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Attorneys for Plaintiffs
ROSE CALISE, individually and as the Representative of the Estate of DANIEL CALISE, and PAUL CALISE

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

ROSE CALISE, individually and as the Representative of the Estate of DANIEL CALISE, and PAUL CALISE,

Plaintiffs,

vs.

ST. JUDE MEDICAL, INC.; PACESETTER, INC.; and DOES 1through 50, inclusive,

Defendants.

Case No. CV 13-06768 -E

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs, Rose Calise and Paul Calise, through their attorneys, by way of Complaint against St. Jude Medical, Inc., Pacesetter, Inc., and DOES 1 through 50, inclusive, allege as follows:

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I.

INTRODUCTION

1. Plaintiffs, ROSE CALISE, individually and as the Representative of the Estate of Daniel Calise, and PAUL CALISE, bring this Complaint against ST. JUDE MEDICAL, INC., PACESETTER, INC., and DOES 1 through 50 (collectively referred to as "St. Jude Medical" or "Defendants") for the wrongful death of Daniel Calise caused by manufacturing defects in the St. Jude Riata and Riata ST Leads (hereinafter referred to as "Riata Leads" or "Leads"). Plaintiffs allege that Daniel Calise was implanted with a defective Riata Lead and died as a result of the Lead's malfunction.

2. St. Jude manufactures a variety of medical devices to treat heart conditions including implantable cardiac defibrillators ("ICDs"). Wires called Leads, are attached to the ICD, then inserted through a major vein and attached directly to the muscle on the inside of the heart, thereby connecting the ICD to the heart. Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and correct any irregular rhythms.

3. St. Jude Medical introduced its Riata Leads into the U.S. Market beginning in 2002. Approximately 227,000 Riata leads have been sold worldwide since approved for marketing. 79,000 Riata Leads are estimated to remain active in the United States.

4. Recently, the Food and Drug Administration (FDA) issued a Class I Recall for the following Riata Lead model numbers: Riata (8Fr): 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592; and Riata (7Fr): 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042 (collectively "Riata Leads").

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II.

THE PARTIES

A. Plaintiffs

5. Plaintiffs Rose Calise and Paul Calise are, and at all times relevant herein, were citizens and residents of the State of Florida.

6. Upon information and belief, Daniel Calise, the son of Plaintiffs Rose Calise and Paul Calise, was implanted with a Riata Lead Model # 1580-65 on December 13, 2005. On September 6, 2011, Daniel Calise was taken by ambulance to the hospital after suffering cardiopulmonary arrest as the result of the failure of his Raita lead. He died as a result on September 17, 2011.

7. As a result of the defect in his Riata lead, Plaintiffs lost their son and incurred emotional, economic and other damage.

B. Defendants

8. Defendant St. Jude Medical, Inc. is a Minnesota Corporation that is headquartered in St. Paul, Minnesota at One St. Jude Medical Drive, St. Paul, Minnesota, 55117.

9. Defendant St. Jude Medical manufactures medical devices that are sold in more than 100 countries around the world. St. Jude had net sales of over $5.6 billion in 2011.

10. Defendant Pacesetter, Inc. ("Pacesetter") is a Delaware corporation with its principle place of business at 15900 Valley View Court, in Slymar, California. Pacesetter, doing business as St. Jude Medical Cardiac Rhythm Management Division, develops, manufactures, and distributes cardiovascular and implantable neurostimulation medical devices, including the Riata and Riata ST leads at issue here. Pacesetter operates as a wholly owned subsidiary of St. Jude Medical, Inc. Prior to 1994, Pacesetter was known as Siemens Pacesetter, Inc.

11. Pacesetter also holds the trademark for Riata. Specifically, on September 7, 2001, Pacesetter filed a federal trademark registration. The United

States Patent Trademark Office (USPTO) issued the RIATA trademark, serial number 76310892, to Pacesetter on November 5, 2002. The correspondent listed for RIATA is Steven M. Mitchell of Pacesetter, Inc., 15900 Valley View Court, Sylmar CA 91342. The RIATA trademark is filed in the category of Medical Instrument Products. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority and on behalf of each other Defendant. During the relevant times, Defendants possessed a unity of interest between themselves and St. Jude Medical exercised control over its subsidiaries and affiliates. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's damages.

12. The true names and capacities, whether individual, corporate, associate, or otherwise, of the defendants, DOES 1 through 50, inclusive, are unknown to plaintiffs, who therefore sue such defendants by such fictitious names, and plaintiffs will amend this complaint to show their true names and capacities when the same have been ascertained. Plaintiffs are informed and believe and thereon allege that each of the defendants, DOES 1 through 50, inclusive, are responsible under law in some manner negligently, in warranty, strictly, or otherwise, for the events and happenings herein referred to and thereby proximately caused injuries and damages to plaintiffs as herein alleged.

13. At all times herein mentioned, each of the defendants was the agent, employee, principal, or employer of each of the remaining defendants and was at all times relevant acting within the course and scope of said relationships and each defendant has authorized, ratified and approved the acts of each of the remaining defendants.

14. Upon information and belief, defendants expected or should have expected their actions to have consequences within the State of California, and derived substantial revenue from interstate commerce within the California.

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III.

JURISDICTION

15. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332 as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interests and costs.

16. Assignment to the Western Division of Central District of California is appropriate because Pacesetter, Inc.'s principal place of business is in this district, and the majority of claims and certain of the transactions, acts, practices, and courses of business alleged below occurred within the Central District of California, including in the County of Los Angeles, California.

IV.

FACTUAL ALLEGATIONS

A. Brief History of The Heart Devices

17. In 1980, termination of human arrhythmias with ICDs was reported in the New England Journal of Medicine. Thereafter, a number of devices were approved and manufactured to detect and treat abnormally fast and irregular heart rhythms and to provide pacing for improper heart rhythms. ICDs include pacemakers as well as defibrillators. Pacemakers are used primarily to correct slow heart rates. Defibrillators detect and correct both fast and slow heart rates. Using the pacemaker and defibrillator function, an ICD can correct slow heart rates, pace rapid heart rates, and administer a shock to stop the heart and allow for a return to an appropriate rhythm.

18. Generally, wires, called leads, act to conduct the electrical impulses between the heart and the ICD. Low voltage pacing therapy to treat slow heart rhythms is provided through pace-sense electrodes. High voltage shocks for defibrillation are provided through high voltage conductors. Typically, high voltage leads are inserted through a major vessel and attached directly to the muscle on the inside of the heart. Electrodes that sense the heart's rhythm are built into the

lead wires and positioned in the heart, where they monitor the heartbeat and can transmit an electric shock from the ICD to abort dangerous heart rhythms or pace the heart at a normal rhythm.

19. Any failure that compromises the ability of the lead to conduct electrical signals will result in a failure of the ICD to perform properly. Lead failures may include externalization of the conductors, abrasion, fractured wires, insulation loss, loss of ability to capture, changes in electrical characteristics in the ventricle chamber, abnormal lead impedance, sensing failure, and changes in tissue conductor interface.

20. Such devices are used in patients, like the plaintiff, who have arrhythmias or irregular heartbeats that are considered life-threatening. Plaintiffs with these medical problems include patients who are at risk for ventricular fibrillation (rapid, ineffective contraction of the ventricles of the heart), ventricular tachycardia (excessively rapid heartbeat) that is poorly controlled with medication. These arrhythmias or irregular heartbeats can result in the loss of consciousness or death, unless the patient receives therapy from an appropriate device to put the heart back into a more appropriate cardiac rhythm.

21. If an implanted ICD and lead operate properly, the system can save a patient's life. Any failure that compromises the ability of the lead to conduct electrical signals can result in a failure of the ICD to perform properly. Lead failures may include fractured wires, bending, insulation loss, loss of ability to capture changes in electrical characteristics in the ventricle chamber, abnormal lead impedance, sensing failure and changes in tissue conduct interface. If either the ICD or the lead fails to operate, the patient may die within minutes.

B. <u>The Regulatory Approval Process Specific to the Riata Leads</u>

22. On March 11, 2002, the FDA, pursuant to St. Jude Medical's application number P950022/S014, approved the Riata Series 1500 Defibrillation

Lead System. (FDA PMA Database). This approval applied to Riata Model Numbers 1570, 1571, 1580, and 1581.

23. Relying upon St. Jude Medical's representations about the "state-of-the-art" nature and ease-of-use of the Riata Leads, physicians began broadly using the Riata Leads instead of other lead models.

24. On January 23, 2003, the FDA, pursuant to St. Jude Medical's application number P950022/S015, approved an extension of the shelf-life of the Riata Leads.

25. On March 25, 2003, St. Jude Medical added two new models to the Riata Series (Model No. 1572 and 1582), when the FDA approved application number P950022/S016.

26. On April 12, 2004, the FDA approved St. Jude Medical's application number P950022/S018, a modification to the Riata defibrillation lead family to include integrated bipolar leads (Models 1560, 1561, 1562, 1590, 1591, and 1592).

27. In May 2005, a series of applications for manufacturing modifications were approved by the FDA. These requests involved "dimensional changes" to the Riata Leads, changes from welding to crimping connectors, changes from manual to automated processes, as well as changes to the order of the manufacturing steps for the crimping process, and "changes to the stylet ring and header coupling". See, application numbers: P950022/S020; P950022/S021; P950022/S022; P950022/S019; and P950022/S023.

28. On June 3, 2005, the FDA approved the Riata ST Lead Models 7000, 7001, and 7002 under application number P950022/S024.

29. In March 2006, the FDA approved the following changes to the Riata Leads: (1) modifications to the Riata ST Models 7000, 7001, and 7002 active-fixation defibrillation leads to change the geometric profile of the inner coil and add white pigment to the medical adhesive used for shock coil backfill; (2) modifications to the Riata ST Models 7000, 7001, and 7002 leads to create an

active-fixation integrated bipolar lead. These devices, as modified, are marketed under the trade names Riata ST Models 7010, 7011, and 7012 and are indicated for use with compatible pulse generators; and (3) modifications to the Riata ST Models 7000, 7001, and 7002 to create a passive fixation and a passive fixation integrated bipolar lead. These devices, as modified, will be marketed under the trade names Riata ST Models 7040, 7041, and 7042 (passive fixation) and Riata ST Models 7050, 7051, 7052 (passive fixation integrated bipolar) and are indicated for use with compatible pulse generators. These changes were all included in application numbers P950022/S027 and P950022/S028.

30. In November 2006, the FDA approved St. Jude Medical's application to change the supplier for the DR-1 Boot component of its Riata Leads. (P950022/S031).

31. In December 2006, the FDA approved St. Jude Medical's application for a helix attachment modification for the Riata 1580, 1581 and 1582 leads as well as a crimp-weld coupling modification for the Riata and Riata ST Lead families. (P950022/S032).

32. In February 2007, the FDA approved St. Jude Medical's application to add an automated trimming fixture to trim excess silicone adhesive on the shock electrodes during production of the Riata ST family of leads. (P950022/S033).

33. In March 2007, the FDA approved St. Jude Medical's application for changes to their Riata Leads: (1) Modification to the crimp slug weld tab; (2) Modification to the distal header assembly; (3) Modification to the PTFE liner in the IS-1 connector leg; (4) Removal of the PTFE liners in the two DF-1 connector legs; (5) Addition of a DF-1 plug accessory to the lead package; (6) Addition of an extra-soft stylet accessory to the lead package; (7) Minor modifications to the User Manual; and (8) Modified radius specification for the spring stopper component. (P950022/S034). The FDA also approved a change in the supplier of the front seal component (P950022/S035), added an "alternative welding process."

(P950022/S036), and added alternate vendor of the molded connector boot for the manufacturer of Riata ST Leads (P950022/S037).

34. In June 2007, the FDA approved St. Jude Medical's application to change the suppliers of their connector rings and inner crimp sleeve components. (P950022/S038, P950022/S039, P960013/S031, and P960013/S032).

35. In October 2007, the FDA approved St. Jude Medical's application for an alternate supplier of ETFE coated cables. (P950022/S043).

36. In December 2007, the FDA approved St. Jude Medical's application to change the "shock coil backfill manufacturing process." (P950022/S046), to extend the time between plasma treatment and application of medical adhesive. (P950022/S047), and to alternate oven settings during processing of the shock coils. (P950022/S048).

37. In May 2008, the FDA approved St. Jude Medical's application to transition the manufacturing site located at Steri-Tech, Inc., Salinas, Puerto Rico for Ethylene Oxide sterilization of the pacemakers, ICDs and leads. (P950022/S045).

38. In July 2008, the FDA approved St. Jude Medical's application to transition the manufacturing of the Riata Leads to a plant in Arecibo, Puerto Rico. (P950022/S051).

39. In June 2009, the FDA approved St. Jude Medical's application for an automated heat shrinking process. (P950022/S055).

40. In September 2009, the FDA approved St. Jude Medical's application for a change in temperature and humidity cure operation, and process modifications of the DR-1 connector pin on the Durata, Riata, Riata ST and Riata ST Optim families of leads. (P950022/S064) and (P950022/S063).

41. In January 2010, the FDA approved St. Jude Medical's application for a change in the process water system monitoring frequency and locations at Arecibo, Puerto Rico manufacturing facility. (P950022/S068)

42. In May 2011, the FDA approved St. Jude Medical's application for approval of a manufacturing site at St. Jude Medical Puerto Rico, LLC in Arecibo, Puerto Rico. (P950022/S067).

C. Manufacturing Defects with Regard to Riata Leads

43. From 2005 to 2010 St. Jude Medical applied for over 27 manufacturing or process changes to the Riata Leads. The FDA approved these changes in a PMA and multiple supplements. Upon information and belief, St. Jude Medical failed to manufacture the Riata Leads consistent with these approved changes, thereby creating a defective product and violating federal law and regulation, causing abrasion, lead failure, and the failure of Daniel Calise's Lead.

44. Upon information and belief, one of these defects includes inconsistent insulation diameters surrounding the electric conductors. On information and belief, insulation diameters are required by the PMA and federal requirements to be consistent. Failure to manufacture uniform insulation diameters leads to an increased risk of abrasion at thinner insulation sites, leading to an increased risk of device failure, and in fact caused the failure of Daniel Calise's Lead.

45. A natural process of abrasion occurs in situ with the insulation surrounding the lead wires or electrical conductors. It is foreseeable that such abrasion will occur with the insulation surrounding the lead wires after implantation. As a result, the lead wires protrude through the insulation, causing them to be in contact with materials and fluids that can prevent the proper functioning of the ICD. This protrusion is called "externalization." This process contributed to the failure of Danile Calise's Lead.

46. The breach of insulation and externalization of the lead wires on the Riata Leads can cause the leads to short, and to transmit incorrect information or noise to the pacemaker/defibrillator thereby causing it to produce unnecessary and very painful shocks of electricity, or alternatively, to fail to communicate with the

pacemaker/defibrillator at which point the life-saving therapies of the device are unavailable, and in fact this occurred in the case of Danile Calise's Lead.

47. Additionally, St. Jude Medical applied and received approval for multiple changes to the cure and sterilization processes used in the manufacture of the Riata Leads. Upon information and belief, St. Jude Medical, failed to comply with the approved methods of curing and sterilization during the manufacture of the leads. Upon information and belief, failure to follow the approved cure and sterilization processes resulted in reduced tensile strength of the silicone insulation, abrasion, and lead failure, including the failure of Daniel Calise's Lead.

48. St. Jude Medical applied and received approval for numerous modifications to the welding and crimping procedures in the manufacture of the Riata Leads. Upon information and belief, the PMA and Conditions of Approval required the application of a controlled, uniform degree of force when applying the crimp. Upon information and belief, failure to crimp with a controlled, uniform, degree of force, resulted in insecure crimps over the length of the lead, abrasion, and lead failure, including the failure of Daniel Calise's Lead.

49. Upon information and belief, St. Jude Medical committed to the FDA that the Riata Leads would be manufactured in such a way as to have a useful life years longer than the leads actually have. St. Jude Medical's failure to manufacture the leads such that they meet the useful life is a manufacturing defect that would not have occurred had the leads been manufactured as St. Jude Medical committed to the FDA, and resulted in abrasion and lead failure, including the failure of Daniel Calise's Lead.

50. Failure of the Riata Leads was apparently unrelated to patient age or sex, ICD indication, the primary heart disease, left ventricular ejection fraction, or lead tip position, suggesting that manufacturing problems are responsible for the failure of the devices.

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D. Recall of Several Riata Leads

51. On December 15, 2010, St. Jude Medical published a "Dear Doctor" letter regarding its Riata Leads. In the 2010 letter, St. Jude Medical indicated that issues with defects in the insulation have been identified in the Riata Lead Models 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 7001, 7002, 7010, 7011, 7040, 7041, and 7042.

52. Specifically, St. Jude Medical states that "the Riata and Riata ST Family of Silicone Leads have exhibited an insulation abrasion rate of 0.47% over nine years of use." Additionally, St. Jude Medical noted that the silicone used on these leads was "vulnerable to abrasion."

53. In the 2010 Dear Doctor Letter, St. Jude Medical indicated that lead insulation abrasion had been associated with:

a) Oversensing (leading to inhibition of pacing or inappropriate high voltage therapy);

b) Undersensing;

c) Loss of capture;

d) Changes in pacing and/or high voltage lead impedances; and

e) Inability to deliver high voltage therapy.

54. Despite the dangers associated with these leads, St. Jude Medical did not initiate a voluntary recall of the leads at that time. Rather, St. Jude Medical simply noted that it was "phasing-out" all Riata Lead models by the end of 2010.

55. On November 28, 2011, St. Jude Medical published a second Dear Doctor letter relating to the same set of Riata Lead models as the 2010 Dear Doctor letter.

56. The November 28, 2011, Letter updated the previously published failure rates for the Riata Leads, indicating that it had increased to 0.63% from its 2010 rate of 0.47%. Again, despite the dangers associated with these leads, St. Jude Medical did not initiate a voluntary recall.

57. On December 21, 2011, the FDA reclassified St. Jude Medical's Dear Doctor advisories to a Class I Recall.

58. A Class I Recall is the most serious level of recall and is defined as: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

59. Specifically, the FDA indicated that the reason for the recall was that "failures associated with lead insulation abrasion on the St. Jude Medical Riata and Riata ST Silicone Endocardial Defibrillation Leads may cause the conductors to become externalized. If this occurs, this product may cause serious adverse health consequences, including death."

E. Physicians Expose the Riata Lead Defects

60. Beginning in September 2011, Dr. Robert Hauser of the Minneapolis Heart Institute Foundation (MHI), began researching the FDA's MAUDE database for reported deaths related to the St. Jude Medical Riata Leads.

61. In a manuscript sent to the Heart Rhythm Journal in March 2012, Dr. Hauser detailed his research and conclusions comparing the failure rates of the St. Jude Medical Riata Leads to the reported failure rates of a competitor's leads. Hauser, R.G., Abdelhadi, R., McGriff, D., Retel, L.K., Deaths Caused by the Failure of Riata and Riata ST Implantable Cardioverter-Defibrillator Leads (March 4, 2012) (as yet unpublished manuscript) (on file with author).

62. In his manuscript, Dr. Hauser indicated that the reports showed that 31% of the deaths involving the Riata Leads were lead-related, whereas 8% of the deaths involving the competitor's lead were found to be lead-related. *Id.* It is important to note that adverse events are often under-reported. *Id.*

63. Additionally, Dr. Hauser noted that "Abnormal high voltage impedances were the hallmark of catastrophic Riata and Riata ST Lead Failure, often resulting in failure to defibrillate." *Id.* Finally, Dr. Hauser concludes that the

Riata Leads are prone to high-voltage failures that have resulted in multiple deaths. *Id.*

64. On March 8, 2012, Dr. Hauser's article entitled "Here we Go Again – Another Failure in Postmarketing Device Surveillance" was published in the New England Journal of Medicine. This article exposed the increased harm in failing to have an accurate, active post-market reporting mechanism for medical devices and advocated for greater research and review of medical device failures in order to better protect patients. Robert G. Hauser, Here We Go Again – Another Failure in Postmarketing Device Surveillance, 366 New Eng. J. Med. 873, 873-75 (2012).

65. In May 2012, Dr. Hauser published additional findings regarding the Riata Lead insulation defects in the Heart Rhythm Journal. Hauser, R.G., McGriff, D., Retel, L.K., Riata Implantable Cardioverter-Defibrillator Lead Failure: Analysis of Explanted Leads with a Unique Insulation Defect (May 2012).

F. Plaintiffs' Factual Allegations

66. The son of Plaintiffs ROSE CALISE and PAUL CALISE, Daniel Calise, was implanted with a Riata Lead Model 1580-65, S# RE48482 on or about December 13, 2005 at Holy Cross Hospital in Ft. Lauderdale, Florida.

67. On or about September 6, 2011, Daniel Calise, son of Plaintiffs ROSE CALISE and PAUL CALISE, was taken by ambulance to Holy Cross Hospital in Fort Lauderdale, Florida, following his cardiac arrest.

68. On or about September 17, 2011, Daniel Calise, the son of Plaintiffs ROSE CALISE and PAUL CALISE died. Daniel Calise's death was proximately caused by Daniel's malfunctioning Lead.

69. A thorough interrogation following Daniel Calise's death confirmed that the Lead implanted in Plaintiffs ROSE CALISE and PAUL CALISE' son Daniel Calise was abraded, the shocking coil was fractured, and the Lead malfunctioned when it failed to provide ICD therapy as a result of the fractured shocking coil. Daniel's Lead malfunctioned because its manufacture deviated

from the FDA-imposed manufacturing requirements set forth in the PMAs described above.

70. As a result of the defect in his Riata Lead, Plaintiffs ROSE CALISE and PAUL CALISE lost their son and will continue to suffer emotional, economic and other damage.

V.

CLAIMS FOR RELIEF

COUNT I

STRICT LIABILITY – MANUFACTURING DEFECT

71. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

72. Upon information and belief, the Riata Leads possess a manufacturing defect because the actual manufacture of the Riata Leads differs from the specifications set forth in the PMA and the conditions for approval.

73. This manufacturing defect renders the Riata Lead unreasonably dangerous for its intended use and plaintiff could not have anticipated the danger the defect in this product created.

74. This manufacturing defect was present in the Riata Lead when it left defendants' control.

75. The Riata Leads were expected to and did reach plaintiffs' son without substantial change or adjustment to their mechanical function upon implanting the Riata Leads.

76. As a direct and proximate result of the manufacturing defect, plaintiffs lost their son and have sustained and will continue to sustain severe emotional distress, mental anguish, economic losses, and other damages for which they is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

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COUNT II

NEGLIGENCE IN MANUFACTURING

77. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

78. Defendants have a duty to manufacture the Riata Leads consistent with the PMA and conditions of approval. Defendants breached this duty.

79. As a direct and proximate result of defendants' negligence, plaintiffs lost their son and have sustained and will continue to sustain severe emotional distress, mental anguish, economic losses, and other damages for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT III

NEGLIGENCE PER SE

80. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

81. Federal Regulations impose standards of care on St. Jude Medical related to the manufacture, marketing, and sale of the Riata Leads.

82. Plaintiffs allege the Federal Regulations define the standard of care, and thus, St. Jude Medical's duties are contained in, but not limited to, the following: 21 CFR 803.10; 21 CFR 803.50; 21 CFR 803.52; 21 CFR 803.53; 21 CFR 803.56; 21 CFR 806; 21 CFR 814.1; 21 CFR 814.3; 21 CFR 814.9; 21 CFR 814.20; 21 CFR 814.37; 21 CFR 814.39; 21 CFR 814.80; 21 CFR 814.82; 21 CFR 814.84; 21 CFR 820.5; 21 CFR 820.20; 21 CFR 820.22; 21 CFR 820.25; 21 CFR 820.70.

83. Plaintiffs are within the class of persons the statutes and regulations protect and plaintiff's injuries are the type of harm these statutes and regulations are to prevent.

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84. Upon information and belief, the Conditions of Approval for the Riata Leads incorporate these statutes and regulations. Failure to comply with the Conditions of Approval invalidates the approval order. *See* 21 CFR 814.82(c). St. Jude Medical failed to comply with the Conditions of Approval and Federal Regulations.

85. As a direct and proximate result of defendants' failure to manufacture the Riata Leads consistent with the PMA and conditions of approval, plaintiffs lost their son and have sustained and will continue to sustain severe emotional distress, mental anguish, economic losses, and other damages for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT IV

FAILURE TO WARN

86. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

87. Defendants had a continuing duty to monitor the Riata Leads after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.

88. Defendants failed to timely provide information to the FDA regarding complaints concerning the product and/or adverse health consequences of which it became aware and that were attributable to the product.

89. Had defendants properly reported the adverse events to the FDA as required under federal law, that information would have reached plaintiff and his treating physicians in time to prevent his injuries.

90. As a direct and proximate result of defendants' failure to timely report adverse events to the FDA as required under federal law, plaintiffs lost their son and have sustained and will continue to sustain severe emotional distress, mental

anguish, economic losses, and other damages for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT V
WRONGFUL DEATH

91. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

92. Defendants, and each of them, were negligent and acted unlawfully as referenced herein and caused the hereinafter described injuries and damages to decedent which resulted in the decedent's death.

93. As a proximate result of the aforesaid conduct of defendants, and each of them plaintiffs have been deprived of the love, support, income, services, comfort, protection, care and society of a kind, faithful and loving son, all to plaintiffs' general damage in a sum unknown to plaintiffs at this time, but plaintiffs shall seek leave to amend this pleading when the same has been ascertained, together with prejudgment interest thereon from the date of plaintiffs' first offer to compromise.

94. As a further proximate result of the aforesaid conduct of defendants, and each of them, plaintiffs have been required to bear funeral and burial expenses, and medical bills, as well as other costs, incidental and special damages that are unknown at this time, but plaintiffs shall seek leave to amend this pleading when the same has been ascertained, together with prejudgment interest thereon from the date of plaintiffs' first offer to compromise.

95. As a further proximate result of the aforesaid conduct of defendants, and each of them, plaintiffs were prevented from attending to their usual occupations and plaintiffs are informed and believe and therefore allege, that they will thereby be prevented from attending to their usual occupations for a period of time in the future, all to plaintiffs' further damage in an amount unknown at this

time, and plaintiffs will ask leave to amend this pleading to show the exact amount when determined. Further, plaintiffs are entitled to prejudgment interest on said amount from the date of claimant's offer to compromise.

96. Discovery and investigation have not been completed and contentions of plaintiffs may vary prior to trial.

VII.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs pray for judgment against defendants and each of them as follows:

1. For economic and non-economic damages in an amount as provided by law and to be supported by the evidence at trial;

2. For compensatory damages according to proof;

3. For declaratory judgment that defendants are liable to plaintiffs for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs, and losses caused by defendants' wrongdoing;

4. For disgorgement of profits;

5. For punitive damages in an amount as provided by law and to be supported by the evidence at trial;

6. For an award of attorneys' fees and costs;

7. For prejudgment interest and the costs of suit; and

8. For such other and further relief as this Court may deem just and proper.

VII.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury as to all claims in this action.

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Dated: September 12, 2013

Respectfully Submitted,

KERSHAW, CUTTER & RATINOFF, LLP

By: _____
C. Brooks Cutter
John R. Parker, Jr.
Attorneys for Plaintiffs