**UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| ASEA/AFSCME Local 52 Health Benefits Trust, individually and on behalf of a class of similarly situated third party payors,<br><br>Plaintiff,<br><br>v.<br><br>ABBOTT LABORATORIES, an Illinois corporation, and ST. JUDE MEDICAL, INC., a Minnesota corporation,<br><br>Defendants. | CASE NO.<br><br>CLASS ACTION COMPLAINT<br><br>JURY TRIAL DEMANDED |

# CLASS ACTION COMPLAINT

Plaintiff ASEA/AFSCME Local 52 Health Benefits Trust (the "ASEA Health Trust" or "Plaintiff"), by its undersigned counsel, individually and on behalf of the below-defined Nationwide Class and Alaska Class, each comprised of similarly-situated third party payors, files this Class Action Complaint against Defendants Abbott Laboratories and St. Jude Medical, Inc. (collectively, "Defendants") for their manufacture, sale, and distribution of defective Implantable Cardiac Defibrillator and Cardiac Resynchronization Therapy Defibrillator devices, and states the following:

## I. INTRODUCTION

1. This is a proposed nationwide class action lawsuit brought on behalf of third party payors ("TPPs"),[1] each of which sustained economic injuries caused by defective implantable cardiac defibrillator ("ICD") devices and Cardiac Resynchronization Therapy Defibrillator

[1] A term used to refer to any company that acts as the payor under coverage provided by a health care plan, each of which bears the risk for covering, among other things, medical device expenses.

("CRT-D") devices manufactured and sold by St. Jude Medical, Inc. and recalled on or about October 10, 2016.

2. St. Jude Medical, Inc. ("St. Jude Medical") manufactures a variety of medical devices designed to treat cardiac conditions, including ICDs and CRT-Ds. ICD and CRT-D devices provide pacing therapy to support slow heart rhythms, and electrical shock or pacing therapy to treat fast heart rhythms.

3. St. Jude Medical received FDA approval to manufacture, market, and sell several models of ICDs and CRT-Ds, including the Fortify™, Fortify Assura™, Quadra Assura™, Unify™, Unify Assura™ and Unify Quadra™ models. These models of St. Jude Medical's ICDs and CRT-Ds are powered by lithium-based batteries.

4. In October 2016, the Food and Drug Administration ("FDA") issued a Class I recall of certain models of St. Jude Medical's ICDs and CRT-Ds due to a battery defect, which can cause the batteries in those devices to deplete suddenly and prematurely (the "Battery Depletion Defect"). The defect is caused by deposits of lithium, known as "lithium clusters," which can form within the battery and create abnormal electrical connections that cause the battery to short circuit, leading to rapid battery failure.

5. The recall implicated hundreds of thousands of devices in St. Jude's Fortify™, Fortify Assura™, Quadra Assura™, Unify™, Unify Assura™, and Unify Quadra™ ICD and CRT-D lines (collectively "the Recalled Devices"), including 251,346 devices sold in the United States alone, and 398,740 devices sold worldwide.

6. If the battery unexpectedly runs out on one of the Recalled Devices due to the Battery Depletion Defect, the device becomes unable to deliver life-saving pacing or shocks, which could lead to serious health consequences, including death.

7. St. Jude Medical knew of the Battery Depletion Defect as early as 2011, but failed to take action to investigate and report this known risk, *instead waiting nearly five years before issuing a recall of the defective devices*. St. Jude Medical's knowledge of the defect and concomitant failure to act is evidenced by the following facts:

- St. Jude Medical received evidence from its battery supplier, as early as 2011, that lithium cluster bridging was causing its device batteries to prematurely deplete. Despite this evidence, St. Jude Medical neither reported nor investigated the issue, and, instead, represented that the cause of the battery depletion "could not be confirmed."
- Between 2011 and 2014, St. Jude Medical reviewed 42 product reports showing evidence of premature battery depletion due to lithium cluster bridging; yet failed to take action commensurate with this risk.
- By 2014, St. Jude Medical had received notice that premature battery depletion of one of its ICDs caused at least one patient's death.
- In December 2014, a study published in a medical journal determined that lithium cluster bridging was causing premature battery depletion in St. Jude Medical's ICDs and CRT-Ds.

8. Despite the extensive evidence, and its clear knowledge of the premature battery depletion problem in its devices, St. Jude Medical failed to take prompt action, and knowingly ignored or concealed this evidence from its management boards, from the FDA, and from the public, including Plaintiff and the other Nationwide and Alaska Class members.

9. On November 11 and 12, 2014, St. Jude Medical's management review and medical advisory boards were given two separate presentations on premature battery depletion.

During these meetings, St. Jude failed to tell its own boards about the full scope of the battery issue, presented false or incomplete evidence of the defect, and concealed from the boards evidence of a known death related to this battery defect stating instead that there were no serious injuries or deaths directly related to lithium cluster bridging.

10. St. Jude Medical also concealed the Battery Depletion Defect from the FDA, medical providers, TPPs, and patients, putting hundreds of thousands of its device users at severe risk. As a result, St. Jude Medical allowed thousands of more defective devices to be implanted in patients across the United States at the Nationwide and Alaska Class members' expense.

11. As a result of the Battery Depletion Defect, and Defendants' concealment thereof, Nationwide and Alaska Class members bought defective devices and patients with a Recalled Device have had to undergo the invasive, dangerous, and expensive process of having their defective devices explanted and replacement devices implanted.

12. The overwhelming economic impact of Defendants' conduct has fallen, wrongfully, on the shoulders of public and private health insurance payors—such as Plaintiff and the other Nationwide and Alaska Class members—who (1) paid for defective devices and/or (2) were and are responsible for the explant and replacement costs of the defective devices.

13. As alleged herein, the economic injuries sustained by Plaintiff and the other Nationwide and Alaska Class members were directly and proximately caused by Defendants' failure to comply with FDA and federal requirements and regulations, including its failure to timely disclose the Battery Depletion Defect to the FDA.

14. By not notifying the FDA earlier, Defendants caused Plaintiff and the other Nationwide and Alaska Class members to spend hundreds of millions of dollars needlessly paying for implants (and, subsequently, explants) of known, defective medical devices.

15. At all times relevant to this action, Defendants knew or should have known that the now-recalled ICDs and CRT-Ds were defective, unreasonably dangerous, and unfit for their intended use. Defendants placed thousands of patients (and TPP participants) unnecessarily at risk and caused Plaintiff and the other Nationwide and Alaska Class members to incur substantially greater costs than they should and otherwise would have paid for medical treatment of their participants. These costs will mount, and Nationwide and Alaska Class members will continue to pay for the consequences of Defendants' actions for years to come.

16. Plaintiff, individually and on behalf of the other Nationwide and Alaska Class members, seeks to recover damages caused by Defendants' wrongful conduct and for declaratory and injunctive relief.

## II. PARTIES

***Plaintiff***

17. ASEA/AFSCME Local 52 Health Benefits Trust (the "ASEA Health Trust" or "Plaintiff") is a tax-exempt IRC Section 501(c)(9) Voluntary Employee Benefit Association. The ASEA Health Trust provides health benefits to participants and their eligible family members consisting of permanent and long-term nonpermanent employees of the State of Alaska General Government Unit covered by a collective bargaining agreement between the State of Alaska and ASEA/AFSCME Local 52. The ASEA Health Trust paid costs for the implantation of Defendants' defective ICDs and CRT-Ds, and may be subject to pay costs associated with their explant and replacement.

***Defendants***

18. St. Jude Medical, Inc. ("St. Jude Medical") is a corporation organized and existing under the laws of Minnesota, with its principal place of business in St. Paul, Minnesota. St. Jude Medical is a wholly-owned subsidiary of its parent corporation, Abbott Laboratories. St. Jude

Medical does business throughout the world and throughout the United States, including in the State of Illinois. The ICD and CRT-D devices manufactured by St. Jude Medical were sold throughout the United States and in the State of Illinois. Following its January 4, 2017, acquisition by Defendant Abbott, St. Jude Medical became a wholly-owned subsidiary of Abbott (*see* Paragraph 21, below).

19. Upon information and belief, St. Jude Medical's Cardiac Rhythm Management Division, located in Sylmar, California, oversaw the design, manufacture, labeling, and sale of St. Jude Medical's ICD and CRT-D devices. Upon information and belief, Defendant Abbott Laboratories now owns and operates the Sylmar, California facility.

20. Abbott Laboratories ("Abbott") is St. Jude Medical's parent corporation, organized and existing under the laws of Illinois, with its principal place of business in Abbott Park, Illinois. Defendant does business throughout the world and the United States, including in the State of Illinois.

21. On or about January 4, 2017, Abbott acquired St. Jude Medical. Under the terms of the Merger Agreement, upon completion of the acquisition, St. Jude Medical became a wholly-owned subsidiary of Abbott. Upon information and belief, Abbott assumed liability for St. Jude Medical's actions as its successor.

22. Upon information and belief, at all times herein mentioned, Defendants' employees, subsidiaries, affiliates, and other related entities, as well as the employees of each individual Defendant's subsidiaries, affiliates, and other related entities, were Defendants' agents, servants, and employees and, at all relevant times, were acting within that purpose and scope. Whenever this Complaint refers to any act or transaction of either or both Defendants, such designations shall be deemed to mean that Defendants' principals, officers, employees,

agents, and/or representatives committed, knew of, performed, authorized, ratified, and/or directed such transactions on Defendants' behalf while actively engaged in the scope of their duties.

## III. JURISDICTION AND VENUE

23. This Court has original jurisdiction over this action under the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d)(2). The aggregated amount in controversy in this action exceeds $5,000,000, and "any member of a class of plaintiffs is a citizen of a State different from any defendant." Plaintiff is a citizen of Alaska and Defendants Abbott and St. Jude Medical are citizens of Illinois and Minnesota, respectively.

24. This Court has personal jurisdiction over Plaintiff because Plaintiff submitted to this Court's jurisdiction.

25. This Court has personal jurisdiction over Defendant Abbott because Abbott is incorporated under the laws of the State of Illinois and has its principal place of business and headquarters in Abbott Park, Illinois. Defendant Abbott systematically and continually conducts business throughout the State of Illinois, including marketing, advertising, and selling medical devices.

26. This Court has personal jurisdiction over Defendant St. Jude Medical because St. Jude Medical systematically and continually conducts business throughout the State of Illinois, including marketing, advertising, and selling its ICD and CRT-D devices, including the Recalled Devices at issue in this suit. Further, as explained herein, Abbott, an Illinois company, acquired St. Jude Medical, and St. Jude Medical is now a wholly-owned subsidiary of Abbott.

27. The venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendants are subject to this Court's personal jurisdiction. Defendant Abbott's headquarters are

located in the Northern District of Illinois. Because Abbott purchased St. Jude Medical and thereby assumed responsibility for St. Jude Medical's operations, and assumed control over the facilities that oversaw, manufactured, and/or distributed the Recalled Devices, the venue is proper in the Northern District of Illinois.

## IV. FACTUAL BACKGROUND

### A. Implantable Cardiac Defibrillators

28. Defendants design, manufacture, market, and sell ICDs and CRT-Ds.

29. An ICD is a small device that is surgically placed in a patient's body to treat irregular heart rhythms, known as arrhythmias. ICDs operate by using electrical pulses or shocks to control life-threatening arrhythmias. The shock is sent to the heart muscle to interrupt the rhythm disorder and to allow the heart to resume its normal rhythm.[2]

30. A CRT-D is also used to treat and control arrhythmias. The CRT-D is implanted in a patient's body. Three wires (leads) connected to the device monitor the heart rate to detect heart rate irregularities, and emits tiny pulses of electricity to correct them.[3]

31. St. Jude Medical designed, manufactured, marketed, and sold several different models of ICDs and CRT-Ds, including the Fortify™, Fortify Assura™, Quadra Assura™, Unify™, Unify Assura™ and Unify Quadra™ model lines, which were recalled in October 2016 due to a battery-related defect with the devices (the "Recalled Devices," as defined above).

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[2] *Implantable Cardioverter Defibrillator (ICD)*, Am. Heart Ass'n, http://www.heart.org/HEARTORG/Conditions/Arrhythmia/PreventionTreatmentofArrhythmia/Implantable-Cardioverter-Defibrillator-ICD_UCM_448478_Article.jsp#.WYS75BWrphE (Sept. 2016).

[3] *Cardiac Resynchronization Therapy (CRT)*, Am. Heart Ass'n, http://www.heart.org/HEARTORG/Conditions/HeartFailure/Cardiac-Resynchronization-Therapy_UCM_452920_Article.jsp#.WYS8cRWrphE (Apr. 6, 2015).

32. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective Recalled Devices, either directly or indirectly, to members of the general public throughout the United States.

*Images of a Fortify Assura VR ICD, and a Quadra Assura CRT-D*

33. St. Jude Medical's ICDs and CRT-Ds are powered by lithium batteries. Upon information and belief, Defendants advertise that all of its ICD and CRT-D devices are designed with battery chemistry that provides for enhanced or extended longevity.[4]

## B. Regulatory Approval Process

34. The Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") established the current regulatory framework for medical device approval.

35. The MDA contains a three-class classification system for medical devices. Class I devices pose the lowest risk to consumers' health, and include devices such as tongue depressors

[4] *See, e.g.*, *ICD Devices*, St. Jude Medical, https://www.sjm.com/en/professionals/featured-products/cardiac-rhythm-management/icd-devices (Aug. 16, 2016); *Product Catalog: Fortify Assura™ DR*, St. Jude Medical, https://www.sjm.com/en/professionals/resources-and-reimbursement/technical-resources/cardiac-rhythm-management/implantable-cardioverter-defibrillator-icd-devices/dual-chamber/fortify-assura-dr-dual-chamber-implantable-cardioverter-defibrillator-icd (Apr. 19, 2013); *Product Catalog: Quadra Assura™*, St. Jude Medical, https://www.sjm.com/en/professionals/resources-and-reimbursement/technical-resources/cardiac-rhythm-management/cardiac-resynchronization-therapy-crt-devices/crt-defibrillator/quadra-assura-cardiac-resynchronization-therapy-defibrillator-crt-d (Apr. 19, 2013).

or bandages. Class I devices receive the least FDA oversight. Class II devices pose intermediate risks to consumers, and require more comprehensive FDA approval, which often includes special controls, including post-market surveillance and guidance documents. Finally, Class III devices pose the greatest risk of death or complications and include most implantable surgical devices such as cardiac pacemakers, coronary artery stents, automated external defibrillators, and several types of implantable orthopedic devices for spine and hip surgery. Class III devices are subject to the most extensive FDA oversight. The Recalled Devices are Class III devices.

36. Under Section 515 of the MDA, manufacturers such as Defendants seeking to market Class III devices are required to submit a pre-market approval application ("PMA") to the FDA.[5] During the PMA process, the manufacturer must provide the FDA with "reasonable assurance" that the device is both safe and effective for its intended use.[6] Not only is the design and manufacturing subject to review, but the labeling and packaging are subject to review as well.[7]

37. After a device receives PMA approval, the FDCA requires medical device manufacturers to comply with all device-specific regulations and standards outlined in the device's PMA.[8]

38. A medical device is deemed "adulterated" if the "methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity" with applicable federal requirements.[9] Additionally, if a manufacturer fails to disclose all material

[5] 21 U.S.C. § 360e.

[6] 21 U.S.C. § 360e(d); 21 C.F.R. § 814.20.

[7] 21 C.F.R. § 814.20(b).

[8] 21 C.F.R. § 814.80.

[9] 21 U.S.C. § 351(h).

facts or comply with reporting requirements, the device is considered "misbranded."[10] The distribution of an "adulterated" or "misbranded" medical device is prohibited, under 21 U.S.C. § 331(b).

39. After PMA approval, device manufacturers must also comply with the FDA's current good manufacturing practices ("CGMPs"), set forth at 21 C.F.R. §§ 820.1 – 820.250, which "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use."[11] A device is deemed adulterated if it is not manufactured in accordance with CGMPs.[12]

40. The FDCA provides that a medical device is misbranded if, among other things, the labeling did not contain adequate directions for use, or the manufacturer failed to provide information about adverse events.[13]

41. After the FDA approves a PMA submission, the manufacturer must obtain FDA permission if it wishes to make any additional changes that affect the device's safety, effectiveness, or labeling.[14] To obtain FDA permission to make those changes, a manufacturer must submit apply for supplemental premarket approval,[15] evaluated under criteria similar to those used in the PMA process.

[10] 21 U.S.C. § 352(t).

[11] 21 C.F.R. § 820.1.

[12] 21 U.S.C. § 351(h); 21 C.F.R. § 820.1(c).

[13] 21 U.S.C. § 352(f), (t).

[14] 21 U.S.C. § 360e(d)(5)(A)(i).

[15] 21 U.S.C. § 360e(d)(5).

### C. Approval of the St. Jude ICDs and CRT-Ds

42. In 2004, St. Jude Medical received approval to market St. Jude Medical® Epic™ HF System and the St. Jude Medical® Atlas® + HF System CRT-Ds. Since that time, St. Jude Medical has designed, manufactured, marketed, and sold several models of ICDs and CRT-Ds, including the Fortify™, Fortify Assura™, Quadra Assura™, Unify™, Unify Assura™ and Unify Quadra™ models. The Fortify™, Fortify Assura™, Quadra Assura™, Unify™, Unify Assura™ and Unify Quadra™ devices were based on the original 2004 PMA submission and numerous supplements.

43. The FDA-approved PMA imposes specific requirements a manufacturer must follow for the design, manufacturing, labeling, and sale of a PMA-approved device.

44. The PMA documents, including all specifications, are confidential.[16] As a result, the FDA's device-specific requirements for the Recalled Devices are presently unknown to Plaintiff, and can only be obtained through discovery.

45. The FDA's Center for Devices and Radiological Health, which reviews PMA submissions for ICD and CRT-D devices does not, and did not, evaluate information related to contract liability warranties in the PMA review and approval process.[17] Any such warranty statements the Defendants made must be truthful, accurate, and not misleading.

### D. Post-Approval Continuing Requirements, Including General Reporting Requirements to the FDA Mandated by Federal Regulations

46. A medical device manufacturer's obligations do not end with the PMA approval process. Under federal law, a medical device manufacturer has a continuing duty to monitor the

[16] 21 C.F.R. § 814.9.

[17] PMA Approval Letter to Elisabeth E. Neely, RCA, St. Jude Medical, Inc. from the FDA, re: P030054 (June 30, 2004), at 2.

product after premarket approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are, or may be, attributable to the product.[18]

47. Even after PMA approval, manufacturers are required to report to the FDA when the manufacturer receives, or otherwise becomes aware, of information, from any source, that reasonably suggests that its device may have caused or contributed to death or serious injury or if the device has malfunctioned and is likely to cause or contribute to a death or serious injury if the malfunction were to recur.[19]

48. A medical device manufacturer is required to report adverse events associated with the use of the product, including deaths and serious injuries that the device has or may have caused or contributed to and certain device malfunctions. These reports help the FDA "to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use."[20]

49. Manufacturers must report to the FDA all information reasonably known to the manufacturer, including any information obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession.[21] Also, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event.[22] Manufacturers are required to submit supplemental or follow-up reports if

[18] 21 C.F.R. §§ 803.1, *et seq.*

[19] 21 C.F.R. § 803.50(a).

[20] 21 C.F.R. § 803.1; 21 U.S.C. § 360i(a).

[21] 21 C.F.R. § 803.50(a); 21 C.F.R. § 803.52.

[22] 21 C.F.R. § 803.50(b)(3).

the manufacturer subsequently obtains information that was not available or not known when submitting the initial report.[23]

50. Medical device manufacturers are required by federal regulation to "establish and maintain" adverse event files.[24] Under federal regulations, medical device manufacturers must also describe in every individual adverse event report whether remedial action was taken about the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device.[25]

51. In addition, medical device manufacturers are required to make periodic reports to the FDA regarding approved devices and inform the FDA of new clinical investigations or scientific studies concerning the device about which the manufacturer knows, or reasonably should know.[26]

52. After receiving information on adverse events from manufacturers, the FDA publishes adverse events and medical device reports in a publicly searchable database called the Manufacturer and User Facility Device Experience ("MAUDE"). Physicians and the general public may access MAUDE to view safety data on medical devices.

53. The Medical Device Reporting requirements are one of the key post-market surveillance tools that the FDA uses to monitor device performance and safety, and the FDA uses this information to "detect potential device-related safety issues, and contribute to benefit-

[23] 21 C.F.R. § 803.56.

[24] 21 C.F.R. § 803.1(a).

[25] 21 C.F.R. § 803.52.

[26] 21 C.F.R. § 814.84 (b)(2)

risk assessments of these products."[27] The FDA can revoke its approval based on the manufacturer's post-approval reports.[28]

### E. Post Approval, the FDA, By Its Regulations and PMA Process, Requires a Manufacturer to Follow Good Manufacturing Practices

54. After receiving PMA approval, medical device manufacturers, like Defendants, must comply with FDA's regulations on manufacturing processes. Under 21 C.F.R. §§ 820, *et seq.* of the Quality System (QS) Regulation for Medical Devices, the FDA has set forth current good manufacturing practice (CGMP) requirements. The requirements in this part apply to manufacturers and govern the methods used in, and the facilities and controls used for, the manufacturing, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the FDCA.[29]

55. 21 C.F.R. § 820.5: "Quality Systems," the FDA regulations state, "Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part."

56. 21 C.F.R. § 820.3(z)(2): "Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s)."

57. 21 C.F.R. § 820.22: "Quality Audit" states: "Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system." Reports of each quality audit must be provided to management.

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[27] Medical Device Reporting (MDR), FDA, https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm (Nov. 7, 2016).

[28] 21 U.S.C. §§ 360e(e)(1), 360h(e).

[29] 21 C.F.R. § 820.1(a).

58. 21 C.F.R. § 820.160(a): "Distribution" states: "Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed . . . ."

59. 21 C.F.R. § 820.30: "Design controls" states: "Each manufacturer of any class III . . . device[] . . . shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met."

60. 21 C.F.R. § 820.50: "Purchasing controls" states: "Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements."

61. 21 C.F.R. § 820.70: "Production and process controls" states: "Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications."

62. 21 C.F.R. § 820.90: "Nonconforming product" states: "Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements."

63. 21 C.F.R. § 820.100: "Corrective and Preventive Action" requires that each manufacturer establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for analyzing quality audit reports and quality data to identify existing and potential causes of nonconforming product, investigating the cause of nonconformities, and taking corrective and preventive action to ensure that such quality problems do not adversely affect the finished device.

**F. The Defective Battery in Defendants' Recalled Devices**

64. Defendants' ICD and CRT-D devices rely on lithium batteries for their operation. These ICD and CRT-D devices are designed to deliver a gentle vibratory alert to the patient when the battery is nearing its end of life.

65. Upon information and belief, St. Jude Medical advertises its products based on representations that all of its ICD devices are designed with battery chemistry that provides for enhanced or extended longevity.[30]

66. The batteries used in the Recalled Devices were manufactured by Greatbatch Medical (renamed Integer Holdings, Inc. last year). Greatbatch Medical is a company that produces lithium batteries for use in ICD and pacemaker devices. The Recalled Devices all used Greatbatch battery model number QHR2850 (the "Greatbatch Battery").

67. The Greatbatch Battery used in Defendants' Recalled Devices has a defect that can cause the battery to deplete prematurely. Deposits of lithium, "known as "lithium clusters" can form within the battery and create abnormal electrical connections that cause the battery to short circuit and leads to rapid battery failure.

68. In some cases, it was reported that full battery drainage could occur within a day or a few weeks after the patient receives the gentle vibratory alert. the device is unable to provide life-saving pacing and shock therapy to the patient, after the battery is depleted.

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[30] *See, e.g.*, *ICD Devices*, St. Jude Medical, https://www.sjm.com/en/professionals/featured-products/cardiac-rhythm-management/icd-devices (Aug. 16, 2016); *Product Catalog: Fortify Assura™ DR*, St. Jude Medical, https://www.sjm.com/en/professionals/resources-and-reimbursement/technical-resources/cardiac-rhythm-management/implantable-cardioverter-defibrillator-icd-devices/dual-chamber/fortify-assura-dr-dual-chamber-implantable-cardioverter-defibrillator-icd (Apr. 19, 2013); *Product Catalog: Quadra Assura™*, St. Jude Medical, https://www.sjm.com/en/professionals/resources-and-reimbursement/technical-resources/cardiac-rhythm-management/cardiac-resynchronization-therapy-crt-devices/crt-defibrillator/quadra-assura-cardiac-resynchronization-therapy-defibrillator-crt-d (Apr. 19, 2013).

69. Additionally, because the battery depletion may occur rapidly, some patients may be unable to detect the device alert before full battery drainage.

70. As early as 2011, St. Jude Medical received reports from its supplier that the batteries used in in its ICD and CRT-D devices could deplete prematurely.[31]

71. In December 2014, a study published in the journal *HeartRhythm* reported cases of battery failure in St. Jude Medical's Fortify ICDs. The study attributed the failure to the presence of lithium clusters that form in the battery and cause a short circuit and high current drain.[32]

72. Sometime in 2014, St. Jude Medical requested Greatbatch to implement a design improvement to the Greatbatch Battery to address the lithium cluster bridging defect. Despite the fact that this design change was made to correct a device defect that posed a serious risk to health, St. Jude Medical failed to notify the FDA of a correction until August 2016.

## G. FDA Inspection of Defendants' Facility: Defendants Knew of the Battery Depletion Defect as Early as 2011 and Failed to Follow Federal Regulations and Requirements

73. From February 7-17, 2017, FDA investigators inspected Defendants' facility in Sylmar, California.

74. The inspections revealed that Defendants had deficiencies in their procedures for corrective and preventive action ("CAPA" procedures).[33] The inspections also revealed that Defendants had knowledge of the Battery Depletion Defect as far back as 2011, but failed to

[31] Warning Letter from FDA to Mike Rousseau, President, Abbott, Neurovascular and Neuromodulation (Apr. 12, 2017) (hereinafter "FDA Warning Letter to Abbott").

[32] *See* Sean D. Pokorney, MD, MBA, Ruth Ann Greenfield, MD, Brett D. Atwater, MD, James P. Daubert, MD, FHRS, Jonathan P. Piccini, MD, MHS, FHRS, *Novel mechanism of premature battery failure due to lithium cluster formation in implantable cardioverter-defibrillators*, HeartRhythm, Volume 11, Issue 12, 2190 – 2195 (Dec. 2014).

[33] FDA Warning Letter to Abbott.

report health risks posed by the device, failed to follow reporting requirements, and failed to [] control products that did not conform to specifications. The FDA detailed these deficiencies and violations in two letters to the manufacturer Defendants, described herein.

75. St. Jude Medical had repeated notice of the Battery Depletion Defect and ignored it. ***Forty-two (42) of the Defendants' Product Analysis Reports, produced between the years 2011 and 2014, confirmed that there was an issue with premature battery depletion caused by lithium cluster bridging in the Recalled Devices***. These analysis reports included evidence and analysis from the battery supplier that the cause of premature battery depletion was lithium cluster bridging. Despite this evidence, Defendants ignored the issue and repeatedly concluded that the cause of premature battery depletion "could not be determined."[34]

76. Defendants received information by August 27, 2014, that premature battery failure with one of its devices even led to a death. Defendants investigated the reported death. During its investigation, Defendants completed an analysis of the returned device. Defendants' analysis concluded the cause of premature battery depletion "could not be determined," despite possessing evidence of lithium cluster bridges, which was provided by Defendants' supplier.

77. St. Jude Medical did not tell its own management review and medical advisory boards about the full scope of the Battery Depletion Defect. On November 11 and November 12, 2014, Defendants made two separate presentations for management review concerning premature battery depletions. In these presentations, Defendants only included rates of occurrence of premature battery depletions caused by "confirmed" lithium cluster formations. Neither presentation included information on the potential for "unconfirmed" cases to have been

[34] Form FDA 483, Inspectional Observations, St. Jude Medical Inc., PEI Number 2017865 (Feb. 17, 2017) (hereinafter "St. Jude Form FDA 483"); FDA Warning Letter to Abbott.

caused by premature battery depletions, despite the fact that Defendants possessed evidence provided by their supplier that the premature battery depletion was caused by lithium cluster bridges. As a result, the presentation significantly underestimated of the probability of occurrence of the battery depletion hazard.[35]

78. Additionally, at both presentations, Defendants falsely represented that there was no serious injury or death directly related to lithium cluster formations in the Recalled Devices, failing to disclose that there was a related death to the premature battery depletion issue (MDR#2938836-2014-13599).

79. Defendants based their risk evaluation of the battery defect on "confirmed" cases, but failed to consider the potential for "unconfirmed" cases. In doing so, Defendants underestimated the occurrence of the hazardous situation posed by the battery defect in the Recalled Devices.[36]

80. Defendants' actions violated federal requirements, including a CAPA requirement that requires the level of corrective action and preventive action be commensurate with the significance and risk of the nonconformance, and requirement that the risk evaluation of nonconformances should be based on three factors: severity, probability, and detectability.[37]

81. As a result of its investigation, the FDA concluded that Defendants failed to establish and maintain procedures for implementing corrective and preventative actions, as required by 21 C.F.R. § 820.100(a).[38]

[35] St. Jude Form FDA 483; FDA Warning Letter to Abbott.

[36] St. Jude Form FDA 483; FDA Warning Letter to Abbott.

[37] St. Jude Form FDA 483; FDA Warning Letter to Abbott.

[38] FDA Warning Letter to Abbott.

82. As a result of Defendants' above-described investigation and reporting failures, the FDA investigators determined that Defendants violated – and continued to be in violation of – Defendants' required Quality Management Review SOP (standard operating procedure).[39]

83. The FDA investigators also discovered that Defendants released ten recalled ICDs from its distribution centers after the October 2016 recall had been issued. Between October 14 and October 26, 2016, seven additional recalled ICDs in the control of St. Jude Medical's U.S. Field Representatives were implanted into patients.[40]

84. The FDA investigators also determined Defendants violated 21 C.F.R. § 820.90(a) by "failing to establish and maintain procedures to control product that does not conform to specified requirements."[41]

85. As a result of these deficiencies, the FDA issued a Form FDA 483 Report to Defendants.[42] "An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgement may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific and significant. Observations are made when in the investigator's judgement, conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or

[39] *Id.*

[40] *Id.*

[41] *Id.*

[42] St. Jude Form FDA 483.

rendered injurious to health."[43] The observations listed on the Form 483 are not exhaustive, and there may have also been other objectionable conditions at the time.

86. Specifically, following the February 2017 inspection, the FDA cited numerous deficiencies with respect to the Recalled Devices:

a. Defendants repeatedly concluded that the cause of premature depletion of the Greatbatch QHR2850 battery "could not be determined" ***when 42 Product Analysis Reports produced between 2011 and 2014 provided ample evidence that lithium cluster bridging had prematurely drained the battery***;

b. Defendants' investigations into the Battery Depletion Defect were not timely;

c. Defendants failed to follow CAPA procedures;

d. Defendants failed to provide complete information to management review and medical advisory boards regarding the premature battery depletion issue, including a failure to disclose accurate rates of occurrence and failure to note a death caused by the Battery Depletion Defect; and

e. Defendants failed to timely notify the FDA of a serious risk to health posed by the Recalled Devices.[44]

87. As a result of the FDA investigation, the FDA determined the Recalled Devices were adulterated within the meaning of section 501(h) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 351(h), because the methods used in, or controls used for, their manufacture,

[43] FDA Form 483 Frequently Asked Questions, FDA, https://www.fda.gov/iceci/inspections/ucm256377.htm (July 24, 2017).

[44] St. Jude Form FDA 483; FDA Warning Letter to Abbott.

packing, storage, or installation are not in conformity with the CMGP requirements under 21 C.F.R. part 820.[45]

88. On April 12, 2017, the FDA sent a warning letter to Mike Rousseau, President of Abbott's Cardiovascular & Neuromodulation Division, further detailing the violations found during the FDA inspection of the Recalled Devices, as described herein, and requesting remedial action from Abbott.[46]

89. Because of Defendants' failure to properly investigate and report the Battery Depletion Defect, Defendants failed to promptly take action to remedy the defect and notify the FDA and others of the defect. As a direct result of these failures, Defendants continued to distribute devices containing this battery until October 2016, allowing for the additional implantation of knowingly defective devices at Plaintiff's and the other Nationwide and Alaska Class members' expense.

**H. Recall Notice**

90. 21 C.F.R. § 7.3(g) states: "Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure." Recalls are classified by the FDA into one of three categories. The designation or category "assigned by the Food and Drug Administration to a particular product recall . . . indicate[s] the relative degree of health hazard presented by the product being recalled." 21 C.F.R. § 7.3(m).

[45] FDA Warning Letter to Abbott.

[46] FDA Warning Letter to Abbott.

91. On October 10, 2016, the FDA issued a Class I Recall (the "Recall") of the following 251,346 devices sold in the United States that St. Jude Medical manufactured on or before May 2015:

- Fortify VR: Model No(s). CD1231-40, CD1231-40Q;
- Fortify ST VR: Model No(s). CD1241-40, CD1241-40Q;
- Fortify Assura VR: Model No(s). CD1257-40, CD1257-40Q, CD1357-40C, CD1357-40Q;
- Fortify Assura ST VR: Model No(s). CD1263-40, CD1263-40Q, CD1363-40C, CD1363-40Q;
- Fortify DR: Model No(s). CD2231-40, CD2231-40Q;
- Fortify ST DR: Model No(s). CD2241-40, CD-2241-40Q, CD2263-40, CD2263-40Q;
- Fortify Assura DR: Model No(s). CD2257-40, CD2257-40Q, CD2357-40C, CD2357-40Q;
- Fortify Assura ST DR: Model No(s). CD2363-40C, CD2363-40Q;
- Unify: Model No(s). CD3231-40, CD3231-40Q;
- Unify Quadra: Model No(s). CD3249-40, CD3249-40Q;
- Unify Assura: Model No(s). CD3257-40, CD3257-40Q, CD3357-40C, CD3357-40Q;
- Quadra Assura: Model No(s). CD3265-40, CD3265-40Q, CD3365-40C, CD3365-40Q; and
- Quadra Assura MP: Model No(s). CD3269-40, CD3269-40Q, CD3369-40C.

92. The FDA categorized the Recall as a "Class I" recall. A Class I recall "is 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." 21 C.F.R § 7.3(m).

93. By definition, classifying the Recall as a "Class I" recall confirms that the devices in question were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

94. Had Defendants not omitted or failed to disclose the Battery Depletion Defect or failed to report adverse events information involving the Battery Depletion Defect, information regarding the defect would likely have appeared in MAUDE, and would have been publicly accessible to prescribing physicians and the general public.

95. Had Defendants not omitted or failed to disclose the Battery Depletion Defect, physicians would not have implanted the Recalled Devices in Plaintiff's and the other Nationwide and Alaska Class members' plan participants, and Plaintiff and the other Class members would not have incurred the medical costs of the device explant and replacement surgeries.

96. On October 10, 2016, St. Jude Medical, ***for the first time***, sent a notice to patients, caregivers, and physicians of the premature battery depletion issue, despite knowing of this problem as far back as 2011.

97. In conjunction with the Recall, the FDA sent out a Safety Communication on October 11, 2016, concerning the premature battery depletion of the Recalled Devices, caregivers of patents with a Recalled Devices, and physicians treating patients with heart failure or heart rhythm problems.

98. The FDA's Safety Communication gave further notice of the battery defect and warned that some batteries could run out within *24 hours* of the low battery alert. In the Safety Communication, the FDA warned healthcare providers not to implant any unused affected devices.

99. For patients affected by the Recall, St. Jude Medical has offered to cover the costs of unreimbursed medical expenses incurred by patients in the U.S. (out-of-pocket expenses) related to the device removal and replacement procedure. St. Jude Medical has also offered to provide payments to U.S. patients for one-time office visits needed to address concerns related to the Battery Depletion Defect and the Recall, covering only unreimbursed medical expenses incurred by the patient (out of pocket expenses, co-pays). These offers of financial support do not cover the medical expenses that the Plaintiff and the other Nationwide and Alaska Class members were or will be required to cover.

## I. Conduct in Violation of the FDCA

100. Defendants violated these FDCA statutes and accompanying regulations by:

a. falsely and misleadingly promoting its ICD and CRT-D devices;

b. failing to report to the FDA adverse events;

c. failing to timely conduct failure investigations and analysis;

d. failing to timely report any and all information concerning product failures and corrections;

e. failing to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, and device failures necessitating a labeling, manufacturing or device modification;

f. failing to follow CAPA procedures;

g. failing to follow CGMPs; and

h. selling and distributing a misbranded and adulterated product through interstate commerce.

101. Defendants' violation of these FDCA statutes and accompanying regulations, as discussed above, constitutes a parallel violation of the causes of action alleged in this Complaint, as set forth herein.

102. Defendants' violation of the FDCA statutes and accompany regulations, as discussed above, directly caused or significantly contributed to the use of the Recalled Devices; and Defendants' misconduct in this regard thus caused or contributed to Plaintiff's and the other Nationwide and Alaska Class members' injuries and damages.

**J. The Effect of Defendants' Wrongful Conduct**

103. As a direct and proximate cause of Defendants' conduct and the defective St. Jude Medical ICD and CRT-Ds:

a. Plaintiff and the other Nationwide and Alaska Class members paid for defective devices.

b. Plaintiff's and the other Nationwide and Alaska Class members' plan participants have suffered injuries and/or received related medical treatment and care. Accordingly, Plaintiff and the other Nationwide and Alaska Class members have paid medical costs for the Recalled Devices including, but not limited to, the original defective device, implantation surgery, explant and replacement surgery, and medical monitoring and/or other related healthcare costs.

104. Plaintiff's action benefits the public by, among other things, addressing the prevention or curtailment of false and misleading marketing and sales of life-threatening and otherwise defective products, and seeking reimbursement of damages caused by prevalent deceptive marketing, distribution, and sale of those products.

## V. CLASS ACTION ALLEGATIONS

105. Plaintiff brings this action pursuant to Rules 23(a), 23(b)(2), and 23(b)(3) of the Federal Rules of Civil Procedure, individually and on behalf of all others similarly situated.

106. Plaintiff seeks to represent a class (the "Nationwide Class"), defined as:

> All third party health benefits payors in the United States (including its Territories and the District of Columbia) who (i) have been a party to a contract, issuer of a policy or sponsor of a plan which contract, policy or plan provides medical coverage to natural persons, and (ii) have incurred, pursuant to such contract, policy or plan, full or partial costs for insureds who have had implanted an ICD or CRT-D device manufactured by St. Jude Medical, Inc. subject to the FDA's October 2016 Premature Battery Depletion Recall.

107. Plaintiff also seeks to represent an Alaska statewide class (the "Alaska Class"), defined as:

> All third party health benefits payors in Alaska who (i) have been a party to a contract, issuer of a policy or sponsor of a plan which contract, policy or plan provides medical coverage to natural persons, and (ii) have incurred, pursuant to such contract, policy or plan, full or partial costs for insureds who have had implanted have had implanted an ICD or CRT-D device manufactured by St. Jude Medical, Inc. subject to the FDA's October 2016 Premature Battery Depletion Recall.

108. Excluded from the Nationwide Class and the Alaska Class are Defendants and their subsidiaries, franchises, and affiliates; all employees of Defendants; all persons who make a timely election to be excluded from either Class; government entities; Plaintiff's counsel, and the judge to whom this case is assigned, including his/her immediate family and court staff. Plaintiff reserves the right to modify or amend these Nationwide and Alaska Class definitions, as appropriate, during this litigation.

109. This action has been brought and may properly be maintained on behalf of the Nationwide and Alaska Classes proposed herein under the criteria of Rule 23 of the Federal Rules of Civil Procedure.

110. Plaintiff is a member of the Nationwide and Alaska Classes it seeks to represent.

111. **Numerosity – Federal Rule of Civil Procedure 23(a)(1).** The members of the Nationwide and Alaska Classes are so numerous and geographically dispersed that individual joinder of all class members is impracticable. While Plaintiff is informed and believes that there are thousands of Nationwide and Alaska Class members, the precise number of Class members presently unknown to Plaintiff, but may be ascertained from information contained in a device registry and other records maintained by Defendants and certain third parties, including hospitals. Nationwide and Alaska Class Members may be notified of the pendency of this action by recognized, Court-approved notice dissemination methods, which may include U.S. Mail, electronic mail, Internet postings, and published notice.

112. **Commonality and Predominance – Federal Rule of Civil Procedure 23(a)(2) and 23(b)(3).** This action involves common questions of law and fact, which predominate over any questions affecting individual Nationwide and/or Alaska Class members, including, without limitation:

(a) Whether Defendants engaged in the conduct alleged herein;

(b) Whether Defendants' alleged conduct violates applicable law;

(c) Whether Defendants failed to comply with FDCA and FDA standards and requirements in the design, manufacture, approval, reporting, and correcting of the Recalled Devices;

(d) Whether there are manufacturing defects in violation of FDA standards and requirements in the Recalled Devices that cause an increased risk of failure;

(e) Whether Defendants violated FDCA and FDA standards and requirements by knowingly using a defective battery in the Recalled Devices;

(f) Whether Defendants violated FDCA and FDA standards and requirements by failing to properly investigate, and report evidence of premature battery failure and battery defects to the FDA;

(g) Whether Defendants omitted material facts or made false or misleading claims about the safety, quality, longevity, and usefulness of the Recalled Devices in its advertisements, promotional materials, warranties, and other materials;

(h) Whether Plaintiff and the other members of the Nationwide and Alaska Classes have been injured by Defendants' business practices and conduct;

(i) Whether Defendants negligently and/or fraudulently tested, assembled, marketed, supplied, distributed, and/or sold the Recalled Devices in violation of federal requirements;

(j) Whether Defendants' conduct in manufacturing, marketing, and monitoring the Recalled Devices in violation of federal requirements fell below the duty of care owed by Defendants to Plaintiff and the other members of the Nationwide and Alaska Classes;

(k) Whether Defendants engaged in unfair or deceptive acts or practices when they concealed the inherent defective conditions and dangers of the Recalled Devices and when they failed to warn the FDA of same in violation of the Alaska Consumer Protection Act, Alaska Stat. §§ 45.50.471, *et seq.* or the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. §§ 325F.69, *et seq.*;

(l) Whether Defendants were unjustly enriched by the sale of the Recalled Devices at the expense of Plaintiff and the other members of the Nationwide and Alaska Classes;

(m) Whether Defendants are strictly liable for its failure to warn of the risks of the Recalled Devices as well as manufacturing defects in the Recalled Devices;

(n) Whether Defendants breached express and implied warranties;

(o) Whether Plaintiff and the other members of the Nationwide and Alaska Classes are entitled to damages, restitution, restitutionary disgorgement, equitable relief, statutory damages, exemplary damages, and/or other relief; and

(p) The amount and nature of the relief to be awarded to Plaintiff and the other members of the Nationwide and Alaska Classes.

113. **Typicality – Federal Rule of Civil Procedure 23(a)(3).** Plaintiff's claims are typical of the other Nationwide and Alaska Class members' claims because Plaintiff's claims arise from the same practices and course of conduct that give rise to the claims of the other Nationwide and Alaska Class members, namely Defendants' failure to properly investigate the Battery Depletion Defect, and their subsequent failure to take action concerning the Recalled Devices.

114. **Adequacy of Representation – Federal Rule of Civil Procedure 23(a)(4).** Plaintiff is an adequate Class representative because its interests does not conflict with the interests of the other Nationwide and Alaska Class members it seeks to represent. Plaintiff has retained counsel competent and experienced in complex class action litigation, and Plaintiff intends to vigorously prosecute this action. The Nationwide and Alaska Classes' interests will be fairly and adequately protected by Plaintiff and its counsel.

115. **Declaratory and Injunctive Relief – Federal Rule of Civil Procedure 23(b)(2).** Defendants have acted or refused to act on grounds applicable to Plaintiff and the other Nationwide and Alaska Class members, thereby making appropriate final injunctive relief and

declaratory relief, as described below, with concerning the other Nationwide and Alaska Class members as a whole.

116. **Superiority – Federal Rule of Civil Procedure 23(b)(3).** A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The damages or other financial detriment suffered by Plaintiff and the other Nationwide and Alaska Class members are relatively small compared to the burden and expense that would be required to individually litigate their claims against Defendants, so it would be impracticable for the Nationwide and Alaska Class members to individually seek redress for Defendants' wrongful conduct. Even if the Nationwide and Alaska Class members could afford litigation, the court system could not. Individualized litigation creates a potential for inconsistent or contradictory judgments, and increases the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, the economy of scale, and comprehensive supervision by a single court.

## VI. CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF
### Breach of Express Warranty
### (On behalf of Plaintiff, the Nationwide Class, and the Alaska Class)

117. Plaintiff hereby incorporates by reference Paragraphs 1-116, as if fully set forth herein.

118. The FDA's Center for Devices and Radiological Health, which reviews PMA submissions for ICD and CRT-D devices does not evaluate information related to contract liability warranties in the PMA review and approval process. Thus, the contractual warranties fall outside the scope of PMA review and approval. The FDA requires that any such warranty

statements be truthful, accurate, and not misleading, and consistent with applicable federal and state laws.

119. Upon information and belief, through their public statements and descriptions of Recalled Devices, Defendants expressly warranted among other things, that the Recalled Devices were effective and safe for their intended use, and made claims regarding the devices' longevity.

120. When Defendants made these express warranties, they knew the purpose for which the Recalled Devices were to be used, and warranted that these devices were in all respects safe and proper for that purpose.

121. Defendants drafted the documents and/or made statements upon which these warranty claims are based and, in doing so, defined the terms of those warranties.

122. Because Defendants obtained PMA approval to sell the Recalled Devices as Class III devices, Defendants expressly warranted with "reasonable assurance" that the devices were safe and effective for use.

123. Plaintiff and the other Nationwide and Alaska Class members purchased the devices on behalf of their plan participants relying on these express representations and warranties.

124. The Recalled Devices do not conform to Defendants' representations in that these devices contained a defective battery.

125. As such, the Recalled Devices did not conform to Defendants' promises, descriptions, or affirmations of fact, and was not adequately packaged, labeled, promoted, or fit for the ordinary purposes for which such devices are used.

126. As a direct and proximate result of the breach of Defendants' warranties, Plaintiff and the other Nationwide and Alaska Class members have paid for health care costs related to

the Recalled Devices which they have paid and are expected to pay, in an amount to be proven at trial. Plaintiff's and the other Nationwide and Alaska Class members' claims are limited to damages incurred in association with the reimbursement of medical expenses to those plan participants who have not settled personal injury claims with Defendants.

**SECOND CLAIM FOR RELIEF**
**Breach of Implied Warranty**
**(On behalf of Plaintiff, the Nationwide Class, and the Alaska Class)**

127. Plaintiff hereby incorporates by reference Paragraphs 1-116, as if fully set forth herein.

128. At the time Defendants marketed, sold, and distributed the Recalled Devices, Defendants knew of the use for which the product was intended and impliedly warranted the product to be of merchantable quality, safe, fit, and effective for such use.

129. Defendants knew or had reason to know, that Plaintiff and the other Nationwide and Alaska Class members would rely on Defendants' judgment and skill in providing that the Recalled Devices were safe and fit for their intended use.

130. Plaintiff and the other Nationwide and Alaska Class members reasonably relied upon Defendants' skill and judgment as to whether the Recalled Devices were of merchantable quality, safe, fit, and effective for its intended use when Plaintiff and the other Nationwide and Alaska Class members allowed and paid for the implantation of the Recalled Devices into their plan participants.

131. Contrary to such implied warranty, the Recalled Devices, were not of merchantable quality or safe, fit and effective for its intended use, because the product was adulterated and manufactured in violation of federal law and regulations.

132. As a direct and proximate result of the breach of implied warranty, Plaintiff and the other Nationwide and Alaska Class members have incurred health care costs related to the Recalled Devices, which they have paid in an amount to be proven at trial. Plaintiff's and the other Nationwide and Alaska Class members' claims are limited to damages incurred in association with the reimbursement of medical expenses to those plan participants who have not settled personal injury claims with Defendants.

**THIRD CLAIM FOR RELIEF**
**Negligence**
**(On behalf of Plaintiff, the Nationwide Class, and the Alaska Class)**

133. Plaintiff hereby incorporates by reference Paragraphs 1-116, as if fully set forth herein.

134. Defendants designed, manufactured, marketed, detailed, and advertised the Recalled Devices to Plaintiff and the other Nationwide and Alaska Class members, their plan participants, and their physicians.

135. Defendants thus had a duty to perform each of these functions reasonably and with reasonable and due care for the safety and well-being of patients in whom the devices would be implanted and for the entities that would pay for them, including Plaintiff and the other Nationwide and Alaska Class members. Defendants failed to reasonably execute those duties.

136. Defendants failed to use reasonable and due care for the safety and well-being of those in whom the Recalled Devices would be implanted for the entities that would pay for them, including Plaintiff and the other Nationwide and Alaska Class members, and is therefore negligent in the following respects:

a. Defendants failed to manufacture the Recalled Devices to conform with federal laws, regulations, and requirements;

b. Defendants failed to comply with CGMPs;

c. Upon information and belief, Defendants failed to manufacture the Recalled Devices to conform to the requirements in its PMA;

d. Defendants failed to adequately investigate, assess, and report the premature battery failure risks with the Greatbatch Battery, in violation of federal regulations and requirements;

e. Defendants failed to promptly act upon reports of early failure in violation of federal regulations and requirements, such that the Recalled Devices continued to be implanted in unknowing patients by physicians well after physicians should have been notified of the defect, and the devices should have been recalled or sales suspended.

137. The above conduct illustrates Defendants' failure to exercise reasonable and appropriate care. It was foreseeable that such negligence would cause damage to Plaintiff and the other Nationwide and Alaska Class members, which had or will have to pay costs associated with replacing the defective devices.

138. As a direct and proximate result of Defendants' negligence, Plaintiff and the other Nationwide and Alaska Class members have paid for or will pay for health care costs related to the Recalled Devices, which they have paid or are expected to pay in an amount to be proven at trial. Plaintiff's and the other Nationwide and Alaska Class members' claims are limited to damages incurred in association with the reimbursement of medical expenses to those plan participants who have not settled personal injury claims with Defendants.

**FOURTH CLAIM FOR RELIEF**
**Failure to Warn**
**(On behalf of Plaintiff, the Nationwide Class, and the Alaska Class)**

139. Plaintiff hereby incorporates by reference Paragraphs 1-116, as if fully set forth herein.

140. Defendants had a continuing duty to monitor its ICDs and CRT-Ds after premarket approval and to discover and report to the FDA any complaints about the device's performance and any adverse health consequences which it became aware of and that are or may be attributable to its devices.

141. Defendants have a continuing duty to provide ongoing warnings and instructions regarding safety hazards associated with its ICDs and CRT-Ds, which includes obligations under the FCTA and FDA regulations, to investigate and report adverse events and potential device risks to the FDA.

142. Defendants have a continuing duty under federal law and regulations to warn the FDA of new scientific studies concerning the safety of its PMA approved devices, which it reasonably knows or should know exist.

143. Defendants breached their duty by failing to timely and adequately report potential defective battery issues associated with the Recalled Devices to the FDA in violation of federal law.

144. Defendants also breached this duty by failing to conduct adequate risk analyses and investigations required by federal law and regulations regarding any potential safety defects associated with the Recalled Devices.

145. As a result of Defendants' breaches of their duty under federal law, Defendants breached their duty to use reasonable care under state negligence law.

146. Had Defendants timely and properly investigated or analyzed the potential battery defects in its devices and/or had Defendants timely reported adverse events and potential risks associated with a defective battery to the FDA, they would have appeared on the FDA's MAUDE internet database and in medical journals, and the FDA would have investigated the reports and issued Safety Communications and a Class I recall prior to October 10, 2016. As a result, physicians would not have recommended the specific device be implanted in Plaintiff's and the other Nationwide and Alaska Class members' plan participants before October 10, 2016.

147. As a direct and proximate result of Defendants' failure to warn, its defective devices continued to be sold and implanted in Plaintiff's and the other Nationwide and Alaska Class members' plan participants after Defendants knew or should have known that these devices were associated with a serious undisclosed risk and were unsafe for their intended use. As these devices continued unabated, and additional defective devices were implanted in Plaintiff's and the other Nationwide and Alaska Class members' plan participants.

148. As a direct and proximate result of Defendants' failure to warn, Plaintiff's and the other Nationwide and Alaska Class members' plan participants have received related medical treatment and care and costs associated with replacement and implantation of a new ICD or CRT-D device, which could have been avoided had the risk been disclosed earlier. The costs of this additional medical treatment fell primarily on Plaintiff and the other Nationwide and Alaska Class members, who were required to cover their plan participants' treatment costs and device replacement.

149. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other Nationwide and Alaska Class members have been damaged in an amount to be determined at trial.

**FIFTH CLAIM FOR RELIEF**
**Product Liability – Manufacturing Defect**
**(On behalf of Plaintiff, the Nationwide Class, and the Alaska Class)**

150. Plaintiff hereby incorporates by reference Paragraphs 1-116, as if fully set forth herein.

151. Upon information and belief, the Recalled Devices contain a manufacturing defect because the actual manufacture of the Recalled Devices differs from the specifications and requirements set forth in the PMA and the FDA's conditions for approval.

152. Upon information and belief, the Recalled Devices contain a manufacturing defect because the actual manufacture of the Recalled Devices differs from the requirements under the CGMPs, 21 C.F.R. Part 820.

153. This manufacturing defect was present in the Recalled Devices when they left Defendants' control.

154. The Recalled Devices were expected to and did reach Plaintiff's and other Nationwide and Alaska Class members' plan participants without substantial change or adjustment to their mechanical function upon implanting the devices.

155. As a direct and proximate result of this product defect, Plaintiff's and the other Nationwide and Alaska Class members' plan participants have received or will receive related medical treatment and care and costs associated with replacement and installation of a new ICD or CRT-D device. The costs of this additional medical treatment fell primarily on Plaintiff and the other Nationwide and Alaska Class members, who were and will be required to cover the costs of the treatment and device replacement.

156. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other Nationwide and Alaska Class members have been damaged in an amount to be determined at trial.

**SIXTH CLAIM FOR RELIEF**
**Strict Liability – Manufacturing Defect**
**(On behalf of Plaintiff, the Nationwide Class, and the Alaska Class)**

157. Plaintiff hereby incorporates by reference Paragraphs 1-116, as if fully set forth herein.

158. Federal regulations impose standards of conduct on Defendants related to the manufacture, marketing, and sale of its ICD and CRT-D devices. These regulations include a requirement that Defendants comply with all CGMPs, 21 C.F.R. Part 820, and a provision prohibiting Defendants from manufacturing, distributing, or advertising a device that is in any way inconsistent with the conditions of the device's PMA approval, 21 C.F.R. §§ 814.80, 814.82.

159. Plaintiff and the other Nationwide and Alaska Class members are within the class of persons the regulations were designed to protect. Plaintiff's and the other Nationwide and Alaska Class members' damages are a type of harm these regulations are designed to prevent.

160. Upon information and belief, the Recalled Devices contain a manufacturing defect because the actual manufacture of the Recalled Devices differs from the specifications and requirements outlined in the PMA and the conditions for approval, including from the failure to comply with CGMPs under 21 C.F.R. Part 820.

161. This manufacturing defect was present in the Recalled Devices when they left Defendants' control.

162. The Recalled Devices were expected to and did reach Plaintiff's and the Nationwide and Alaska Class members' plan participants without substantial change or adjustment to their mechanical function upon implanting the devices.

163. As a direct and proximate result of this product defect, Plaintiff's and the other Nationwide and Alaska Class members' plan participants have received related medical treatment and care and costs associated with replacement and installation of a new ICD or CRT-D device. The costs of this additional medical treatment fell primarily on Plaintiff and the other Nationwide and Alaska Class members, who were required to cover the costs of the treatment and device replacement.

164. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other Nationwide and Alaska Class members have been damaged in an amount to be determined at trial.

**SEVENTH CLAIM FOR RELIEF**
**Violation of Minnesota Prevention of Consumer Fraud Act - Minn. Stat. §§ 325F.69, 325F.67 & Minn. Stat. § 8.31, subd. 3a (Private Attorney General Statute)**
**(On behalf of Plaintiff and the Nationwide Class)**

165. Plaintiff hereby incorporates by reference Paragraphs 1-116, as if fully set forth herein.

166. Minnesota has significant contacts with each class member by defendant St. Jude Medical's domicile and its activities related to the claims alleged herein. Although later purchased by its parent company Abbott (which is located in Illinois), St. Jude Medical is incorporated, headquartered, and has its principal place of business in Minnesota, where the corporation oversaw and controlled the sale of its products and related FDA and regulatory affairs.

167. Defendants deceptively omitted or misrepresented material information regarding the Battery Depletion Defect and the safety of the Recalled Devices, violating their duty to disclose under federal requirements.

168. If Defendants had not omitted to disclose or misrepresented the defects in the Recalled Devices, physicians would not have used the Recalled Devices, and the Recalled devices would not have been implanted in the Plaintiff's and the other Nationwide Class members' plan participants. Accordingly, Plaintiff and the other Nationwide Class members would not have incurred costs for the Recalled Devices and the medical costs of device removal and replacement surgery and other related medical costs.

169. By reason of the conduct as alleged herein, and by inducing Plaintiff's and the other Nationwide Class members' plan participants, and the plan participants' physicians to use the Recalled Devices, and inducing Plaintiff and the other Nationwide Class members to pay for it, through the use of deception, fraud, false advertising, false pretenses, misrepresentations, omissions, unfair and/or deceptive practices and the concealment and suppression of material facts, including but not limited to fraudulent statements, concealments and misrepresentations identified herein and above in violation of federal laws and regulations, Defendants engaged in unfair or deceptive acts and practices in the conduct of trade or commerce in violation of the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F.69, and Fraudulent Advertising, Minn. Stat. § 325F.67.

170. As a direct and proximate result of Defendants' unlawful conduct, Plaintiff's and the other Nationwide Class members' plan participants were implanted with a Recalled Device, which would not have occurred had Defendants not used unfair and/or deceptive practices and not omitted or concealed its knowledge of the Battery Depletion Defect.

171. But-for Defendants' unfair and/or deceptive practices described above, physicians would not have prescribed the use of a Recalled Device in Plaintiff's and the other Nationwide Class members' plan participants, and Plaintiff and the other Nationwide Class members would not have purchased the Recalled Devices and would not have incurred medical costs related to explanation of the Recalled Devices and replacement with a new device.

172. By reason of such violations, and pursuant to the Minnesota Prevention of Consumer Fraud Act and the Minnesota Private Attorney General Statute, Plaintiff, individually and on behalf of the other Nationwide Class members, is entitled to recover damages, including but not limited to the costs incurred for the Recalled Devices, the cost of their plan participants' medical care arising out of the use of the defective Recalled Devices, and to recover any and all consequential damages recoverable under the law including, but not limited to both past and future medical expenses for which Plaintiff and the other Nationwide Class members will be responsible. Plaintiff, individually and on behalf of the other Nationwide Class members, is entitled to seek compensatory damages, attorney's fees, injunctive and equitable relief, and other remedies as determined by Minnesota law. Plaintiff's and the other Nationwide Class members' claims are limited to damages incurred in association with the reimbursement of medical expenses to those plan participants who have not settled personal injury claims with Defendants.

**EIGHTH CLAIM FOR RELIEF**
**Misrepresentation by Omission**
**(On behalf of Plaintiff, the Nationwide Class, and the Alaska Class)**

173. Plaintiff hereby incorporates by reference Paragraphs 1-116, as if fully set forth herein.

174. Under federal law, a medical device manufacturer has a continuing duty to monitor the device after premarket approval and to discover and report to the FDA any complaints

or potential risks concerning the device's performance, and any adverse health consequences, of which it became aware, and that are or may be, attributable to the product.

175. Defendants had notice as early as 2011, in the form of information submitted to Defendants by its supplier, that the Greatbatch batteries used in its ICD and CRT-D devices were defective and could prematurely deplete as a result of a defect concerning lithium clusters.

176. Between 2011 and 2014, Defendants received 42 product analysis reports indicating that lithium cluster bridging could cause the batteries used in its ICD and CRT-D devices to prematurely deplete. Despite evidence that lithium clusters were the cause of the premature battery depletion, Defendants represented that the cause of the depletion "could not be determined." Defendants violated its continuing duty under federal law to investigate and report evidence that the Greatbatch batteries used in its ICD and CRT-D devices were defective and could prematurely deplete as a result of a defect.

177. Defendants knew or should have known that the Greatbatch batteries used in its ICR and CRT-D devices were defective and could prematurely deplete as a result of a defect, but failed to comply with federal laws and regulations that required Defendants to report this information.

178. Defendants fraudulently, negligently, or recklessly concealed from or failed to disclose to, the FDA the Battery Depletion Defect in violation of the FDCA and federal regulations.

179. Had Defendants timely and reported adverse events and potential risks associated with a defective battery to the FDA, they would have appeared on the FDA's MAUDE internet database and in medical journals, and/or the FDA would have investigated the reports and issued Safety Communications and a Class I recall prior to October 10, 2016. And as a result,

physicians would have ceased recommending the specific device be implanted in Plaintiff's and the other Nationwide and Alaska Class members' plan participants before October 10, 2016.

180. As a direct and proximate result of Defendants' failure to warn, its defective devices continued to be sold and implanted in Plaintiff's and the other Nationwide and Alaska Class members' plan participants after Defendants knew or should have known that these devices were associated with a serious undisclosed risk and were unsafe for their intended use.

181. As a direct and proximate result of Defendants' failure to warn, Plaintiff's and the other Nationwide and Alaska Class members' plan participants have received related medical treatment and care and costs associated with replacement and installation of a new ICD or CRT-D device, which could have been avoided had Defendant properly notified the FDA in accordance with federal regulations and requirements. The costs of this additional medical treatment fell primarily on Plaintiff and the other Nationwide and Alaska Class members, who were required to cover the costs of the treatment and device replacement.

182. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other Nationwide and Alaska Class members have been damaged in an amount to be determined at trial.

**NINTH CLAIM FOR RELIEF**
**Unjust Enrichment**
**(On behalf of Plaintiff, the Nationwide Class, and the Alaska Class)**

183. Plaintiff hereby incorporates by reference Paragraphs 1-116, as if fully set forth herein.

184. This cause of action is alleged in the alternative to Plaintiff's warranty-based claims.

185. To Plaintiff's and the other Nationwide and Alaska Class members' detriment, Defendants have been and continue to be unjustly enriched as a consequence of the wrongful collections of payments from Plaintiff and the other Nationwide and Alaska Class members for the purchase of the Recalled Devices.

186. In exchange for the payments made for Defendants' ICD and CRT-D devices, and at the time they made these payments, Plaintiff and the other Nationwide and Alaska Class members expected that the Defendants' ICD and CRT-D devices were safe, not defective, and medically effective treatment for the condition, disorder, or symptom for which they were prescribed.

187. As an intended and expected result of its conscious wrongdoing as set forth in this Complaint based on its failure to comply with FDCA and federal regulations for the manufacture and reporting of its devices, Defendants have profited and benefited from payments Plaintiff and the other Nationwide and Alaska Class members made for the Recalled Devices with defective batteries.

188. Defendants have voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of its wrongdoing, Plaintiff and the other Nationwide and Alaska Class members paid for Defendants' defective, recalled ICD and CRT-D devices and have been or will be forced to pay for replacement devices when they otherwise would not have done so. Defendants have only offered to reimburse patients for out of pocket medical expenses related to medical treatment incurred as a result of the recall of its defective ICD and CRT-D devices. Defendants' failure to provide Plaintiff and the other Nationwide and Alaska Class members with the remuneration they expected unjustly enriched Defendants.

189. Plaintiff and the other Nationwide and Alaska Class members are entitled in equity to seek restitution of Defendants' wrongful profits, revenues, and benefits to the extent and in the amount deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

190. Accordingly, Plaintiff, individually and on behalf of the other Nationwide and Alaska Class members, seeks full restitution of Defendants' enrichment, profits, revenues, benefits and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

**TENTH CLAIM FOR RELIEF**
**Violation of Alaska Consumer Protection Act - AS §§ 45.50.471, *et seq.***
**(On behalf of Plaintiff and the Alaska Class)**

191. Plaintiff hereby incorporates by reference Paragraphs 1-116, as if fully set forth herein.

192. Defendants deceptively omitted or misrepresented material information regarding the Battery Depletion Defect and the safety of the Recalled Devices, violating their duty to disclose under Federal requirements.

193. Had Defendants disclosed or accurately represented the defects in the Recalled Devices, physicians would not have used the Recalled Devices the Recalled devices would not have been implanted in the Plaintiff's and the other Alaska Class members' plan participants. Accordingly, Plaintiff and the other Alaska Class members would not have incurred costs for the Recalled Devices and the medical costs of device removal and replacement surgery and other related medical costs.

194. By reason of Defendants' conduct alleged herein, and by inducing Plaintiff's and the other Alaska Class members' plan participants, and the plan participants' physicians to use

the Recalled Devices, and inducing Plaintiff and the other Alaska Class members to pay for them, through the use of deception, fraud, false advertising, false pretenses, misrepresentations, omissions, unfair and/or deceptive practices and the concealment and suppression of material facts, including but not limited to fraudulent statements, concealments and misrepresentations identified herein and above in violation of federal laws and regulations, Defendants engaged in unfair or deceptive acts and practices in the conduct of trade or commerce in violation of the Alaska Consumer Protection Act, Alaska Stat. §§ 45.50.471, *et seq.*

195. As a direct and proximate result of Defendants' unlawful conduct, Plaintiff's and the other Alaska Class members' plan participants were implanted with a Recalled Device, which would not have occurred had Defendants not used unfair and/or deceptive practices and not omitted or concealed its knowledge of the Battery Depletion Defect.

196. But-for Defendants' unfair and/or deceptive practices described above, Plaintiff and the other Alaska Class members would not have purchased the Recalled Devices and would not have incurred medical costs related to replacement of the Recalled Devices.

197. But-for Defendants' unlawful conduct described above, Plaintiff and the other Alaska Class members would not have purchased and/or paid for the Recalled Devices, and would not have incurred medical costs related to replacement of the Recalled Devices.

198. By reason of such violations, and pursuant to the Alaska Consumer Protection Act, Plaintiff and the other Alaska Class members are entitled to recover damages, including but not limited to the cost of the Recalled Devices, the cost of their plan participants' medical care arising out of the use of the devices, and to recover any and all consequential damages recoverable under the law including, but not limited to both past and future medical expenses for which Plaintiff and the other Alaska Class members will be responsible. Plaintiff, individually

and on behalf of the other Alaska Class members, is entitled to seek compensatory damages, attorney's fees, injunctive and equitable relief, and other remedies as determined by Alaska law. Plaintiff's and the other Alaska Class members' claims are limited to damages incurred in association with the reimbursement of medical expenses to those plan participants who have not settled personal injury claims with Defendants.

## VII. REQUEST FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the other members of the Nationwide and Alaska Classes, respectfully requests that this Court enter judgment in its favor and against Defendants Abbott Laboratories and St. Jude Medical, Inc., as follows:

A. Declaring that this action is a proper class action, certifying the Nationwide and Alaska Classes as requested herein, designating Plaintiff as Nationwide and Alaska Class Representative, and appointing Plaintiff's attorneys as Class Counsel;

B. Enjoining Defendants from continuing the unfair business practices alleged in this Complaint;

C. Ordering Defendants to pay actual and statutory damages (including punitive damages) and restitution to Plaintiff and the other Nationwide and Alaska Class members, as allowable by law;

D. Ordering Defendants to pay the costs of medical monitoring, whether denominated as damages or in the form of equitable relief;

E. Ordering Defendants to pay both pre- and post-judgment interest on any amounts awarded;

F. Ordering Defendants to pay attorneys' fees and costs of suit; and

G. Ordering such other and further relief as may be just and proper.

## VIII. JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff, individually and on behalf of the other Nationwide and Alaska Class members, demands a trial by jury for all issues so triable.

Dated: September 18, 2017

By: /s/ Adam J. Levitt

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***Counsel for Plaintiff and the Proposed Nationwide and Alaska Classes***

* *Pro hac vice* motion to be filed