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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

Michael V. Thompson, Plaintiff, v. St. Jude Medical, Inc. and Pacesetter, Inc., Defendants.	Court File No. CV13-02715-DSF (CFMx) **COMPLAINT** **JURY TRIAL DEMANDED**

I. INTRODUCTION

1. Plaintiff, Michael V. Thompson (hereinafter "Plaintiff"), brings this Complaint against St. Jude Medical, Inc., and Pacesetter, Inc. (collectively referred to as "St. Jude" or "Defendants") for injuries caused by defects in his St. Jude Riata Lead (hereinafter referred to as "Riata Leads" or "Leads") and by violations of Defendants' state-law duty of care to report known risks with the use of the Leads. Plaintiff alleges that he was implanted with a defective Riata Lead and subsequently suffered injury as a result of these defects and violations.

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 via cables and conductors and are positioned in the heart, where they monitor the heartbeat and correct any irregular rhythms.

3. In 1996, St. Jude received approval to market the Ventritex TVL lead, the predecessor of the Riata and Riata ST Leads. St. Jude Medical ultimately introduced its Riata Leads into the U.S. Market beginning in 2002. These Leads were based on the original submission to the U.S. Food and Drug Administration ("FDA") in 1996 and numerous supplements. Approximately 227,000 Riata leads have been sold worldwide since being approved for marketing. 79,000 Riata Leads are estimated to remain active in the United States.

4. Defendants soon realized that the Riata leads were subject to higher than expected rates of insulation abrasion and commissioned an internal audit to investigate the abrasion issues, but did not disclose adequate information to the public regarding the increased risk of abrasion.

5. In late 2010, Defendants ceased marketing of the Riata leads and issued a Dear Doctor letter on November 28, 2011.

6. On December 14, 2011 the Food and Drug Administration (FDA) classified Defendants' November 2011 advisory as a Class I Recall. This Recall includes 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").

II. PARTIES

A. Plaintiff

7. Plaintiff is a citizen and resident of Brentwood, Tennessee.

8. Plaintiff was implanted with a Riata Lead Model 1580, serial number RE33685, in 2004. On or about April 19, 2012, Plaintiff's physician advised him that his Riata lead was failing and that the Riata lead needed to be replaced.

9. On June 18, 2012, Plaintiff presented to Vanderbilt Medical Center where his defective Riata lead was removed via laser extraction.

10. As a result of the defect in his Riata lead, Plaintiff has been injured and will continue to suffer physical, emotional, economic and other damage. Plaintiff's damages include but are not limited to multiple fluoroscopy procedures, extrusion of the conductor, compromised lead insulation, increased lead impedance, and electrical abnormalities in his Riata Lead resulting in invasive and dangerous laser extraction surgery.

B. Defendant

11. 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.

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

13. Defendant Pacesetter, Inc. ("Pacesetter") is a Delaware corporation with its principle place of business at 15900 Valley View Court, in Sylmar, 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.

14. Pacesetter also holds the trademark for Riata. Specifically, on September 07, 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.

III. JURISDICTION AND VENUE

15. The Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332 insofar as the parties are citizens of different states and the amount in controversy in this matter exceeds Seventy-Five Thousand Dollars ($75,000), exclusive of interest and costs.

16. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391 (a)(2) because Defendants regularly solicited and engaged in business and other persistent courses of conduct and derived substantial revenues from goods used in the State of California. Defendants also hold offices in the State of California.

III. 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 stabilize the heart and allow for a return to an appropriate rhythm.

18. Generally, 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, also known as 'leads'. 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 via cables and/or conductors and are 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, if necessary, into a normal rhythm.

19. Any failure that compromises the ability of the lead to sense and/or transmit electrical signals will result in a failure of the ICD to perform properly. Lead failures may include externalization of the conductors, abrasion, fractured wires/cables/conductors, 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.

B. <u>The Regulatory Approval Process Generally</u>

20. A pre-market approval application ("PMA") must be submitted to the FDA for any Class III medical device. *See* 21 U.S.C. 515(b); 21 C.F.R. §814.3(e). A PMA must contain certain information which is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue. A PMA and/or PMA Supplement application must provide:

a) proposed indications for use;

b) device description including the manufacturing process;

c) any marketing history;

d) summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk considerations);

e) methods used in manufacturing the device, including compliance with current good manufacturing practices; and

f) information relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the manufacturer from any source, including commercial marketing experience.

C. The Regulatory Approval Process Specific to the Riata Leads

21. In May, 1996, the FDA approved the original (P950022). From 1996 to 2002 Defendants submitted and the FDA approved 14 supplements to this original PMA. These supplements altered various aspects of the design and manufacture of the leads.

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. This approval applied to Riata Model Numbers 1570, 1571, 1580, and 1581.

23. On January 22, 2003, the FDA, pursuant to St. Jude Medical's application number P950022/S015, approved an extension of the shelf-life of the Riata Leads.

24. 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.

25. On July 1, 2003, the FDA, pursuant to St. Jude Medical's application number P950022/S017, approved the addition of a fluoroscopic marker in the helix tip and the addition of new lead lengths and modifications to the suture sleeve.

26. On April21, 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 of 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 addition the Riata ST Lead Models 7000, 7001, and 7002 under application number P950022/S024.

29. On November 4, 2005, the FDA approved, pursuant to St. Jude Medical's application number P950022/S025 the addition of six lead models with elast-eon 2a lead body insulation materials to the Leads.

30. In March of 2006, the FDA approved changes to the Riata Leads, including: 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 addition of white pigment to the medical adhesive used for shock coil backfill; 2) modifications to the Riata ST Models 7000, 7001, and 7002 leads including creation of 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.

31. On July 7, 2006, the FDA approved, pursuant to St. Jude Medical's application number P950022/S030, an overlay over the silicone lead body of the Riata ST leads to create the new Riata ST Optim lead models 7020, 7021, 7022, 7030, 7031, 7070, 7071.

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

33. 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).

34. 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).

35. In March 2007, the FDA approved St. Jude Medical's application for changes to their Riata Leads, including: 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 an alternate 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).

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

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

38. 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).

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

40. In July 2008, the FDA approved St. Jude Medical's application to use a manufacturing site for the Riata Leads in Arecibo, Puerto Rico. (P950022/S051).

D. <u>FDA Inspections of Defendants Manufacturing Facilities and Processes</u>

41. In 2009, the FDA conducted a For-Cause Quality Systems Inspection Technique (QSIT) of Defendants' manufacturing facility in Sylmar, California. As part of this inspection, the FDA requested a list of all Corrective and Preventative Action (CAPA) and Product Improvement Requests (PIR) opened since 2002. Defendants provided the following PIRs regarding High Voltage Leads:

- 09-005 – Helix extension retraction failure due to the spring popping out of its location and getting jammed between the header coupling and stopper
- 09-001 – Cable Fracture under Strain Relief Coil DF-1 leg

- 07-006 – Outer Coil Fractures at IS-1 Connector Ring
- 06-014 – Hypot Failures in Riata ST Leads Manufacturing
- 06-012 – Riata Coil Fracture at Inner coil Shaft
- 06-005 – Missing DF-1 Crimps in HV Lead Manufacturing
- 06-004 – Swapped DF-1 Labels in HV Lead Manufacturing
- 06-003 – Riata Lead With Incorrect Conduction Paths
- 05-016– Riata Integrated Bipolar IS-1 Connector Dielectric Strength Improvement
- 05-009- Riata Lead Abrasion
- 04-006 – Insufficient Crimp on RV shock coil termination ring employed on the Riata Integrated Bipolar Leads seen in Manufacturing
- 04-003- Riata Perforation
- 03-006 – Riata Lead Cable Coating Abrasion
- 02-004 – Riata, Missing Weld, DF-1 Conn. Pin.

42. The inspection revealed that Defendants had deficiencies in the handling of complaints, making Medical Device Reporting (MDR) determinations, CAPA procedures, and receiving protocols.

43. MDRs are the mechanism by which the Food and Drug Administration receives significant medical device adverse events from **manufacturers, importers and user facilities**, so that problems can be detected and corrected quickly.

44. The FDA publishes the adverse events and MDRs in a public, searchable database called the MAUDE database and updates the report monthly with "all reports received prior to the update." *See,* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm. The general public, including physicians, and patients, may use the MAUDE database to obtain safety data on medical devices. For example, Dr. Hauser published a

study in the Heart Rhythm Journal that assessed the number of deaths associated with the Riata leads. *See* Hauser et al. *Deaths caused by the failure of Riata and Riata ST implantable cardioverter-defibrillator leads*. HEART RHYTHM, 2012 Aug; 9(8):1227-35. Dr. Hauser's assessment was based on his search and analysis of the MAUDE database.

45. Indeed, doctors reported abrasion problems with the Riata leads to St. Jude. However, doctors were left with the impression that such problems were rare because St. Jude did not adequately submit this information to the FDA and/or otherwise advise the public. Specifically, an October 2012 article in the Wall Street Journal reports that physicians including Dr. Alan Cheng, director of Johns Hopkins Medicine's arrhythmia service; Dr. Samir Saba, chief of electrophysiology at the University of Pittsburgh Medical Center; and Dr. Ernest Lau at the Royal Victoria Hospital in Belfast, Ireland, had encountered abrasion in the Riata leads between 2006 and 2009. However, when these doctors brought the incidents to the attention of St. Jude they were told by company officials and field representatives that the incidents were isolated.

46. The Wall Street Journal further reported that St. Jude had been tracking the abrasion issue for "several years" and that abrasion became a focus of an internal St. Jude audit, which examined multiple instances of that type of failure before April 2008.[1] According to the article, St. Jude's internal audit concluded in 2008 that Riata had "potentially serious insulation problems including inside-out abrasion." The audit, which had been looking broadly at insulation problems by 2006, included a special section on inside-out abrasion, which cited examples of inside-out abrasion in at least two devices extracted from patients, as well as in lab

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[1] Christopher Weaver, St. Jude Riata Heart Device – Device Flaws Known For Years, Wall St. J., Oct. 11, 2012, at http://online.wsj.com/article/SB10000872396390444223104578036752346768278.html.

testing. The report, which didn't address whether the problems resulted in injuries or deaths, said 32 of the 246 leads examined were damaged enough to inhibit lifesaving shocks. The company had sold more than 120,000 Riata leads in the U.S. by that time, and the risk of all abrasion-related failures appeared "remote," the audit said.

47. Accurate reporting of adverse events is essential, as it serves to notify the public that a potential problem with the device exists, and can prompt an informed person or organization to develop a solution. The FDA and others, including the public, rely upon accurate and timely reporting of adverse events. Post-market surveillance by FDA is hampered when mandatory reporting terminology is not clear, accurate and consistent.

48. The FDA 2009 inspection also revealed that Defendants failed to follow their procedure for product design developments of the Leads.

49. As a result of these deficiencies, the FDA issued an eight-item FDA-483 Report on July 8, 2009. An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic Act and related Acts. FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific, and significant.

50. Specifically, these deficiencies identified by the FDA in the Form 483 2009 included the following:

a. Defendants failed to include all information that was reasonably known to the manufacturer on an MDR Report in violation of 21 CFR 803 *et seq.*

b. Defendants failed to timely submit MDRs to the FDA and such submissions were significantly past the mandatory reporting

timeframes without written explanation in violation of 21 CFR 803 *et seq.*

c. Defendants failed to define the procedures for implementing corrective and preventative actions in violation of 21 CFR 820 *et seq.* Specifically, the Standard Operating Procedure for risk analysis failed to define the methodology for obtaining the Probability of Occurrence that is used in Risk evaluations resulting in inconsistent risk analyses.

d. Defendants failed to review their sampling methods for adequacy of their intended use in violation of 21 CFR 820 *et seq.* Specifically, the procedure "Receiving Inspection Sampling Program" allows components to be accepted without receiving inspections and review of vendor certificates (Dock to Stock method). The procedure did not have a monitoring program for receiving components that were subject to Dock to Stock methods. As of June 23, 2009, a significant number of "critical components for defibrillation leads were Dock to Stock components." Also, the sections of "Dock to Stock General Requirements" and "Dock to Stock Part Declassification" were purged without written justifications.

e. Defendants failed to perform design reviews at appropriate times in violation of 21 CFR 820 *et seq.* Specifically, Design Phase reviews were not conducted as required by the procedure for Global Product Development Protocol and the Product Development Plan. Additionally, team meeting minutes were not maintained as required.

f. Defendants failed to perform a complete risk analysis in violation of 21 CFR 820 *et seq.* Specifically, the Failure Mode,

Effects, and Criticality Analysis (FMECA) did not include all drawings and St. Jude was unable to explain why component drawings were not evaluated for failure mode, effect, and criticality analysis. The design FMECA analysis for components and top assembly drawings were part of the risk analysis for the Riata leads.

g. Defendants failed to establish procedures for the validation or verification review, and approval of design changes before their implementation in violation of 21 CFR 820 *et seq.* Specifically, Defendants had no written procedure describing the review and approval process of the design verification plan and report, when design changes require a verification plan.

h. Defendants failed to resolve discrepancies noted at the completion of design verification in violation of 21CFR 820 *et seq*. Specifically, the review of Quality Test Report (QTR) 1403 for Riata Series 1500 shows someone who reviewed the data sheets had made a change to the specification of DC resistance on the Qualification Test Data Sheets for Composite Lead Tensile Test, but the reason for the discrepancy and reason for the change were not discussed in the QTR or meeting minutes.

51. Additionally, the 2009 Establishment Inspection Report indicated that "complaints representing events that are MDR reportable were not promptly reviewed, evaluated, and investigated by the designated individual per 21 CFR 820.198(d)."

52. The FDA also noted that training on complaint handling by Defendants' field staff needed improvement. Specifically, "many products [were] returned for analysis without an associated complaint, although obtaining the

reason for explant would not be expected to be difficult for the field staff attending procedures."

53. Additionally, "review of the MDRs submitted from 2007 through June 2009 found no evidence that the events described in [medical or scientific literature] were submitted to FDA as required by regulations and company procedures."

54. The FDA also reported that Defendants' Standard Operating Procedure for Global Risk Management (SOP 4.7.2) was inadequate as it related to "clinical risk in new product development and throughout the product life cycle, [and] was inadequate in that the procedure did not establish a methodology for obtaining a Probability of Occurrence used in Risk Evaluations." Defendants' Product Improvement Requests (PIRs) demonstrated these inadequacies.

55. The FDA noted that Defendants had the required written procedure to cover design changes. However, according to the FDA, the reasons and justifications for design changes were not always properly documented.

56. As part of the inspection, the FDA also requested Defendants' World Wide Product Disposition Review Board (WWPDRB) meeting minutes, which dated back to 2006. Specifically, the WWPDRB meetings were held to "discuss issues that had a Criticiality value of four or five. The meeting minutes consisted of a brief summary, list of participating members, and PowerPoint slides used for the presentation of issues."

57. During the 2009 inspection, the FDA also inquired about the design controls related to the Riata leads, including but not limited to Conceptual Design Review Reports, Product Development Plans, Hazard Analysis, FME and FMECA's, Design Verification Test Reports and Qualification Test Reports.

58. On October 17, 2012, the FDA conducted a subsequent 483-inspection of Defendants' Sylmar, California manufacturing facility and identified several deficiencies including failures regarding design verification, complaint

handling, CAPA procedures, risk analyses, inspection/measuring/testing/calibration of equipment, document control, and employee training.

E. Manufacturing Defects with Regard to Riata Leads

59. From 2005-2010 St. Jude applied for over 27 manufacturing or process changes to the Riata Leads. The FDA approved many of these changes in PMA supplements. Upon information and belief, Defendants failed to manufacture the Riata Leads consistent with the approved specifications and/or procedures set forth in the PMA and/or federal regulations thereby creating a defective product.

60. Upon information and belief, one of the failures to follow specifications, federal regulations, and/or the PMA includes the failure to manufacture the internal conductors, or cables, at sizes consistent with the specifications. This failure results in increased movement of the conductors, or cables, within the insulation thereby causing inside out abrasion.

61. Upon information and belief, one of these defects also includes inconsistent insulation diameters surrounding the electric conductors, also known as cables. On information and belief, insulation diameters are required by the design specifications, PMA, and/or federal requirements to be consistent. Failure to manufacture insulation diameters consistent with the specifications leads to increased movement of the cables within the outer silicone as well as an increased risk of abrasion at thinner insulation sites, leading to an increased risk of device failure.

62. Further, upon information and belief, one of the failures to follow specifications, federal regulations, and/or the PMA includes St. Jude's failure to consistently apply a lubricious interface inside the lumen between the inner and outer insulation in violation of the design specifications and/or PMA. Upon

information and belief this inconsistent application may have led to increased friction within the lead body, promoting abrasion and/or externalization.

63. Additionally, St. Jude applied for 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, failed to comply with the approved methods and/or specifications 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.

64. Upon information and belief, St. Jude processed the leads in a solution which caused the cables and/or conductors to stretch and then vibrate when exposed to electrical charge thru the silicone, further increasing the risk of abrasion to the leads. Upon information and belief, this process failed to follow the approved specifications, and procedures set forth in the PMA and/or federal regulations.

65. Upon information and belief, St. Jude also failed to consistently trim and/or remove excess adhesive and/or silicone from the outer lead body consistent with approved specifications and procedures set forth in the PMA and/or federal regulations. The inconsistencies in this removal and failure to follow specifications and procedures set forth in the PMA and/or federal regulations results in both inconsistent thickness and less smooth insulation both of which contribute to the abrasion of the lead.

66. Finally, St. Jude applied and received approval for numerous modifications to the welding and crimping procedures in the manufacture of the Riata Leads. Upon information and belief, a controlled, uniform degree of force was required 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, which also leads to increased movement of the lead and diminishes the integrity of the insulation – both of which lead to abrasion.

67. These defects result in abrasion which occurs in situ with the insulation surrounding the cables and/or conductors. As a result, the cables may 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."

68. The breach of insulation and externalization of the cables and/or conductors 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.

69. Finally, upon information and belief, Defendants failed to adequately inspect and/or test the leads and their component parts to ensure consistent with approved specifications and procedures set forth in the PMA and/or federal regulations.

F. Recall Of The Riata Leads

70. On December 15, 2010, St. Jude Medical published a "Dear Doctor" letter regarding its Riata Leads. In the 2010 letter, St. Jude 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.

71. Specifically, St. Jude 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 noted that the silicone used on these leads was "vulnerable to abrasion."

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72. In the 2010 Dear Doctor Letter, St. Jude 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

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

74. 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.

75. 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 did not initiate a voluntary recall.

76. On December 21, 2011, the FDA reclassified St. Jude's Dear Doctor letters as a Class I Recall.

77. 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.

78. 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 causes, including death."

G. Physicians Expose the Riata Lead Defects

79. By September 2011, Dr. Robert Hauser of the Minneapolis Heart Institute Foundation (MHI), was researching the FDA's MAUDE database for reported deaths related to the St. Jude Riata Leads.

80. 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 Riata Leads to the reported failure rates of a competitor's leads. Hauser et al. *Deaths caused by the failure of Riata and Riata ST implantable cardioverter-defibrillator leads*. HEARTRHYTHM 2012 Aug;9(8):1227-35.

81. 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 grossly under-reported. See generally U.S. GAO Report to Congressional Committees: Medical Device Reporting; Improvements Needed in FDA's System for Monitoring Problems with Approved Devices (Jan. 1997) (citing previous GAO findings that "less than 1 percent of the device problems occurring in hospitals were reported to FDA, and that, the more serious the problem with the device, the less likely it was to be reported to the FDA"), available at www.**gao**.gov/archive/1997/he97021.pdf

82. 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." Hauser et al. *Deaths caused by the failure of Riata and Riata ST implantable cardioverter-defibrillator leads*. HEARTRHYTHM 2012 Aug;9(8):1227-35Finally, Dr. Hauser concluded that the Riata Leads are prone to high-voltage failures that have resulted in multiple deaths. *Id.*

83. On March 8, 2012, Dr. Hauser published an article in the New England Journal of Medicine, exposing 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).

84. St. Jude Medical reacted to Dr. Hauser's article in what industry analysts have described as a "rare," "unprecedented," and "confounding" manner by urging the peer reviewed journal, HeartRhythm, retract Dr. Hauser's article. *See* Barry Meier and Katie Thomas, *At St. Jude, Firing Back at Critics*, N.Y. TIMES, Apr. 11, 2012, at B1; Susan Kelly and Debra Sherman, *Analysis: Heart device troubles cloud St. Jude's outlook*, Reuters.com, Apr. 13, 2012, http://www.reuters.com/ article/2012/04/13/us-stjude-idUSBRE83C0ME20120413.

85. 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).

86. In 2012, the FDA ordered Defendants to collect clinical data related to the potential for premature insulation failure in Riata and Riata ST Leads. The FDA required Defendants to conduct three-year post-market surveillance studies, or section 522 studies, to address concerns related to premature insulation failure and to address important questions related to follow up of affected patients.

87. In January 2013, a study published in the Heart Rhythm Journal indicated that Defendants had recently advised that the rate of cable externalization was 24% in the Riata 8fr Leads and 9% in the Riata ST 7fr Lead – despite previous reports that such rates were only .63%. The article also stated that a number of studies have confirmed that Riata Leads fail more often than other brands.

V. CLAIMS FOR RELIEF

COUNT I

STRICT LIABILITY – MANUFACTURING DEFECT

88. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

89. Upon information and belief, the Riata Leads possess a manufacturing defect because the actual manufacture of the Riata Leads differs from the specifications and protocols set forth in the federal regulations, PMA and/or the conditions for approval.

90. This failure results in a manufacturing defect that renders the Riata Lead unreasonably dangerous for its intended use and Plaintiff could not have anticipated the danger the defect in this product created.

91. This manufacturing defect was present in the Riata Lead when it left St. Jude's control.

92. The Riata Leads were expected to and did reach Plaintiff without substantial change or adjustment to their mechanical function upon implanting the Riata Leads.

93. As a direct and proximate result of the manufacturing defect, Plaintiff has sustained and will continue to sustain severe physical injuries, 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 II

NEGLIGENCE IN MANUFACTURING

94. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

95. Defendants have a duty to manufacture the Riata Leads consistent with the specifications, PMA, and/or conditions of approval. Defendants breached

this duty. Plaintiff's lead possesses a manufacturing defect because the actual manufacture of the Leads differs from the specifications set forth in the PMA and/or conditions of approval.

96. As a direct and proximate result of St. Jude's failure to manufacture the Riata Leads consistent with the specifications, PMA, and/or conditions of approval, Plaintiff has sustained and will continue to sustain severe physical injuries, 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

97. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

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

99. Plaintiff alleges the Federal Regulations define the standard of care, and thus, St. Jude'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.

100. Plaintiff is 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.

101. 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 failed to comply with the Conditions of Approval and Federal Regulations.

102. As a direct and proximate result of St. Jude's failure to comply with the PMA and conditions of approval for manufacturing the Riata Leads, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which he is entitled to compensatory and other damages and in an amount to be proven at trial.

COUNT IV
NEGLIGENCE RES IPSA LOQUITUR

103. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

104. The manufacturing defects found in the Riata Leads can only occur while the devices are under the control of Defendant.

105. Plaintiff's injury was of a kind that, in the ordinary course of events, would not have happened if Defendant had manufactured the Riata Leads consistent with the specifications, PMA, and/or Conditions for Approval.

106. Defendant was responsible for the manufacturing defect that was the direct cause of Plaintiff's injury.

107. The manufacturing defect that caused the injury was not due to the actions of Plaintiff or any third person.

108. As a direct and proximate result of St. Jude's failure to comply with the PMA and conditions of approval for manufacturing the Riata Leads, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which he is entitled to compensatory and other damages and in an amount to be proven at trial.

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COUNT V

NEGLIGENCE – POST APPROVAL FAILURE TO WARN

109. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

110. Defendants have a continuing duty to monitor the Riata Leads post-approval and to discover and report to the FDA any complaints about the product performance and any health consequences of which it became aware that may be attributable to the product.

111. Defendants also have a continuing duty provide ongoing warnings and instructions regarding safety hazards associated with the Leads.

112. Defendants breached this duty by failing to *inter alia* provide timely and adequate post approval reports regarding safety hazards and/or potential defects associated with the Leads.

113. Defendants also breached this duty by failing to conduct adequate risk analyses and investigations regarding safety hazards and/or potential defects associated with the Leads.

114. Had Defendants properly and timely reported the adverse events to the FDA as required under federal law, this information would have reached the public, including Plaintiff's treating physician and/or Plaintiff, in time to prevent Plaintiff's injury.

115. As a direct and proximate result of St. Jude's failure to comply with the PMA and conditions of approval for manufacturing the Riata Leads, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which he is entitled to compensatory and other damages and in an amount to be proven at trial.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

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

B. For compensatory damages according to proof;

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

D. For disgorgement of profits;

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

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

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

VII. DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all claims in this action.

Dated: April 17, 2013

Respectfully Submitted,

By: _____

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