IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA

WENDY SHARP, Individually, and as Administrator of the ESTATE OF MILTON SHARP,	*	**Civil Action File No.**
Plaintiff.	*	**JURY TRIAL DEMANDED**
v.	*	
ST. JUDE MEDICAL, S.C., INC., ST. JUDE MEDICAL, INC., PACESETTER, INC., d/b/a ST. JUDE MEDICAL CARDIAC RHYTHM MANAGEMENT DIVISION, ST. JUDE MEDICAL, LLC and ABBOTT LABORATORIES, INC.	*	
Defendants.		

COMPLAINT FOR DAMAGES

COMES NOW, Wendy Sharp, individually and as Administrator of the Estate of Milton Sharp ("Plaintiff" or "Ms. Sharp") and files this Complaint for Damages against the Defendants as follows:

INTRODUCTION

1. St. Jude Medical, Inc., St. Jude Medical S.C., Inc., Pacesetter, Inc. d/b/a St. Jude Medical Cardiac Rhythm Management Division and St. Jude Medical, LLC (collectively referred to as "St. Jude" or "Defendant") manufacture a variety of medical devices to treat heart conditions, including implantable cardiac defibrillators ("ICDs") and the wire that connects the ICD to the heart, known as a "lead." The lead and ICD are collectively referred to as the "Device" throughout this Complaint.

2. ICDs are used in patients who have potentially fatal heart rhythms such as ventricular fibrillation (rapid, ineffective contraction of the ventricles of the heart) and ventricular tachycardia (excessively rapid heartbeat) that are not adequately controlled with medication. These arrhythmias can result in injuries or death, unless the patient receives therapy from an appropriate device to restore a functionally adequate cardiac rhythm. These Devices are inherently dangerous because patients rely upon them to provide life-saving treatment.

3. ICDs are typically implanted primarily under the skin of the chest wall. The device's power source, or pulse generator, is implanted in a pouch formed in the chest wall usually over the left pectoral muscle.

4. Leads act to conduct the electrical impulses between the heart and the ICD. Low voltage pacing therapy is provided through pace-sense electrodes to treat slow heart rhythms. High voltage shocks for defibrillation are provided through high voltage conductors. Typically, high voltage leads are inserted through a major blood 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 eliminate or "convert" abnormal heart rhythms or pace the heart at a normal rhythm.

5. When the ICD and lead operate properly together, the system is potentially life-saving. However, compromise of electrical conduction by the lead will result in ICD malfunction and failure. Lead-related failures may result from, among other things, abrasion to the outer cover of the lead that can prevent the ICD from administering a high voltage shock to the patient's heart. If either the ICD or the lead fail to operate, the patient may die within minutes.

6. St. Jude introduced its Riata Leads into the U.S. Market in 2002. Approximately 227,000 Riata Leads have been sold world-wide since

being approved for marketing and 79,000 Riata Leads are estimated to remain implanted in patients in the United States. The Fortify ICD devices were first introduced into the U.S. Market in 2005 and since then approximately 400,000 units were sold within the U.S.

7. Soon after introduction of the Riata lead, Defendants recognized that the Riata Leads were subject to higher than expected rates of insulation abrasion, and commissioned an internal audit to investigate the abrasion issues. Despite being required to under federal law, Defendants did not disclose adequate information to the public regarding the increased risk of abrasion that ultimately resulted in a Class I Recall of the devices.

8. Similarly, due to premature battery failure of the Fortify ICDs, the ICDs were subject to a Class I Recall for the Fortify ICD on October 10, 2016.[1]

9. Milton Sharp relied on the Device manufactured by St. Jude to treat his serious heart condition – cardiomyopathy, atrial fibrillation and ventricular tachycardia.

[1] This recall included the following St. Jude ICD models: Fortify VR, Fortify ST VR, Fortify Assura VR, Fortify Assura ST VR, Fortify DR, Fortify ST DR, Fortify Assura DR; Fortify Assura ST DR, Unify, Unify Quadra, Unify Assura, Quadra Assura and Quadra Assura MP.

10. On August 23, 2015 between approximately 6:45 and 7:00 a.m., Mr. Sharp experienced an episode of cardiac arrhythmia while operating his automobile. At that time, his ICD failed to administer an appropriate shock to his heart, which would have corrected the arrhythmia. The ICD failed to convert the arrhythmia because friction between the external insulation on the Riata lead and the ICD exposed the wires inside the lead, causing the ICD to malfunction when it attempted to administer the shock.

11. As a direct and proximate cause of the malfunction that resulted from the violation of federal regulations and led to the Class I recall of this product, Mr. Sharp drove off the road and was in a collision. He was pronounced dead on arrival at the hospital on August 23, 2015.

12. In this action for money damages, Ms. Sharp asserts product liability claims under Georgia law, including claims of strict product liability for manufacturing defects and failure to warn, negligence based manufacturing defects, negligent failure to warn and negligence per se against the Defendants. The claims asserted by Ms. Sharp arise out of the Defendants' violation of FDA regulations, policies and procedures

applicable to the testing, evaluation, manufacture, sale, recall and warnings related to this Device. The violations of federal regulations, policies and procedures directly led to and caused Mr. Sharp's death. These Georgia law claims are parallel to the failure to abide by federal regulations and therefore provide a cause of action for Mrs. Sharp. The claims Mrs. Sharp asserts herein are not in addition to, but parallel to, the Defendants' violations of federal regulations.

PARTIES

13. Plaintiff Wendy Sharp is a resident of the State of Georgia.

14. Ms. Sharp brings this action for the wrongful death of her husband, Milton Sharp, as his next of kin and seeks damages in excess of $75,000.00 for the value of his life pursuant to O.C.G.A. § 51-4-2.

15. Prior to his demise, Mr. Sharp was also a resident of the State of Georgia; therefore, in her capacity as the Administrator of the Estate of Milton Sharp, Ms. Sharp is deemed to be a resident of the State of Georgia. 28 U.S.C. § 1332(c)(2).

16. As Administrator of the Estate of Milton Sharp, Ms. Sharp brings this action on behalf of the Estate and seeks damages in excess of $75,000.00 for Mr.

Sharp's conscious pain and suffering and his funeral, medical and other necessary expenses.

17. Defendant St. Jude Medical, Inc., is a Minnesota corporation headquartered in St. Paul, Minnesota at One St. Jude Medical Drive, St. Paul, Minnesota 55117. St. Jude Medical, Inc. is registered with the Georgia Secretary of State as a foreign for profit corporation authorized to conduct business within the State of Georgia. St. Jude may be served with summons and a copy of the complaint upon its registered agent, CT Corporation System, 1201 Peachtree St. NE, Atlanta, GA 30361.

18. Defendant St. Jude Medical, S.C., Inc., is a Minnesota corporation headquartered in St. Paul, Minnesota at One St. Jude Medical Drive, St. Paul, Minnesota 55117. St. Jude Medical, S.C., Inc. is registered with the Georgia Secretary of State as a foreign for profit corporation authorized to conduct business within the State of Georgia. St. Jude may be served with summons and a copy of the complaint upon its registered agent, CT Corporation System, 1201 Peachtree St. NE, Atlanta, GA 30361.

19. Defendant Pacesetter, Inc. ("Pacesetter") is a Delaware corporation operating as a wholly owned subsidiary of St. Jude Medical, Inc. Pacesetter's principal place of business is located at St. Jude's

manufacturing facility 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.

20. St. Jude Medical, LLC recently acquired St. Jude Medical, Inc., St. Jude Medical S.C. Inc. and Pacesetter, Inc., d/b/a St. Jude Medical Cardiac Rhythm Management Division on or about January 4, 2017. St. Jude Medical, LLC is a Delaware limited liability corporation headquartered in St. Paul, Minnesota at One St. Jude Medical Drive, St. Paul, Minnesota 55117. At all times relevant to this Complaint, St. Jude Medical, LLC conducted business in Georgia. St. Jude may be served with summons and a copy of the complaint upon its registered agent, CT Corporation System, Inc. at 1010 Dale Street N, St. Paul, MN 55117.

21. St. Jude Medical, LLC is wholly owned by Abbott Laboratories, Inc. Abbott Laboratories, Inc. is a Delaware corporation headquartered at 100 Abbott Park Road, Abbott Park, IL 60064. Abbott Laboratories, Inc. is registered with the Georgia Secretary of State as a foreign for profit corporation authorized to conduct business within the State of Georgia. Abbott

Laboratories may be served with summons and a copy of the complaint upon its registered agent, CT Corporation System, 289 S Culver Street, Lawrenceville GA 30046.

JURISDICTION AND VENUE

22. This Court has original jurisdiction over this action for money damages in excess of $75,000.00 involving citizens of different states. 28 U.S.C. § 1332.

23. This Court has personal jurisdiction over the Defendants because they placed the Device into the stream of interstate and worldwide commerce and transacted, solicited and conducted business in the State of Georgia, including in the geographic area comprising the jurisdiction of the Atlanta Division of the Northern District of Georgia.

24. Venue is proper in this Court as a substantial part of the events or omissions giving rise to the claim occurred in the geographic area comprising the jurisdiction of the Atlanta Division of the Northern District of Georgia. 28 U.S.C. § 1391(b)(2).

25. This court retains jurisdiction over the state law claims pursuant to supplemental jurisdiction since the claims arise out of the same facts as the federal law claim under 28 U.S.C. § 1367(a).

FACTUAL ALLEGATIONS

A. THE DEATH OF MILTON SHARP

26. At the time of his death, Milton Sharp ("Mr. Sharp") was a 68-year-old man at high risk for cardiac arrest.

27. Mr. Sharp experienced an aborted sudden cardiac death on August 23, 2015.

28. St. Jude had knowledge about the dangerous conditions of the Lead and ICD implanted in Mr. Sharp. Defendants failed to provide Mr. Sharp and the public with accurate and complete information with regard to the safety and danger of the Device. This included, but was not limited to, the risk of abrasion of the Riata leads causing insulation failure as well as rapid depleting battery life of the Fortify ICD. These failures to provide Mr. Sharp and the public with accurate and complete information with regard to the safety and danger of the device specifically violated federal regulations requiring the defendants to provide proper notification, warnings and monitoring instructions to patients, there treating doctors and the public at large. Further, these violations caused Mr. Sharp's death.

29. Specifically, the Riata leads such as the one implanted in Mr. Sharp were recalled in March of 2012 due to premature erosion of the insulation around

the electrical conductor wires, known as insulation failure. Mr. Sharp died as a result the defects in the leads that led to the class I recall.

30. The Fortify generators such as the one implanted in Mr. Sharp were recalled on October 1, 2016 due to the lithium battery in the ICD which was prone to lithium ion deposits (known as lithium clusters) that could cause a short circuit between the battery terminals resulting in the unpredictable and rapid draining of battery power leaving those who relied on it such as Mr. Sharp vulnerable to injury and death as a result of the failure of the ICD to perform its life-saving functions. Mr. Sharp died as a result of the defects in the Fortify generators.

31. Defendants knew or should have known that these batteries were subject to rapid depletion without warning, the Fortify generators contained life-threatening defects, and that the leads were subject to insulation failure. Defendants failed to conduct adequate pre-market testing, manufacturing, representations to regulators, post-market monitoring and surveillance, warning and recall of these devices. As a result of these failures, Mr. Sharp's device failed in his time of need and he died.

32. Despite knowing of these failures, Defendants failed to adequately warn patients and their healthcare providers of the risks associated with the

Device. Defendants failed to issue any subsequent warnings when the Device did in fact exhibit early failure. These failures to provide adequate safety and monitoring procedures or to follow accepted protocols dictated by the FDA led to the failure of the device to deliver life-saving treatment.

33. Defendants' actions deprived Mr. Sharp and his physicians of the opportunity to make informed and time-critical medical decisions such as whether to keep, remove or replace the Device. This inability to make informed and time-critical medical decisions about whether to keep, remove or replace the Device ultimately led to Mr. Sharp's death.

34. Prior to his death, Mr. Sharp suffered from episodes of atrial fibrillation.

35. Mr. Sharp's first ICD, an Atlas DRV-243, was implanted on or about October 15, 2004 by Dr. Heather Bloom at the Veterans Administration Hospital in Atlanta, Georgia. One week later, the ICD was replaced due to lead perforation. It was replaced with a Riata Active Fixation Lead, Model No. 1581/65, Serial No. RH31645.

36. On September 9, 2011, Mr. Sharp had another operation to replace the generator with a St. Jude Fortify DR, Model No. CD2231-40, Serial No 608440 ICD. The Riata lead remained intact and the new generator was connected to the leads.

37. Physicians monitor ICD devices to ensure that they are functioning correctly using a non-invasive process known as "interrogation." During an interrogation, the device is connected to a device programmer using a special wand placed on the skin over the ICD. The data is transmitted from the device to the programmer and evaluated.

38. Before Mr. Sharp left the care of Dr. Bloom, his ICD was interrogated and found to be in good working order and the ICD battery was fully charged.

39. Dr. Bloom referred Mr. Sharp to Dr. Harold Carlson at the Piedmont Heart Institute and the device was regularly interrogated to make sure it was working properly.

40. Mr. Sharp's device was first interrogated on November 23, 2011. At the time, the device was found to be in good working order.

41. On March 22, 2012, Mr. Sharp's device was interrogated and revealed a patient safety alert of a recall of the Riata lead stating: "Medical device advisory on St. Jude Medical in Riata and Riata ST silicone endocardial defibrillator leads issued on 27 February 2012. Recommendations for closely monitoring and registration of device for remote TTM have been implemented as recommended." The lead interrogation also revealed a warning stating that: "HV Lead impedance greater than upper limit." This

alert was due to premature erosion of the insulation around the electrical conductor wires, known as insulation failure.

42. Mr. Sharp's lead was again interrogated on August 30, 2013 where the same Patient Alert was recorded.

43. Similarly on July 16, 2013, a lead interrogation revealed that "PT HAS RIATA LEAD ALERT, PARAMETERS ARE IN PLACE".

44. This same safety alert was documented during Mr. Sharp's July 3, 2014, January 9, 2014, and July 23, 2015 interrogations.

45. On January 13, 2015 the device was evaluated via FastPath software. This interrogation included an ability of the software to post an Alert notifying that Mr. Sharp's device had a recalled Riata lead. Specifically, the message stated: "PT HAS RIATA 1581 LEAD ALERT, PARAMETERS ARE IN PLACE."

46. Finally, just one month before Mr. Sharp's death, on July 23, 2015 when Mr. Sharp visited St. Jude Medical for a FastPath Summary which interrogates the Lead device. During this visit, the interrogation revealed the same warning stating: "PT HAS RIATA LEAD ALERT, PARAMETERS ARE IN PLACE".

47. Despite this, no additional measures, warnings, or procedures were ever provided to Mr. Sharp or even addressed, such as replacing the defective lead. Additionally, Mr. Sharp's Device never had any warnings related to the Fortify ICD, despite the known problem of rapid battery depletion. These failures violated federal regulations and, specifically, the instructions fromthe U.S. government related to the recall, and directly contributed to Mr. Sharp's death.

48. On August 23, 2015, Mr. Sharp suffered a cardiac arrest as he was driving on the Highway 400 in Sandy Springs, GA between 6:45 and 7:00 a.m., causing him to veer off the road and hit a tree stump. Mr. Sharp was unresponsive when EMT personnel arrived and he was rushed to St. Joseph's Hospital of Atlanta at 5665 Peachtree Dunwoody Road, NE, Atlanta GA 30342 .

49. Mr. Sharp was unable to be resuscitated and pronounced Dead on Arrival ("DOA") at approximately 11:08 a.m on August 23, 2015.

50. Following protocols set forth in the Federal regulations governing medical devices, Dr. Harold Carlson, took steps to ensure that the ICD and Riata lead were returned to St. Jude for inspection and testing.

51. Interrogation of the lead by St. Jude revealed that the device delivered HV therapy for VF on August 23, 2015 at 6:56 a.m. but that the HV shock was ineffective in reducing the arrhythmia. The first HV therapy delivery was unsuccessful because the RV to CAN arc damaged two high voltage output transistors on the electronic circuit board. As a result, the ICD device attempted four subsequent VF episodes on August 23, 2015, two at 7:02 a.m., one at 7:11 a.m. and one at 7:17 am, all of which were aborted due to detection of possible HV circuit damage. None of the VF and HV therapy was successful. The device entered into a Power-On Reset at approximately 7:17 a.m. on August 23, 2015.

52. Victor Tran, a St. Jude employee, was responsible for conducting the inspection of Mr. Sharp's ICD and partial Riata lead.

53. The visual inspection of the ICD revealed an arc mark on the back of the ICD under the header and near the RV Coil DF-1 lead bore opening and detected the presence of lead conductor material at the site of the arc mark. A test shock was performed and was aborted due to the detection of "possible HV circuit damage or other conditions."

54. Mr. Tran concluded that during the high voltage therapy delivery, the device detected VF and HV therapy was delivered but it was not successful.

Analysis of the Riata lead indicated that the malfunction of the first HV therapy delivery was attributed to an RV to CAN arc damage to two high voltage output transistors on the electronic circuit board and that the remaining HV delivery was aborted due to HV circuit damage.

55. Circuitry and transistor defects as well as lead abrasion were conditions known to the Defendants, and for which they recalled the Device. These conditions were the product of known manufacturing defects which inpaired the function of of the Device, and caused Mr. Sharp's ICD malfunction and ultimately caused his death.

B. THE FEDERAL FOOD, DRUG & COSMETIC ACT AND THE FDA'S REGULATORY PROCESS RELATED TO THE DESIGN, PRODUCTION, MANUFACTURE AND SALE OF MEDICAL DEVICES.

56. The Food Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., addresses the development, manufacturing, and distribution of medical devices in the United States. The Food and Drug Administration ("FDA") is responsible for ensuring that medical device manufacturers abide by the FDCA and applicable regulations.

57. A pre-market approval application ("PMA") must be submitted to the FDA for any Class III medical device, such as the Riata lead and Fortify ICD. *See* 21 U.S.C. § 515(b) & § 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 Practice ("CGMP") requirements set forth in the Code of Federal Regulations (*See* 21 CFR § 820 et seq.); 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.

58. The FDCA makes it illegal to sell "adulterated" medical devices. A device is adulterated under the FDCA if the methods used in its manufacture do not conform to CGMP.

59. Exercising its authority under a related statute, The Safe Medical Devices Act ("MDA"), the FDA has also created the quality system ("QS")

regulation. Under the QS regulation, manufacturers must establish various specifications and controls for devices; that devices be designed and manufactured under a quality system to meet such specifications; that devices be correctly installed, checked and serviced; that quality data be analyzed to identify and correct quality problems; and that complaints be processed. The QS regulation is thus intended to help assure that medical devices are safe and effective for their intended use.

60. The FDA conducts inspections of FDA-regulated facilities to determine a manufacturer's compliance with the FDCA and the QS regulations applicable to manufacturers of medical devices.

61. FDA Form 483 is issued to manufacturer's management after an inspection when FDA investigators have observed conditions that they believe may constitute violations of the FDCA and related statutes and regulations. Observations listed on a Form 483 notify management of objectionable conditions and are typically noted when conditions or practices are observed indicating that a device (or other FDA-regulated product) has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health.

62. Failure to adequately respond to or correct issues raised in a Form 483 may result in the FDA's issuance of a Warning Letter. Warning Letters are intended for violations of the statute or regulations that are deemed to be of "regulatory significance." A matter is of regulatory significance where the violation is such that it may lead to an enforcement action if not promptly and adequately corrected.

63. The FDA is authorized to recall medical devices that pose health risks. Recalls are categorized by classes. Class I recalls are the most severe. The FDA will issue a Class I recall when there is a potential for serious injury or death if the product or device is used as intended.

C. THE REGULATORY APPROVAL PROCESS SPECIFIC TO THE DEVICE.

64. St. Jude Riata Leads and Fortify ICDs are Class III medical devices.

65. In May 1996, the FDA approved the original PMA which included "the methods used in, and the facilities and control used for, the manufacture, processing, packing, storage and, where appropriate, installation of the device in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device."

66. Pursuant to 21 C.F.R. § 814(e), Defendants' PMA application also included all information submitted with [the application] or "incorporated by reference."

67. Defendants were also required to "establish and maintain procedures to control the design of the device in order to ensure that specific design requirements are met" consistent with 21 C.F.R. § 820.30. Defendants maintained copies of documents that memorialized these controls during the manufacturing of the Device.

68. Pursuant to 21 C.F.R. § 820.70, Defendants were also required to have several process controls in place which ... include[d] documented instructions, standard operating procedures and methods that define and control the manner of production." Defendants maintained copies of documents that memorialize these process controls during the manufacture of the Device.

69. Pursuant to 21 C.F.R. § 820.181. Defendants were required to maintain "device master records (DMRs)." The DMR for the Device included or referred the following information: "(a) device specifications including appropriate drawings, composition, formulation component

specifications and software specifications; (b) product process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications." Defendants maintained the DMR for the Device.

70. Pursuant to 21 C.F.R. § 820.30(j), Defendants were also required to maintain a "design history file (DHF)." The DHF for the Device "contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part." Defendants maintained copies of the DHF for the Device.

71. Pursuant to 21 C.F.R. § 820.180. Defendants were required to maintain "all records required by this part … at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections." Federal regulations, including but not limited to 21 C.F.R. § 820.180, require that such records "shall be made readily available for review and copying by FDA employee(s)."

72. Pursuant to 21 U.S.C. § 360(h), Defendants are required to be inspected by the FDA "at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter." The process controls and other documents referenced above were available to the FDA during the time for such inspections.

73. PMA Supplements are "supplemental applications to an approved PMA for approval of a change or modification in a Class III medical device, including all information submitted with or incorporated by reference therein." 21 C.F.R. § 814.3(g).

74. From 1996 to 2002 Defendants submitted and the FDA approved 14 supplements to this original PMA. These supplements purported to alter various aspects of the design and manufacture of the Leads. Pursuant to 21 C.F.R. § 814.3(g), these and the other Riata PMA Supplements included "all information submitted with the PMA Supplement or incorporated by reference therein."

75. To the extent that Defendants made "modifications to manufacturing procedures or methods of manufacture that affect the safety and

effectiveness of a device subject to an approved PMA," Defendants submitted such changes to the FDA in 30 day reports in accordance with 21 C.F.R. § 814.39. The FDA reviews these reports.

76. On March 11, 2002, the FDA approved the Riata Series 1500 Defibrillation Lead System for Riata Model Numbers 1570, 1571, 1580, and 1581. St. Jude's application number P950022/S014. 21 C.F.R. § 814.20(b)(4)(V).

77. Over the next several years, the FDA approved a series of supplemental PMAs submitted by St. Jude for design, manufacturing, supply chain changes, as well as the introduction of new Riata models, including the Riata ST.

78. The FDA relied on the representations and commitments made by St. Jude in the PMA and PMA supplements, particularly related to St. Jude's testing, validation, manufacturing and monitoring methods and protocols, when it approved the PMA and PMA supplements. However, these representations and commitments were not true and accurate and ultimately led to the Class I recall of the Device and Mr. Sharp's death.

79. In May of 2005, the FDA approved a series of applications for manufacturing modifications. These requests involved "dimensional changes" to the Riata leads, changes to welding to crimping connectors,

changes to 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.

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

81. 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.

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

83. In March 2007, the FDA approved St. Jude Medical's application for changes to their Riata Leads, including: 1) modifications to the crimp slug weld tab; 2) modification to the distal header assembly; 3) modification to the crimp slug weld tab; 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 style accessory to the lead package; 7) minor modifications to the user manual and 8) modified radius specification to the spring stopper component. P95022/S034. The FDA also approved a change in the supplier of the front seal component (P950022/S035) and added an "alternative welding process" P950022/S036.

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

85. In December 2007, the FDA approved St. Jude Medical's application for an alternate supplier of EFTE coated cables (P950022/S046), to extend the time between plasma treatment and application of medical adhesive (P950022/S047), and the alternate oven settings during processing of the shock coils. P950022/S048.

86. 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.

87. 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.

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

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

90. Similarly, for the Fortify ICD, in October 2009, the FDA approved St. Jude's application for the pulse generator. P910023.

91. In June 2010, the FDA approved St. Jude's application for a labelling change for the ICD. P910023.

92. In September 2010, the FDA approved St. Jude's application for changes to the labeling to include longevity information based upon additional bench testing. P910023/S239.

93. In June 2011, the FDA approved St. Jude's application for monitoring software of home devices. P910023/S257.

94. In August 2012, the FDA approved St. Jude's application for a change in the tooling used during the routing step of the manufacturing process for the feedthrough. P910023/S299.

95. In February 2013, the FDA approved St. Jude's application for an alternate suppler for encapsulation material. P910023/S313.

96. In June 2013, the FDA approved St. Jude's application for a change for the additional of a barrier layer of the hybrid substrates as well as modifications for testing of devices. P910023/S319, S318.

97. Also in June 2013, the FDA approved St. Jude's application for a change in design to the manufacturing of the circuit of the ICD. P910023/S331.

98. In September 2014, the FDA approved St. Jude's application for patient care monitoring. P91023/S342.

99. In November 2014, the FDA approved St. Jude's application for a design modification to the battery header. P91023/S343.

100. In January 2015, the FDA approved St. Jude's application for modified design of insulating tape. P91023/S351.

D. FDA INSPECTION OF DEFENDANTS' MANUFACTURING FACILITIES AND PROCESSES

101. In 2009, the FDA conducted a For-Cause Quality Systems Inspections 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.

102. The Defendants provided the following PIRs regarding High Voltage Leads:

a. 09-005 – Helix extension retraction failure due to the spring popping out of its location and getting jammed between the header coupling and stopper

b. 09-001 – Cable fracture under stain relief coil DF-1 leg

c. 07-006 – Outer coil fractures as IS-1 connector ring

d. 06-014 – Hypot failures in Riata ST Leads Manufacturing

e. 06-012 – Riata Coil Fracture at Inner coil Shaft

f. 06-005 – Missing DF-1 Crimps in HV Lead Manufacturing

g. 06-004 – Swapped DF-1 Labels in HV Lead Manufacturing

h. 06-003 Riata Lead with Incorrect Conduction Paths

i. Riata Integreated Bipolar IS-1 Connector Dielectric Strength Improvement

j. 05-009 – Riata Lead Abrasion

k. 04-006 – Insufficient Crimp on RV shock coil termination ring employed on the Riata Integrated Bipolar Leads seen in Manufacturing;

l. 04-003 – Riata Perforation;

m. 03-006 – Riata Lead Cable Coating Abrasion

n. 02-004- Riata, Missing Weld, DF-1 Conn. Pin.

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

104. These failures violated 21 C.F.R. § 803.50(b) ("[f]ailure to submit MDR reports containing all information reasonably known to them in accordance with the provisions of 21 C.F.R. § 803.50(b)"). Specifically, the inspection report stated that St. Jude Medical's complaint files noted adverse events that St. Jude internally evaluated but did not report to the FDA. These failures to report to the FDA ultimately contributed to Mr. Sharp's death.

105. As part of the inspection, FDA interviewed Nestor Kusnierz, St. Jude's Director of Regulatory Compliance. According to the Report, Mr. Kusnierz is a 25-year veteran with St. Jude whose primary task is to assure the inspection runs smoothly and within the firm's regulatory procedures. Mr. Kusnierz answered questions regarding complaints and MDRs.

106. During the inspection, Mr. Kusnierz provided an Excel spreadsheet to the FDA for all complaints for the Riata and their successors, Durata lead models, dating back to 2002. This represented the time period from the device approval through June 9, 2009 and totaled 8,643 complaints. For all complaints identified as "perforation, patient", it was indicated that an MDR had been submitted. However, the FDA adverse event database contained only 3,689 MDRs from the firm for these devices during this period. These discrepancies in complaint reporting contributed to Mr. Sharp's death.

107. Prior to the inspections, 32 MDRs were identified from the adverse event database as possible Riata perforation events, and the complaint files for these were requested and reviewed during the inspection.

108. Review of these complaint files and the associated MDRs revealed that in some cases Defendants failed to submit MDR reports containing all information reasonably known to them in accordance with the provisions of 21 C.F.R. § 803.50(b). Specifically, the complaint files show that the complainants reported perforation adverse events to the Riata and Durata devices, but these events were not reported as "perforations" in the associated MDRs submitted to FDA by the manufacturer. Additionally, perforation was not identified in the submitted Form 3540A either in the patient or device problem codes. A sampling of 8 complaints that were identified as by Defendants as "capture anomaly," "dislodgment" or "patient discomfort" were also retrieved from the MAUDE database by device serial number for further review. Six of these reports "in fact described a suspected perforation and it could not be ruled out as possible for the other two events." "As the FDA noted in its Establishment Inspection Report ("EIR"), "post-market surveillance by FDA is hampered when mandatory reporting terminology is not clear, accurate and consistent." This underreporting of device failures contributed to Mr. Sharp's death.

109. Additionally, the 2009 Establishment Inspection Report noted that complaints representing events that are MDR reportable were not promptly reviewed, evaluated and investigated by the designated individual per 21 C.F.R. § 802.198(d), and MDRs were not submitted within the mandatory reporting timeframes required by 21 C.F.R. §803.50 for device manufacturers. For example, MDR # 2017865-2008-0044 provides a manufacturer aware date and perforation event in 2003. The 3500A was submitted without explanation to FDA on January 10, 2008. Similarly, MDR #2017865-2008-00447 provides a perforation event date and manufacturer aware date in 2004, but the 3500A was also submitted without explanation to the FDA on January 10, 2008. These delays in reporting to the FDA contributed to Mr. Sharp's death.

110. The EIR continues to state that additional review of the MDRs submitted from 2007 through June 2009 found no evidence that the perforation events described in the medical or scientific literature were submitted to the FDA as required by regulations and company procedures. This lack of reporting contributed to Mr. Sharp's death.

111. Similarly, a 2011 report by an FDA Safety Officer, Jessica Paulsen, noted that Defendants' CAPAs limited the analysis to "externalized cables and [did] not include exposed cables or all other forms of abrasion, which FDA considers important contributors to the published rate of all abrasion presented in [Defendants'] November 2011 Product Performance Report (PPR)." The FDA also noted that the "published failure rate based on PPR is based only upon reported events and returned product analysis, and therefore underestimates the actual rate of occurrence." This underreporting of failures contributed to Mr. Sharp's death.

112. The FDA also noted that Defendants' "calculation of the proportion of leads associated with inappropriate high voltage shock delivery, based on their assumptions appear[ed] to have a clerical error" and required correction.

113. The 2011 Report also notes numerous instances of underreporting and states that the term "'externalized cable' or even 'abrasion' may not be employed when it is a contributing cause to the reporter having been unaware that externalized cable occurred. The clinical presentation (noise, inappropriate therapy, no therapy, etc.,) may be what is reported and not the diagnosis of

the lead mechanical failure." Again, this underreporting contributed to Mr. Sharp's death.

114. The FDA further noted that while Defendants reported only "1 instance of 'inappropriate high voltage shock delivery, The Office of Science and Engineering Laboratories's ("OSEL") analysis from last January counted 71 cases of inappropriate shock, noise, and/or over sensing (out of) 172 inside-out abrasion cases)." Thus, OSEL concludes that Defendants "may underestimate the actual number of inappropriate shocks due to their limiting terminology."

115. Continuing with the November 2011 Report, it is noted that "OSB identified a total of 794 reports of insulation abrasion and 116 of those reports mentioned inside-out abrasion." The Report further notes that "the reports submitted by SJM to FDA concerned externalized cables and abrasion failures are not up to date."

116. The inspection also revealed that Defendants failed to follow their procedure for product design development of the Leads. This failure violated federal regulations and contributed to Mr. Sharp's death.

117. 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.

118. The FDA publishes the adverse events and MDRs in the Manufacturer and User Facility Device Experience ("MAUDE") database, which is updated monthly. The general public, including physicians and patients may use the MAUDE database to obtain safety data on medical devices. For example, Dr. Robert Hauser of the Minneapolis Heart Institute Foundation (MHI) 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 RYTHYM, 2012 Aug.; 9(8); 1227-35. Dr. Hauser's assessment was based on his search and analysis of the MAUDE database.

119. Indeed, doctors reported abrasion problems with the Riata leads to St. Jude. However, because of St. Jude's failure to report this vital information to the FDA and/or otherwise advise the public, medical professionals mistakenly believed that Riata lead failures were rare. 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. The misrepresentation of the frequency of failure events led to a misinformed public and treating physicians and ultimately led to Mr. Sharp's preventable death.

120. 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. According to the article, St. Jude's internal audit concluded in 2008 that Riata had "potentially serious insulation problems including inside-out abrasion" which results in the breakdown of the lead and its failure to deliver high voltage shocks.

121. 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 explanted from patients, as well as in lab testing. The report, which did not address whether the problem 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. This inaccurate reporting violated federal regulations and contributed to Mr. Sharp's death.

122. 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. Defendants' post-market reporting was intentionally misleading and contributed to Mr. Sharp's death.

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

to follow product design development procedures contributed to Mr. Sharp's death.

124. 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 at the conclusion on an inspection when an investigator has observed any conditions that in their judgment may constitute violations of the FDCA and related Acts. The FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific and significant.

125. Specifically, each of the deficiencies identified by the FDA in the Form 483 directly contributed to Mr. Sharp's death and 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 C.F.R. § 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 explanations in violation of 21 C.F.R. § 803 et seq.

c. Defendants failed to define the procedures for implementing corrective and preventative actions in violation of 21 C.F.R. § 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 C.F.R. § 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 any monitoring program for receiving stock 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 C.F.R. § 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 C.F.R. § 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 C.F.R. § 802 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 21 C.F.R. 820 et seq. Specifically, the review of Quality Test Report 1403 for Riata Series 1500 indicates that a reviewer of the data sheets changed the specification of DC resistances on the Qualification Test Data Sheets for Composite Lead Tensile Test, but the cause of the discrepancy and reason for the change were not discussed in the QTR or meeting minutes.

126. 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 individuals per 21 C.F.R. § 820.198(d)."

127. 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."

128. 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." These violations directly contributed to Mr. Sharp's death.

129. 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 or Occurrences used in Risk Evaluation." Defendants' Product Improvement Requests demonstrated these inadequacies and, as a result, the public and treating physicians were misinformed. These failures directly contributed to Mr. Sharp's death.

130. The FDA noted that although Defendants maintained a required written procedure to cover design changes, the reasons and justifications for design changes were not always properly documented.

131. As part of the inspection, the FDA also requested Defendants' World Wide Product Disposition Review Board (WWPDRB) meeting minutes, which dated back to 2006.

132. 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.

133. On October 17, 2012, the FDA conducted a subsequent inspection of defendants' Sylman 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 resulting in a second Form 483 Letter. These deficiencies contributed to the death of Mr. Sharp.

134. Although it is redacted, the Form 483 shows that the observations of objectionable conditions pertained to the Riata lead. *See e.g.* "Your Corrective Action # PIR-10-005 for your Riata lead was inadequate in

that you failed to evaluate the validity of some of your [] lead design verification and validation activities.")

135. The FDA report found significant flaws in St. Jude's testing and oversight of the Company's heart device equipment that were of significance considering clinical findings calling into question durability over time. FDA inspectors found that the St. Jude failed to follow its own written protocols for testing the product, and did not properly evaluate some study results. The agency also concluded that St. Jude did not adequately follow up on problems it identified in the manufacturing process, and did not properly investigate some complaints the company received about incidents of failure involving Riata leads. These deficiencies led to a misinformed public about the safety of simply leaving these defective devices implanted and ultimately led to Mr. Sharp's death.

136. Following on the heels of the October 17, 2012 inspection, the FDA issued a warning letter to St. Jude on January 10, 2013 relating to the Durata and Riata ST ICDs. In pertinent part, the warning letter stated:

> This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in

conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

These violations include, but are not limited to, the following:

1. Failure to ensure, when the results of a process cannot be fully verified by subsequent inspection and test, that the process shall be validated with a high degree of assurance and approved according to established procedure, as required by 21 CFR § 820.75(a). For example, your firm created multiple different holders to hold leads during (b)(4). Your firm did not specify how these holders were installed or qualified to ensure they met their intended use.

2. Failure to establish procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met, as required by 21 CFR § 820.75(b). For example, your firm does not monitor the flow of the **(b)(4)** to the **(b)(4)** machines to ensure the appropriate amount of **(b)(4)** is supplied, as specified in section 3.4.1.9 of the **(b)(4)** manual, **(b)(4).** The manual specifies a **"(b)(4)."**

3. Failure to establish and maintain adequate procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements, as required by 21 CFR § 820.30(b). For example:

b. Your firm failed to follow its test procedure, **(b)(4)** *Rev. D, released 05109/2003,* during design verification testing of the **(b)(4).** Specifically, the procedure required each lead to be tested 5 times and the mean of the 5 tests would be considered the result. However, your firm only tested each lead one time to determine the results.

5. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR § 820.100(a). For example:

   a. Your firm's procedure, *Corrective and Preventive Action Procedure, SOP 3.3.5 Rev. Y, dated May 30, 2012, states* that a CAPA (PIR: Product Improvement request) closure memo shall include a statement of effectiveness of the CAPA. However, your firm's CAPAs designated as PIR 12-004 and PIR 11-013 were closed on August 16, 2012, and September 14, 2012, respectively, without a statement or reference to a verification of effectiveness.

   b. Your firm's procedure, *Corrective and Preventive Action Procedure, SOP 3.3.5 Rev. Y, dated May 30, 2012, states* that an effectiveness check shall be performed on any PIR that has been closed, unless there is a justification that no effectiveness check is required. However, your firm's CAPAs designated as PIR 12-008 and PIR 12-007 were closed on September 10, 2012, and September 11, 2012, respectively, and state that "no effectiveness check is required" without any documented justification.

   c. Your firm's CAPA procedures do not require a determination as to whether the action taken adversely affects the finished device.

137. The sale and implantation of this adulterated device in Mr. Sharp directly caused his untimely death.

138. During the FDA's review of St. Jude's Product Analysis Reports between 2011 and 2014 showed evidence that lithium cluster bridging had

prematurely drained the battery yet St. Jude repeatedly concluded that the cause of premature depletion "could not be determined."

139. St. Jude delayed the initiation of a CAPA (#13-017) until December 18, 2013 and St. Jude continued distributing devices containing the battery until October 2016. This delay directly contributed to Mr. Sharp's death.

140. Additionally, the FDA found that St. Jude's Quality Management Review SOP in November 2014 omitted information from St. Jude's supplier regarding premature battery depletion resulting in a "significant underestimation of the probability of the occurrence of the hazardous situation." Additionally, the FDA found that St. Jude did not disclose a patient death due to premature battery depletion on August 27, 2014.

141. Additionally, a February 2017 inspection of the Sylmar facility into the Fortify ICDs issued a warning letter for the following violations:

1. Procedures for corrective and preventative action have not been adequately established:

    a. A review of 42 Product Analysis Reports produced between 2011 and 2014 showed that the firm repeatedly concluded that the cause of premature depletion could not be determined in instances when the analysis provided ample evidence that lithium cluster bridging had prematurely drained the battery.

b. Failure investigations were not timely revealing discussion about redesign in 2013 which was formally initiated on March 1, 2013. However, the CAPA #13-017 for the premature battery depletion issue was not initiated until the following December.
c. Failure to follow CAPA procedures SOP(b)(4) and SJM Corrective and Preventive Action.

2. Procedures for management review have not been adequately established:

a. Incomplete information was provided to the management review and medical advisory boards relative to the premature battery depletion issue in 2014.

3. A correction or removal, conducted to reduce a risk to health posed by the device, was not reported in writing to the FDA:

a. In 2014, St. Jude formally requested a design improvement to eliminate lithium cluster bridging but St. Jude failed to notify FDA of a correction until August 2016.

E. MANUFACTURING DEFECTS OF RIATA LEADS AND FORTIFY ICD

142. From 2005-2010 St. Jude applied for at least 27 manufacturing or process changes to the Riata leads. The FDA approved these changes in a PMA and multiple supplements, but St. Jude failed to manufacture the Riata leads in a manner consistent with these approved changes, thereby creating a defective product. These failures and defective product directly caused Mr. Sharp's death.

143. One of these defects includes inconsistent insulation diameters surrounding the electric conductors. These 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.

144. It is foreseeable that abrasion of the insulation surrounding the lead wires will occur after implantation. This "externalization" of the leads allows them to come in contact with materials and fluids that can prevent the proper functioning of the ICD.

145. The breach of insulation and externalization of the lead wires on the Riata Leads can cause the Leads to short and transmit incorrect information to the pacemaker/defibrillator, in turn causing the device to produce unnecessary and painful shocks of electricity, or alternatively, to fail to communicate with the pacemaker/defibrillator thereby preventing it from delivering life-saving therapy. This failure occurred in Mr. Sharp's device and led to his death.

146. Further, St. Jude inconsistently applied a lubricious interface between the inner and outer insulation in violation of the PMA. This inconsistent

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

147. Additionally, St. Jude applied and received approval for multiple changes to the cure and sterilization processes used in the manufacture of the Riata Leads. However, St. Jude failed to follow the approved methods of curing and sterilization during the manufacture of the Leads. Failure to follow the approved cure and sterilization processes resulted in reduced tensile strength of the silicone insulation. These failures directly led to Mr. Sharp's death.

148. Finally, St. Jude applied and received approval for numerous modifications to the welding and crimping in the manufacture of the Riata Leads. The PMSA and Conditions of Approval required the application of a controlled, uniform degree of force when applying the crimp. Failure to crimp with a controlled, uniform, degree of force, resulted in insecure crimps over the length of the Lead.

149. ICDs are powered by lithium-based batteries. Lithium batteries are generally capable of functioning without need for replacement for approximately seven to eight years. Following implantation, the battery power slowly begins to deplete until it reaches a certain charge level at

which point it sends a notification to the patient informing them it's time to have the battery replaced.

150. This notification, known as an Elective Replacement Indicator ("ERI") is a vibration which is sent when remaining battery life reaches approximately three months, thus providing the patient with sufficient time to evaluated by a physician for battery replacement. However, not all patient are able to sense the ERI vibration; therefore the Defendants also recommend regular monitoring of the ICDs by cardiac specialists.

151. St. Jude manufactured the Fortify device with an ion battery known to form lithium cluster bridging which would prematurely drain the battery.

152. Despite this potential hazard, St. Jude marketed the ICDs as safe and effective despite knowing from the outset that lithium cluster formation was a known phenomenon in the type of battery the Defendants were using. The defect was not disclosed by Defendants to the FDA, patients or health care providers and/or was not disclosed in a timely fashion.

153. The failure of the Device was unrelated to patient age, sex, ICD indication, primary heart disease, left ventricular ejection fraction, or lead tip position,

suggesting that the manufacturing problems are responsible for the failure of the devices.

F. RECALL OF RIATA LEAD

154. On December 15, 2010, St. Jude Medical published a "Dear Doctor" letter regarding its Riata Leads. In the letter. St. Jude acknowledged the existence of issues with Riata Lead insulation. St. Jude indicated that issues with defects in insulation had been identified in at least nineteen Riata Lead Models, including 1560, 1561, 1562, 1570, 1571, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 70001, 7002, 7010, 7011, 7040, 7041 and 7042.

155. Specifically, St. Jude stated 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."

156. In the 2010 Dear Doctor Letter, St. Jude further acknowledged that Lead insulation abrasion was associated with: 1) oversensing (leading to inhibition of pacing or inappropriate high voltage therapy); 2) undersensing; loss of capture; changes in pacing and/or high voltage lead impedances; and inability to deliver high voltage therapy. Mr. Sharp's device suffered from one or both of these issues and led to his death.

157. 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. The failure to issue a recall at that time contributed to Mr. Sharp's death.

158. St. Jude introduced a new line of Durata leads by December 2010, and ceased marketing and selling the Riata and Riata ST leads. St. Jude stopped manufacturing Riata leads at least in part because of the apparent design defects in the Riata and Riata ST leads that were causing internal insulation breaches. These design defects led to Mr. Sharp's death.

159. 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.

160. The 2011 Dear Doctor 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. Again, the failure to initiate a recall at this time contributed to Mr. Sharp's death.

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

162. 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.

163. 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 be externalized. If this occurs, this product may cause serious adverse health causes, including death." That is what happened with Mr. Sharp which led to his untimely death.

164. By this time, over 21,000 Riata ST Optim and 114,000 Riata leads had been sold in the USA by September 2011, including the Riata lead that was implanted in Mr. Sharp

165. In November 2011, St. Jude updated physicians on the abrasion failures associated with the Riata and Riata ST leads, informing them that the failure rate was higher than previously reported by the Company.

166. Then on November 28, 2011, St. Jude recalled these leads due to premature erosion of the insulation around the electrical conductor wires, known as insulation failure. According to St. Jude, as of 2011, approximately 79,000

Riata leads remained implanted in patients in the United States. Mr. Sharp was in that class of patients.

167. The FDA also ordered St. Jude to conduct post marketing surveillance on all Riata leads. Despite this class I recall, St. Jude did not tell patients or physicians that it was dangerous to leave the defective leads (and Fortify devices) inside patients. St. Jude instituted a monitoring program despite its knowledge that it was dangerous to not remove the defective products and it did not tell the FDA that it knew about the dangers. These failures led to Mr. Sharp's death.

G. PHYSICIANS EXPOSE THE RIATA LEAD DEFECTS AND RAPID DEPLETING BATTERY LIFE OF ICD LEADING TO ABRASIONS PRIOR TO THE DEATH OF MILTON SHARP.

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

169. 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. Robert G. Hauser et al., *Deaths Caused by the Failure of Riata and Riata*

ST Implantable Cardioverter-Defibrillator Leads, Heart Rhythm 9(8): 1227 (Aug. 2012).

170. 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 deaths involving a competitor's lead were lead-related. It is important to note that adverse events are often grossly underreported. *See generally U.S. General Accounting Office, Medical Device Reporting: Improvements Needed in FDA's System for Monitoring Problems with Approved Devices* (Jan. 1997) (citing previous GAO findings that "less than one percent of the device problems occurring in hospitals were reported to the FDA" and that "the more serious the problem with the device, the less likely it was to be reported to the FDA"), *available at*: http://www.gao.gove/archive/1997/he97021.pdf. The failures to report and warn directly contributed to Mr. Sharp's death.

171. Additionally, Dr. Hauser noted that "[a]bnormal high voltage impedances were the hallmark of catastrophic Riata and Riata ST Lead failure, often resulting in failure to defibrillate." Robert G. Hauser et al., *Deaths Caused by the Failure of Riata and Riata ST Implantable Cardioverter-Defibrillator Leads*, Heart Rhythm 9(8): 1227 (Aug. 2012). Finally, Dr.

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

172. 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 Postmarkting Device Surveillance*, 366 New Eng. J. Med. 873, 873-75 (2012). The Defendants did not protect patients like Mr. Sharp and as a result, he died.

173. 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 Heart Rhythm to retract Dr. Hauser's article. *See* Barry Meier & Katie Thomas. *At St Jude, Firing Back at Critics*, N.Y. Times (Apr. 11, 2012); Susan Kelly & Debra Sherman, *Heart Device Troubles Cloud St. Jude's Outlook*, Reuters (Apr. 13, 2012), available at: *http://www.reuters.com/article/2012/04/13/us-stjude-idUSBRE83COME20120413*.

174. In May 2012, Dr. Hauser published additional findings regarding the Riata Lead insulation defects in the Heart Rhythm Journal. *Riata Implantable Cardioverter-Defibrillator Lead Failure: Analysis of Explanted Leads with a Unique Insulation Defect*, Heart Rhythm (May 2012).

175. In 2012, the FDA ordered Defendants to collect clinic 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, also called section 522 studies, to address concerns related to premature insulation failure and to address important questions related to follow up of affected patients.

176. In January 2012, a study published in the Heart Rhythm journal indicated that Defendants had recently advised that the rate of the cable externalization was 24% in the Riata Leads and 9% in the Riata ST Lead – despite previous reports that such rates were only 0.63%. The article also stated that a number of studies have confirmed that Riata Leads fail more often than other brands. Again, the misrepresentation of the facts related to this Device contributed to Mr. Sharp's death.

177. Between January 1, 2010 and November 30, 2013 the Defendants were notified of, and had confirmed, at least 48 premature battery depletions in

ICDs. Other cases had been reported and suspected, but the devices were not returned to the manufacturer for inspection. By early 2014, numerous defective devices had been returned to St. Jude Medical, Inc. for testing, and thus Defendants had actual knowledge of the defect in the ICDs. Defendants had issued no warnings or recalls. These failures led to Mr. Sharp's death.

178. Between 2011 and 2014 St. Jude Medical Inc. conducted at least 42 product analyses of failed ICDs which showed in each instance evidence of lithium cluster bridging which had prematurely drained the battery, yet St. Jude repeatedly concluded that the cause of the prematiure depletion could not be determined.

179. By December 2014, a Duke Study revealed defects in ICDs making the product inherently dangerous due to unanticipated battery depletion. See Pokorney et al., *Novel mechanism of premature battery failure due to lithium cluster formation in implantable carioverter-defibrillators*, Duke Division of Electrophysiology, Duke University Medical Center, HeartRythm, December 2014, Vol. II, Issue 12, pp. 2190-2195.

180. Once Defendants knew of the dangerous and life-threatening defect in the defibrillators they failed to warn Mr. Sharp or others of the defect and failed to recall the defibrillators. After making a design change to address the defect, Defendants continued elling their existing stock of defective devices into the stream of commerce for at least 17 months after the publication of the Duke Study. Defendants gave no warnings regarding the battery defect in the old stock, thereby putting patients such as Mr. Sharp at risk of death.

181. Finally, the ICD's were subject to a Class 1 recall by the U.S. Food and Drug Administration on October 1, 2016 for devices manufactured between January 2010 and May 2015, such as Mr. Sharp's.

182. On that same day, the FDA issued a Safety Communication providing information and recommendations regarding Defendants' recall due to the fact that "ICD batteries may fail earlier than expected." The FDA Safety Communication directed patients to respond immediately to ERI alerts because "[d]ue to problems with these batteries, patients do not have the normal 3-month lead time … some batteries have run out within 24 hours of the patient receiving an ERI alert."

183. If the battery is depleted completely due to this defective design, the ICD "will be unable to deliver life-saving pacing or shocks, which could lead

to patient death." According to the report, 398,470 devices were sold worldwide and 841 were returned to St. Jude for analysis due to premature battery depletion caused by lithium clusters resulting in two deaths like Mr. Sharp's and countless other injures.

184. Grant Sharp's defibrillator failed on August 23, 2015 due to the known defects in the Riata leads and Fortify device. As a direct result of this defective Device, Grant Sharp died. His death would not have occurred if Defendants had not sold defective products and failed to warn users of the dangers associated with the products.

185. Although the Fortify Device was not recalled prior to Mr. Sharp's death, Defendants had knowledge at the time of Mr. Sharp's death of the defective nature of the Device. *See* ¶¶ 163-166 infra. For example, the N.Y. Times published an article on April 13, 2017 documenting the FDA's findings that St. Jude played down the failure of its batteries and shipped them for years before recalling the devices. *See* Katie Thomas. *St. Jude Played Down Defibrillator Failures for Years, FDA Says,* N.Y. Times (Apr. 13, 2017); available at: https://www.nytimes.com/2017/04/13/health/st-jude-medical-defibrillator-abbot-fda.html. St. Jude also failed to inform its own management and medical advisory board that the battery problems had led

to the death of a patient. Based upon these findings, the FDA declared that St. Jude's effort to fix the problems was insufficient. *Id*.

186. Defendants failed to warn patients like Grant Sharp and their treating doctors that they knew leaving the defective devices in place and simply monitoring them caused an undue risk of injury and death.

CLAIMS FOR RELIEF

COUNT I
STRICT LIABILITY- MANUFACTURING DEFECT

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

188. The Riata leads possess a manufacturing defect because the actual manufacture of the leads differs from the specifications set forth in the PMA and the conditions for approval as herein before alleged and thereby violate the MDA and Federal regulations and give rise to a parallel claim for Strict Liability – Manufacturing Defect under Georgia law.

189. The Fortify ICDs possess a manufacturing effect because the lithium batteries used in the ICDs were susceptible to forming lithium clusters which would lead to premature battery depletion. Defendants failed to include a necessary layer of insulation to avoid the formation of lithium

clusters or to prevent the clusters from causing rapid battery depletion in violation of the PMA and conditions of approval.

190. These manufacturing defects render the Device unreasonably dangerous for its intended use and Mr. Sharp could not have anticipated the danger the defect in this product created.

191. This parallel claim does not impose any manufacturing requirements greater than those imposed by the MDA and Federal regulations; rather, this claim seeks redress for St Jude's violations of federal standards.

192. St. Jude is liable to Plaintiff because the Riata lead was not merchantable and reasonably suited to the use intended, and was defective at the time it left St. Jude's possession in the manner set forth more fully herein.

193. St. Jude's manufacturing processes for the Riata lead and Fortify UCD resulted in insulation defects which cause short circuiting between high-voltage components of the lead, and lithium ion clustering leading to depleted battery life of the Fortify ICD.

194. St. Jude applied for and received approval for original manufacturing processes, verification procedures, specific protocols, recordkeeping procedures, reporting procedures to the FDA, use of calibrated and

specialized manufacturing equipment, training procedures for personnel, and testing procedures for manufactured samples.

195. To gain approval of the PMA and supplemental PMAs, St. Jude represented to the FDA that it would comply with existing Federal regulations by, among other things, verifying that testing and manufacturing protocols were being followed through subsequent inspection and testing, establishing and maintaining a design history file for each type of device, establishing and maintaining procedures for implementing corrective and preventive action.

196. St. Jude failed to adhere to the commitments made to the FDA in the PMA and supplemental PMA in the ways set forth in the FDA's Warning letter, as well as other ways, resulting in the production of defective Riata leads like the lead implanted in Mr. Sharp. *See infra* ¶¶ 55-99.

197. Defendants violated 21 C.F.R. § 820.75(b) by failing to ensure that the process of manufacturing the Riata lead was validated to a high degree of assurance and approved per established procedures.

198. Defendants violated 21 C.F.R. § 820.75(b) by failing to establish procedures for control of process parameters and/or by failing to establish

procedures for validating the processes of the production of the Riata lead to ensure that specified FDA requirements continue to be met.

199. Defendants violated 21 C.F.R. § 820.100(a) by failing to establish and maintain procedures for implementing corrective and preventive action pertaining to the Device.

200. Defendants violated federal law by failing to take proper action in petitioning the FDA for a label change to more accurately reflect the risks associated with the Device, including premature deterioration, premature battery depletion and device failure.

201. From 1996 to 2002 Defendants submitted and the FDA approved 14 supplements to this original PMA for the Riata lead and more than 10 supplements for the Fortify ICD from 2009-2016. These supplements altered various aspects of the design and manufacture of the Device. Pursuant to 21 C.F.R. § 814.3(g) these and the other PMA Supplements included "all information submitted with the PMA Supplement or incorporated by reference therein."

202. Defendants violated federal law by failing to comply with the Device's FDA premarket approval requirements.

203. Defendants manufactured the Device in violation of the terms, conditions, standards and specifications of the FDA Investigational Device Exemption Approval.

204. The Riata lead and/or defibrillator implanted in Plaintiff had an impurity, imperfection and/or other product defect that was a deviation from the quality manufacturing standards for the Device, leaving the device in a defective condition and unreasonably dangerous to Plaintiff when it left Defendants' control.

205. These defects include inconsistent insulation diameters surrounding the electric conductors. These insulation diameters are required by the PMA and federal requirements to be consistent. Failure to manufacture uniform insulation diameters lead to an increased risk of abrasion at thinner insulation sites, leading to an increased risk of device failure.

206. It is foreseeable that abrasion of the insulation surrounding the lead wires will occur after implantation. As a result, the lead wires protrude through the insulation. This “externalization” of the leads allows them to come in contact with materials and fluids that can prevent the proper functioning of the ICD.

207. The breach of insulation and externalization of the lead wires on the Riata Leads can cause the Leads to short and transmit incorrect information to the pacemaker/defibrillator, in turn causing the device to produce unnecessary and painful shocks of electricity, or alternatively, to fail to communicate with the pacemaker/defibrillator thereby preventing it from delivering life-saving therapy.

208. Further, St. Jude inconsistently applied a lubricious interface between the inner and outer insulation in violation of the PMA. This inconsistent application may have led to increased friction within the lead body, promoting abrasion and/or externalization.

209. Additionally, St. Jude applied and received approval for multiple changes to the cure and sterilization processes used in the manufacture of the Riata Leads. St. Jude failed to comply with the approved methods of curing and sterilization during the manufacture of the Leads. Failure to follow the approved cure and sterilization processes resulted in reduced tensile strength of the silicone insulation.

210. St. Jude applied and received approval for numerous modifications to the welding and crimping in the manufacture of the Riata Leads. The PMA and Conditions of Approval required the application of a controlled, uniform

degree of force when applying the crimp. Failure to crimp with a controlled, uniform, degree of force, resulted in insecure crimps over the length of the Lead.

211. Similarly, the lithium battery in the ICD which was prone to lithium ion deposits (known as lithium clusters) that could cause a short circuit between the battery terminals resulting in the unpredictable and rapid draining of battery power leaving those who relied on it such as Mr. Sharp vulnerable to injury and death as a result of the failure of the ICD to perform its life-saving functions. Despite St. Jude's knowledge of this it failed to timely report these problems and injuries to the FDA in violation of its federal obligations.

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

213. As a direct and proximate cause of St. Jude's failure to adhere to its commitments to test, validate and manufacture the Device in conformance with its own PMA as well as CGMPs of the FDA's QS regulation, St. Jude manufactured a defective Device susceptible to abrasions and premature

battery life like the one that caused Mr. Sharp's death. The actions and failures to act directly led to Mr. Sharp's death.

COUNT II
NEGLIGENCE - MANUFACTURING DEFECT

214. Plaintiff hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

215. Defendants have a duty to exercise reasonable care in manufacturing the Device to make it reasonably safe for their intended and foreseeable uses by, among other things, strictly adhering to the testing, validation, manufacturing and monitoring protocols contained in the PMA and conditions of approval, as well as applicable Federal regulations controlling the manufacture of medical devices.

216. As fully set forth herein, Defendants failed to exercise the degree of care, precaution and vigilance as the circumstance demanded by manufacturing the Riata leads and Fortify ICD by, among other things, strictly adhering to the testing, validation, manufacturing and monitoring protocols contained in the PMA and conditions of approval, as well as applicable Federal regulations controlling the manufacture of medical devices.

217. Defendants knew or should have known that failing to strictly adhere to the testing, validation, manufacturing and monitoring protocols contained in the PMA and conditions of approval, as well as applicable federal regulations controlling the manufacture of medical devices, was likely to result in the production of the Device with a latent defect that, in turn, would present a reasonably foreseeable risk of severe injury or death to users like Mr. Sharp.

218. This defect was due to the negligence of Defendants.

219. The Device in question was defective in that, among other things, it was made of improper and defective material; it was improperly designed; it was improperly manufactured; it failed to have adequate and proper warnings or instructions; it was not safe to be used for the purposes intended; it was inherently and/or unreasonably dangerous; its utilization violated FDA regulations; and it caused severe injuries while being used and the products were otherwise defective.

220. As a direct and proximate result of the manufacturing defect, Mr. Sharp suffered catastrophic injuries and death giving rise to claims for damages to his Estate and his heirs as more fully set forth herein.

COUNT III
STRICT LIABILITY – FAILURE TO WARN

221. Plaintiff hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

222. Defendants have a duty to provide ongoing warnings and instructions regarding safety hazards associated with the Leads. A manufacturer has a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of a product. The manufacturer owes this duty to warn to all persons whom the manufacturer should reasonably foresee may use or or be affected by the product. This duty arises when the manufacturer knows or reasonably should know of the danger presented by the use of a product. Therefore, a manufacturer has a continuing duty to adequately warn the public of defects in a product even after that product has left the control of the manufacturer to be sold or distributed to the consumer.

223. A manufacturer's duty to warn may be breached by failing to provide an adequate warning of the product's potential dangers or by failing to adequately communicate to the ultimate user the warning provided. A product, however well made may be said to be in a defective condition.

224. Defendants breached this duty by failing to, inter alia. provide timely and adequate reports regarding safety hazards and/or potential defects associated with the Leads. As set forth above, many of the untimely and/or inadequate reports regarding safety hazards concerned abrasion-related defects, including but not limited to externalization of cables, perforation, inappropriate therapy, sensing problems and abrasion.

225. Defendants also breached this duty by failing to, inter alia, warn patients and physicians of all dangers inherent in the ordinary use of ICDs of which they were aware, or of which they became aware.

226. Defendants also had a continuing duty to monitor the Device post-approval and to discover and report to the FDA any complaints about produce performance and any health consequences of which they are aware that may be attribute to the product.

227. Defendants also have a continuing duty to provide ongoing warnings and instructions regarding safety hazards associated with the Device.

228. This includes but is not limited to filing a PMA supplement to include information relevant to an evaluation of the safety and effectives of the device known to or that should reasonably be known to the manufacturer

from any source, including commercial marketing experience. Defendants violated this by failing to report the insulation abrasion and lithium cluster bridging. *See* infra ¶¶ 135-140.

229. Defendants' failure to provide ongoing warnings and/or failure to adequately warn patients such as Mr. Sharp of defects with the Device violates federal law and Georgia law.

230. Specifically, Defendants violated 502(t)(2) of the FFDCA, by failing to report to the FDA no later than 30 calendar days after receipt of information that the Riata malfunctioned, as required by 21 C.F.R. § 803.50(a)(2).

231. Defendants also breached the duty to warn by failing to conduct adequate risk analyses and investigations required by federal regulations regarding safety hazards and/or potential defects associated with the Leads. As set forth above, many of the untimely and/or inadequate reports regarding safety hazards concerned abrasion-related defects, including but not limited to externalization of cables, performation, inappropriate therapy, sensing problems and inside-out abrasion. Defendants failed to promptly recall the Device after learning both the

lead and generator were prone to early failure based upon abrasion and rapid battery depletion.

232. Defendants' failure to warn and investigate rendered the devices unreasonably and dangerously defective beyond the extent contemplated by ordinary patients with ordinary knowledge regarding the devices.

233. Defendants violated federal law by failing to take proper action in petitioning the FDA for a label change to more accurately reflect the risks associated with the Riata lead, including premature deterioration and unpredictable, rapidly-depleting battery life of the ICD. Had Defendants provided a timely and sufficient warning about the defective Device, Mr. Sharp could have had the Device explanted or replaced prior to his death. St. Jude not only failed to report this to Mr. Sharp and his physician but failed to report to timely report it to the FDA. *See* Compl., infra ¶ 151.

234. This parallel claim does not impose any warning requirements greater than those imposed by the Federal regulations; rather, this claim seeks to enforce St Jude's violations of federal standards and creates a parallel claim.

235. Had defendants not breached their duty to warn, relevant information relating to the safety and efficacy of the leads would have reached Plaintiffs

and Plaintiff Sharp's doctors and would have caused Mr. Sharp to undergo explantation of the device, prior to his death, as alleged above.

236. Finally, Defendants breached the duty to warn by not relaying adequate information to the federal government, patients and doctors regarding the risk of harm by leaving the defective products inside patients and monitoring their effectiveness as opposed to replacing them. This lack of information inhibited the ability of doctors and patients to make informed decisions as to whether to replace St. Jude's defective products.

237. As a direct and proximate result of Defendants' failure to warn, Mr. Sharp suffered catastrophic injuries and death giving rise to claims for damages to his Estate and his heirs as more fully set forth herein. Ms. Sharp suffered and will continue to suffer loss of consortium for which she is entitled to compensatory and equitable damages, in an amount to be proven at trial.

COUNT IV
NEGLIGENT FAILURE TO WARN

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

239. A manufacturer has a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of a product. The

manufacturer owes this duty to warn to all persons whom the manufacturer should reasonably foresee may use or or be affected by the product. This duty arises when the manufacturer knows or reasonably should know of the danger presented by the use of a product. Therefore, a manufacturer has a continuing duty to adequately warn the public of defects in a product even after that product has left the control of the manufacturer to be sold or distributed to the consumer.

240. A manufacturer's duty to warn may be breached by failing to provide an adequate warning of the product's potential dangers or by failing to adequately communicate to the ultimate user the warning provided. A product, however well made may be said to be in a defective condition.

241. Federal Regulations impose standards of care on the Defendants related to the manufacture, marketing and sale of the Riata leads.

242. Plaintiffs allege the Federal Regulations define the standard of care, and thus, the Defendants 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 § 814.80; 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.

243. 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.

244. Defendants, as herein before alleged, did not adequately establish the suitability of the Riata leads for long-term use and/or, in the alternative, knew that insulated leads were not suitable for long-term use in human beings. Through their routine service and monitoring of the Devices, Defendants knew or should have known that patients like Mr. Sharp and his health care providers would rely upon representations that although the Device had been recalled, routine monitoring was all that was necessary. These representations were the basis for which Mr. Sharp made the decision not to replace the Device.

245. Defendants negligently failed to adequately warn doctors, the public and Plaintiff of their lack of knowledge and/or knowledge of unsuitability such that Mr. Sharp, prior to implantation in September 2011 would not have had

a Riata leads implanted in his body and/or he would have decided in concert with his physician whether or not to have the device explanted after it was recalled in 2012.

246. Defendants also failed to warn patients such as Mr. Sharp of the potential dangers associated with implantation of the Riata leads including abrasion and shortened battery life of the Fortify device.

247. The failure to warn constitutes a violation of federal law and state law. This parallel claim does not impose any warning requirements greater than those imposed by the Federal regulations; rather, this claim seeks to enforce St Jude's violations of federal standards and creates a parallel claim.

248. Defendants had a continuing duty to monitor the Riata leads after pre-market approval and to discover and report to the FDA and to the doctors, public and Plaintiff, any complaints about the product's performance and any adverse health consequences of which they became aware and that are or may be attributable to the product.

249. St. Jude negligently failed to timely provide, before Mr. Sharp's implantation in September 2011, information to the FDA, doctors, public and Plaintiff, regarding complaints concerning the product and/or adverse

health consequences, manufacturing defects and procedures, and significant improvements of which it became aware and that were attributable to the product.

250. If Defendants properly had reported the adverse events and amended their user instructions as required under law, that information would have reached Mr. Sharp and his treating physicians prior to implantation of the device, and Mr. Sharp would not have permitted implantation. Alternatively, if Mr. Sharp had acquired the knowledge to which he was entitled under federal and state law after implantation, he would have had the device explanted. In either event, his death would not have occurred on August 23, 2013.

251. As a direct and proximate result of Defendants' failure to warn of their lack of knowledge of long-term use and/or knowledge of the unsuitability of the Riata leads, timely report adverse events and failures as required under law, Mr. Sharp suffered catastrophic injuries and death giving rise to Mr. Sharp's claims for damages to his Estate and his heirs, as more fully set forth herein.

COUNT V
NEGLIGENCE PER SE

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

253. Federal Regulations impose standards of care on the Defendants related to the manufacture, marketing and sale of the Riata leads.

254. Plaintiffs allege the Federal Regulations define the standard of care, and thus, the Defendants 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 § 814.80; 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.

255. 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.

256. 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.

257. This parallel claim does not impose any warning requirements greater than those imposed by the Federal regulations; rather, this claim seeks to enforce St Jude's violations of federal standards and creates a parallel claim.

258. As a direct and proximate result of Defendants' failure to warn of their lack of knowledge of long-term use and/or knowledge of the unsuitability of the Riata leads, and timely report adverse events and failures as required under law, Mr. Sharp suffered catastrophic injuries and death giving rise to Mr. Sharp's claims for damages to his Estate and his heirs, as more fully set forth herein.

COUNT VI
LOSS OF CONSORTIUM

259. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

260. On August 23, 2015, Plaintiff was the lawful wife of Milton Sharp, and she has suffered damages of the loss companionship and consortium as a direct and proximate result of the defective design and/or manufacture of the Riata Lead and/or the Defendants' negligence and/or negligence *per se*, as set forth above.

261. The Defendants are liable to Ms. Sharp for such damage as was caused by them.

COUNT VII
PUNITIVE DAMAGES

262. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

263. Defendant's conduct set forth herein demonstrated reckless disregard and an entire want of care for the right consideration of mankind, entitling the Plaintiff to an award of punitive damages to punish and deter Defendants from repeating and continuing such unlawful conduct.

PRAYER FOR RELIEF

264. As a direct and proximate cause of Defendants' acts and omissions set forth herein, Mr. Sharp suffered a catastrophic injury and experienced tremendous physical and emotional pain and suffering prior to his death, damages for which his estate is entitled to recover.

265. As a direct and proximate cause of Defendants' acts and omissions set forth herein, Plaintiff is entitled to all damages resulting from the wrongful death of Mr. Sharp.

266. As a direct and proximate cause of Defendants' acts and omissions set forth herein, Mr. Sharp's estate is entitled to payment of damages associated with medical expenses, as well as funeral and burial costs.

WHEREFORE, Plaintiff respectfully request that the Court grant the following relief:

a. That judgment be entered in favor of the Plaintiff and against Defendants jointly and severally, in an amount more than $75,000.00 for damages for the full value of Milton Sharp's life, as well as for injuries, conscious pain and suffering endured by Mr. Sharp prior to death, and for his funeral and burial expenses;

b. For punitive damages;

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

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

DEMAND FOR JURY TRIAL

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

This 22nd day of August, 2017.

Respectfully Submitted,

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Counsel for Plaintiff

CERTIFICATION OF COMPLIANCE WITH LOCAL RULE 5.1C

Pursuant to the Local Rules of the Northern District of Georgia, the above-signed counsel certifies that this pleading complies with all formatting requirements of the Local Rules and further certifies that this pleading is printed in Times New Roman, 14-point type.

PENN LAW LLC

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JS44 (Rev. 6/2017 NDGA)

CIVIL COVER SHEET

The JS44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form is required for the use of the Clerk of Court for the purpose of initiating the civil docket record. (SEE INSTRUCTIONS ATTACHED)

I. (a) PLAINTIFF(S)

WENDY SHARP, Individually and as Administrator of the Estate of MILTON SHARP

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF FULTON
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANT(S)

ST. JUDE MEDICAL, S.C., INC., ST. JUDE MEDICAL, INC., PACESETTER, INC. d/b/a ST. JUDE MEDICAL CARDIAC RHYTHM MANAGEMENT DIVISION, ST. JUDE MEDICAL, LLC and ABBOTT LABORATORIES, INC.

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT FULTON
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, TELEPHONE NUMBER, AND E-MAIL ADDRESS)

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ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION

(PLACE AN "X" IN ONE BOX ONLY)

- ☐ 1 U.S. GOVERNMENT PLAINTIFF
- ☐ 3 FEDERAL QUESTION (U.S. GOVERNMENT NOT A PARTY)
- ☐ 2 U.S. GOVERNMENT DEFENDANT
- ☑ 4 DIVERSITY (INDICATE CITIZENSHIP OF PARTIES IN ITEM III)

III. CITIZENSHIP OF PRINCIPAL PARTIES

(PLACE AN "X" IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)
(FOR DIVERSITY CASES ONLY)

PLF	DEF		PLF	DEF	
☑ 1	☐ 1	CITIZEN OF THIS STATE	☐ 4	☐ 4	INCORPORATED OR PRINCIPAL PLACE OF BUSINESS IN THIS STATE
☐ 2	☐ 2	CITIZEN OF ANOTHER STATE	☐ 5	☑ 5	INCORPORATED AND PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE
☐ 3	☐ 3	CITIZEN OR SUBJECT OF A FOREIGN COUNTRY	☐ 6	☐ 6	FOREIGN NATION

IV. ORIGIN (PLACE AN "X "IN ONE BOX ONLY)

- ☑ 1 ORIGINAL PROCEEDING
- ☐ 2 REMOVED FROM STATE COURT
- ☐ 3 REMANDED FROM APPELLATE COURT
- ☐ 4 REINSTATED OR REOPENED
- ☐ 5 TRANSFERRED FROM ANOTHER DISTRICT (Specify District)
- ☐ 6 MULTIDISTRICT LITIGATION - TRANSFER
- ☐ 7 APPEAL TO DISTRICT JUDGE FROM MAGISTRATE JUDGE JUDGMENT
- ☐ 8 MULTIDISTRICT LITIGATION - DIRECT FILE

V. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE - DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY)

STRICT LIABILITY AND NEGLIGENT MANUFACTURING, AND STRICT LIABILITY AND NEGLIGENT FAILURE TO WARN CLAIMS UNDER GEORGIA LAW.

(IF COMPLEX, CHECK REASON BELOW)

- ☐ 1. Unusually large number of parties.
- ☐ 2. Unusually large number of claims or defenses.
- ☐ 3. Factual issues are exceptionally complex
- ☑ 4. Greater than normal volume of evidence.
- ☑ 5. Extended discovery period is needed.
- ☐ 6. Problems locating or preserving evidence
- ☐ 7. Pending parallel investigations or actions by government.
- ☑ 8. Multiple use of experts.
- ☐ 9. Need for discovery outside United States boundaries.
- ☑ 10. Existence of highly technical issues and proof.

CONTINUED ON REVERSE

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT $_____ APPLYING IFP _____ MAG. JUDGE (IFP) _____

JUDGE _____ MAG. JUDGE _____ NATURE OF SUIT _____ CAUSE OF ACTION _____
(Referral)

VI. NATURE OF SUIT (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT - "0" MONTHS DISCOVERY TRACK
- ☐ 150 RECOVERY OF OVERPAYMENT & ENFORCEMENT OF JUDGMENT
- ☐ 152 RECOVERY OF DEFAULTED STUDENT LOANS (Excl. Veterans)
- ☐ 153 RECOVERY OF OVERPAYMENT OF VETERAN'S BENEFITS

CONTRACT - "4" MONTHS DISCOVERY TRACK
- ☐ 110 INSURANCE
- ☐ 120 MARINE
- ☐ 130 MILLER ACT
- ☐ 140 NEGOTIABLE INSTRUMENT
- ☐ 151 MEDICARE ACT
- ☐ 160 STOCKHOLDERS' SUITS
- ☐ 190 OTHER CONTRACT
- ☐ 195 CONTRACT PRODUCT LIABILITY
- ☐ 196 FRANCHISE

REAL PROPERTY - "4" MONTHS DISCOVERY TRACK
- ☐ 210 LAND CONDEMNATION
- ☐ 220 FORECLOSURE
- ☐ 230 RENT LEASE & EJECTMENT
- ☐ 240 TORTS TO LAND
- ☐ 245 TORT PRODUCT LIABILITY
- ☐ 290 ALL OTHER REAL PROPERTY

TORTS - PERSONAL INJURY - "4" MONTHS DISCOVERY TRACK
- ☐ 310 AIRPLANE
- ☐ 315 AIRPLANE PRODUCT LIABILITY
- ☐ 320 ASSAULT, LIBEL & SLANDER
- ☐ 330 FEDERAL EMPLOYERS' LIABILITY
- ☐ 340 MARINE
- ☐ 345 MARINE PRODUCT LIABILITY
- ☐ 350 MOTOR VEHICLE
- ☐ 355 MOTOR VEHICLE PRODUCT LIABILITY
- ☐ 360 OTHER PERSONAL INJURY
- ☐ 362 PERSONAL INJURY - MEDICAL MALPRACTICE
- ☑ 365 PERSONAL INJURY - PRODUCT LIABILITY
- ☐ 367 PERSONAL INJURY - HEALTH CARE/ PHARMACEUTICAL PRODUCT LIABILITY
- ☐ 368 ASBESTOS PERSONAL INJURY PRODUCT LIABILITY

TORTS - PERSONAL PROPERTY - "4" MONTHS DISCOVERY TRACK
- ☐ 370 OTHER FRAUD
- ☐ 371 TRUTH IN LENDING
- ☐ 380 OTHER PERSONAL PROPERTY DAMAGE
- ☐ 385 PROPERTY DAMAGE PRODUCT LIABILITY

BANKRUPTCY - "0" MONTHS DISCOVERY TRACK
- ☐ 422 APPEAL 28 USC 158
- ☐ 423 WITHDRAWAL 28 USC 157

CIVIL RIGHTS - "4" MONTHS DISCOVERY TRACK
- ☐ 440 OTHER CIVIL RIGHTS
- ☐ 441 VOTING
- ☐ 442 EMPLOYMENT
- ☐ 443 HOUSING/ ACCOMMODATIONS
- ☐ 445 AMERICANS with DISABILITIES - Employment
- ☐ 446 AMERICANS with DISABILITIES - Other
- ☐ 448 EDUCATION

IMMIGRATION - "0" MONTHS DISCOVERY TRACK
- ☐ 462 NATURALIZATION APPLICATION
- ☐ 465 OTHER IMMIGRATION ACTIONS

PRISONER PETITIONS - "0" MONTHS DISCOVERY TRACK
- ☐ 463 HABEAS CORPUS- Alien Detainee
- ☐ 510 MOTIONS TO VACATE SENTENCE
- ☐ 530 HABEAS CORPUS
- ☐ 535 HABEAS CORPUS DEATH PENALTY
- ☐ 540 MANDAMUS & OTHER
- ☐ 550 CIVIL RIGHTS - Filed Pro se
- ☐ 555 PRISON CONDITION(S) - Filed Pro se
- ☐ 560 CIVIL DETAINEE: CONDITIONS OF CONFINEMENT

PRISONER PETITIONS - "4" MONTHS DISCOVERY TRACK
- ☐ 550 CIVIL RIGHTS - Filed by Counsel
- ☐ 555 PRISON CONDITION(S) - Filed by Counsel

FORFEITURE/PENALTY - "4" MONTHS DISCOVERY TRACK
- ☐ 625 DRUG RELATED SEIZURE OF PROPERTY 21 USC 881
- ☐ 690 OTHER

LABOR - "4" MONTHS DISCOVERY TRACK
- ☐ 710 FAIR LABOR STANDARDS ACT
- ☐ 720 LABOR/MGMT. RELATIONS
- ☐ 740 RAILWAY LABOR ACT
- ☐ 751 FAMILY and MEDICAL LEAVE ACT
- ☐ 790 OTHER LABOR LITIGATION
- ☐ 791 EMPL. RET. INC. SECURITY ACT

PROPERTY RIGHTS - "4" MONTHS DISCOVERY TRACK
- ☐ 820 COPYRIGHTS
- ☐ 840 TRADEMARK

PROPERTY RIGHTS - "8" MONTHS DISCOVERY TRACK
- ☐ 830 PATENT
- ☐ 835 PATENT-ABBREVIATED NEW DRUG APPLICATIONS (ANDA) - a/k/a Hatch-Waxman cases

SOCIAL SECURITY - "0" MONTHS DISCOVERY TRACK
- ☐ 861 HIA (1395ff)
- ☐ 862 BLACK LUNG (923)
- ☐ 863 DIWC (405(g))
- ☐ 863 DIWW (405(g))
- ☐ 864 SSID TITLE XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS - "4" MONTHS DISCOVERY TRACK
- ☐ 870 TAXES (U.S. Plaintiff or Defendant)
- ☐ 871 IRS - THIRD PARTY 26 USC 7609

OTHER STATUTES - "4" MONTHS DISCOVERY TRACK
- ☐ 375 FALSE CLAIMS ACT
- ☐ 376 Qui Tam 31 USC 3729(a)
- ☐ 400 STATE REAPPORTIONMENT
- ☐ 430 BANKS AND BANKING
- ☐ 450 COMMERCE/ICC RATES/ETC.
- ☐ 460 DEPORTATION
- ☐ 470 RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS
- ☐ 480 CONSUMER CREDIT
- ☐ 490 CABLE/SATELLITE TV
- ☐ 890 OTHER STATUTORY ACTIONS
- ☐ 891 AGRICULTURAL ACTS
- ☐ 893 ENVIRONMENTAL MATTERS
- ☐ 895 FREEDOM OF INFORMATION ACT
- ☐ 899 ADMINISTRATIVE PROCEDURES ACT / REVIEW OR APPEAL OF AGENCY DECISION
- ☐ 950 CONSTITUTIONALITY OF STATE STATUTES

OTHER STATUTES - "8" MONTHS DISCOVERY TRACK
- ☐ 410 ANTITRUST
- ☐ 850 SECURITIES / COMMODITIES / EXCHANGE

OTHER STATUTES - "0" MONTHS DISCOVERY TRACK
- ☐ 896 ARBITRATION (Confirm / Vacate / Order / Modify)

*** PLEASE NOTE DISCOVERY TRACK FOR EACH CASE TYPE. SEE LOCAL RULE 26.3**

VII. REQUESTED IN COMPLAINT:

☐ **CHECK IF CLASS ACTION UNDER F.R.Civ.P. 23** **DEMAND $**_____

JURY DEMAND ☑ **YES** ☐ **NO (CHECK YES ONLY IF DEMANDED IN COMPLAINT)**

VIII. RELATED/REFILED CASE(S) IF ANY

JUDGE_____ **DOCKET NO.**_____

CIVIL CASES ARE DEEMED RELATED IF THE PENDING CASE INVOLVES: (CHECK APPROPRIATE BOX)

- ☐ **1. PROPERTY INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.**
- ☐ **2. SAME ISSUE OF FACT OR ARISES OUT OF THE SAME EVENT OR TRANSACTION INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.**
- ☐ **3. VALIDITY OR INFRINGEMENT OF THE SAME PATENT, COPYRIGHT OR TRADEMARK INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.**
- ☐ **4. APPEALS ARISING OUT OF THE SAME BANKRUPTCY CASE AND ANY CASE RELATED THERETO WHICH HAVE BEEN DECIDED BY THE SAME BANKRUPTCY JUDGE.**
- ☐ **5. REPETITIVE CASES FILED BY PRO SE LITIGANTS.**
- ☐ **6. COMPANION OR RELATED CASE TO CASE(S) BEING SIMULTANEOUSLY FILED (INCLUDE ABBREVIATED STYLE OF OTHER CASE(S)):**

- ☐ **7. EITHER SAME OR ALL OF THE PARTIES AND ISSUES IN THIS CASE WERE PREVIOUSLY INVOLVED IN CASE NO.** **, WHICH WAS DISMISSED. This case** ☐ **IS** ☐ **IS NOT (check one box) SUBSTANTIALLY THE SAME CASE.**

/s/ Darren W. Penn — 08/22/2017

SIGNATURE OF ATTORNEY OF RECORD **DATE**