members without programmatic relief as described above is inadequate, inefficient, and/or inferior to a judicial injunctive, declaratory, or equitable degree, establishing and supervising class-wide medical monitoring services as described and as sought herein. Plaintiffs have no adequate remedy at law, in that monetary damages cannot compensate for the increased risks of long-term physical and economic losses associated with future injury from the Cook IVC Filter, or the uncertainty associated with living with a defective and dangerous medical device. Without a Court-supervised comprehensive medical monitoring fund as described herein, Plaintiffs will continue to face increased risks of injury without proper diagnosis and opportunity for rehabilitation.

CAUSE OF ACTION
NEGLIGENCE/MEDICAL MONITORING
(ON BEHALF OF MEMBERS OF ARIZONA, CALIFORNIA, MARYLAND, AND OHIO CLASSES)

88. Plaintiffs repeat and incorporates by reference each of the foregoing allegations of this Complaint.

89. The following jurisdictions recognize medical monitoring as a remedy and/or recoverable item of damages for negligent or tortious conduct: Arizona, California, Maryland and Ohio.

90. Plaintiffs were exposed to a significantly higher risk of injury and death from an IVC Filter, and will be exposed to injury and death on an ongoing basis as a result of Defendants' negligent conduct.

91. Cook was fully aware of yet failed to adequately warn, protect, and educate Plaintiffs concerning these increased risks.

92. Cook had a duty to provide necessary and adequate warnings of the increased risks of these IVC Filters. By such negligent conduct, Cook breached their duties of care to the Plaintiffs and Class Members, and caused significantly increased risk of injury and damages to Plaintiffs, giving rise to the need for diagnosis, assessment, and/or monitoring of the IVC filter.

93. As a proximate result of Cook's negligent conduct, Plaintiffs have experienced and been exposed to significantly increased risks of injury from the IVC Filter (including the device's migration, tilting, fracturing, and perforation of the vena cava), including hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels, and organs; and death.

94. Diagnostic and/or monitoring procedures exist that comport with contemporary scientific principles and the standard of care and make possible early detection of potential injury to Plaintiffs and Class Members, which would not be possible without such diagnostic and/or monitoring procedures. The proposed Court-supervised diagnostic and/or monitoring program includes, but is not limited to, baseline exams and diagnostic exams. This program is necessary and includes more monitoring than will be typically provided to Class Members in order to detect, prevent, and mitigate injury that may occur if treatment was delayed, and enable prompt treatment of the adverse consequences of these IVC Filters.

95. The program and procedures set forth above are non-routine, and are fundamentally different from and more extensive than the normally prescribed medical treatment and/or diagnostic procedures for those with IVC Filters, including non-defective devices.

96. As set forth above, the Court-supervised monitoring procedures are reasonably necessary according to contemporary scientific principles, to enable Plaintiffs and Class Members to obtain early detection and diagnosis of the potential injury and increased risk of injury as a result of the implantation of the IVC Filters described above.

97. By monitoring and testing Plaintiffs and Class Members who are at increased risk of injury from the Cook IVC Filters, the risk of Class Members suffering injury, disease, and losses as described above may be significantly reduced, as Class Members and their physicians will have gained information necessary to choose appropriate interventions and treatments.

98. Plaintiffs therefore seeks an injunction creating a Court-supervised comprehensive medical monitoring fund for Plaintiffs and the Class Members, which would facilitate the early diagnosis and treatment to mitigate future injury to Plaintiff and Class Members.

99. Accordingly, Cook should be required to establish a Court-supervised and Court-administered trust fund, in an amount to be determined, to pay for the medical monitoring protocol for all Class Members, which includes, among other things: (1) a notice campaign to all Class Members informing them of the availability and necessity of the medical motoring protocol and (2) an imaging procedure to be performed on every Class Member who still has a Cook IVC Filter installed by an interventional radiologist who will then consult with the Class Member's physician within 60 days to determine if retrieval is clinically necessary and, if so, to provide the physician with necessary information regarding how much force to exert in removing the Cook IVC Filter.

100. Cook's negligent conduct has caused significant increased risk, as described above, that the law of these states recognizes as an injury to legally protected rights, giving rise to claims for injunctive/equitable relief. The distribution of damages to individual Class Members without programmatic relief as described above is inadequate, inefficient, and/or inferior to a judicial injunctive, declaratory, or equitable degree, establishing and supervising class-wide medical monitoring services as described and as sought herein. Plaintiffs have no adequate remedy at law, in that monetary damages cannot compensate them for the increased risks of long-term physical and economic losses associated with future injury from the IVC Filters, or the uncertainty associated with living with a defective and dangerous medical device. Without a Court-supervised comprehensive medical monitoring fund as described herein, Plaintiff will continue to face increased risks of injury without proper diagnosis and opportunity for rehabilitation.

Prayer for Relief

WHEREFORE, Plaintiffs pray for relief as follows:

1. This action to be certified as a class action on behalf of the proposed classes; that the named plaintiffs be appointed as Class representatives, and that counsel below be designated Class Counsel;

2. Creation of a comprehensive, Court-supervised notice and diagnostic/medical monitoring program for the proposed classes;

3. Judgment to be entered against all Defendants on all causes of action and damages suffered;

4. Plaintiffs be awarded the full, fair, and complete recovery for all causes of action;

5. Plaintiffs be awarded all appropriate costs, fees, expenses, and pre-judgment and post-judgment interest, as authorized by law; and

6. Such other relief that the Court deems just and proper.

Jury Trial Demand

Plaintiffs requests a jury trial on all questions of fact raised by this Complaint.

Dated: March 8, 2017

Respectfully submitted,

By: /s/Roland Tellis
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On behalf of Plaintiffs and the proposed Classes