UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

HUMANA INC., Plaintiff, v. ST. JUDE MEDICAL, LLC; and ABBOTT LABORATORIES, Defendants.	Case No.

COMPLAINT

Plaintiff Humana Inc. sues defendants St. Jude Medical, LLC ("St. Jude") and Abbott Laboratories ("Abbott") as follows:

1. For over four years, St. Jude Medical, Inc. (defendants' predecessor-in-interest) marketed pacemakers and other cardiac devices that it knew to be defective. Finally, in 2015, St. Jude issued a recall and acknowledged its primary responsibility for those defective devices. Thereafter, St. Jude and its corporate parent, Abbott, devised a scheme to stick Humana and other secondary payers with the costs of surgically removing and replacing the defective devices that had been implanted in the chests of their insureds. Humana brings this suit to recover the costs it incurred as a result of defendants' wrongdoing.

Introduction

2. From 2011 through 2015, St. Jude Medical, Inc. suppressed evidence that its cardiac-defibrillator devices had defective batteries which had the potential to deplete prematurely. Defective defibrillator batteries pose substantial risks to patients with heart-pacing conditions. Despite that risk, St. Jude Medical, Inc. ignored the problem.

3. St. Jude Medical, Inc. was forced to reassess the matter only during negotiations

for a business combination with defendant Abbott that would ultimately convert the company to defendant St. Jude Medical, LLC, an Abbott subsidiary. Defendants then revealed the matter to the FDA, which after a ten-day inspection directed a nationwide recall of the devices. St. Jude's four-year delay in reporting and recalling the defective devices led to thousands of defective devices being implanted in patients, including Humana insureds, at great expense.

4. Defendants' faulty devices and delayed reporting of those faults not only put these patients at grave risk from the faulty devices themselves, but it also caused a substantial number of those patients to require defective or at-risk devices to be surgically removed from their chests. That surgery alone costs tens of thousands of dollars, but it also came with the risk of further health complications and attendant costs.

5. After the recall of their defective devices, defendants offered to compensate patients for the cost of a replacement device and their out-of-pocket medical expenses (up to $2,500). But they then secretly stuck Humana and other secondary payers with the remainder of the bill, which in most cases totaled tens of thousands of dollars. Generally, where patients are injured through the bad acts of another, they sue to recover damages. But because Humana's insureds had their out-of-pocket costs covered by defendants, those patients were not incented to make a claim against defendants. These side payments effectively deprived Humana of its right to assert its own claims against defendants as the party that was primarily responsible for the medical costs associated with the recalled devices.

6. By making these payments to Humana insureds, defendants have demonstrated their responsibility for the costs arising from the defective devices and qualify as a "primary plan." That is the statutory term of art under the MSP Act for self-insured entities that reimburse Medicare enrollees for costs that a Medicare Advantage Organization ("MAO" or "MA organization") such

as Humana has already paid on a conditional basis. In the ordinary insurance context, the insurer generally has a right of subrogation, entitling the insurer to recover monies it expended on the insured's behalf when a third party is primarily responsible for those expenditures. The MSP Act codifies several avenues for similar rights of recovery by Medicare or MAOs to recover expenditures that they made on behalf of their insureds for which third parties are ultimately responsible.

7. To protect the pockets of the taxpayer—who ultimately foots all Medicare bills—the MSP Act shifts the burden to reimburse Medicare or MAOs to the "primary plan" (i.e., the responsible third-party) or risk the imposition of double damages if legal action is required to recover those expenditures.

8. Humana was never notified by St. Jude or Abbott of the recall-related payments by defendants to Humana's insureds. On the contrary, defendants engineered the payment to Humana members and directed medical providers in such a way as to completely subvert Humana's ability to even know about, let alone recover, its costs under the normal means of recovery for secondary payers.

9. By this suit, Humana seeks damages for defendants' failure to abide by the MSP Act's requirements, for common law relief, and for declaratory relief and an injunction going forward to require that defendants bear the entirety of medical costs arising out of their defective medical devices.

Parties

10. Humana Inc. is a Delaware corporation with its principal place of business at 500 West Main Street, Louisville, Kentucky. The following subsidiaries of Humana Inc. provide medical coverage in various states and regions throughout all 50 States and Puerto Rico: Arcadian Health Plan, Inc.; CarePlus Health Plans, Inc.; Cariten Health Plan, Inc.; Cariten Insurance

Company; CHA HMO, Inc.; CompBenefits Insurance Company; Emphesys Insurance Company; Health Value Management, Inc. d/b/a ChoiceCare Network; Humana Behavioral Health, Inc.; HumanaDental, Inc.; Humana Benefit Plan of Illinois, Inc.; Humana Employers Health Plan of Georgia, Inc.; Humana Health Benefit Plan of Louisiana, Inc.; Humana Health Company of New York, Inc.; Humana Health Insurance Company of Florida, Inc.; Humana Health Plan of California, Inc.; Humana Health Plan of Ohio, Inc.; Humana Health Plan of Texas, Inc.; Humana Health Plan, Inc.; Humana Health Plans of Puerto Rico, Inc.; Humana Insurance Company; Humana Insurance Company of Kentucky; Humana Insurance Company of New York; Humana Medical Plan of Michigan, Inc.; Humana Insurance of Puerto Rico, Inc.; Humana Medical Plan of Pennsylvania, Inc.; Humana Medical Plan of Utah, Inc.; Humana Medical Plan, Inc.; Humana Pharmacy Solutions, Inc.; Humana Regional Health Plan, Inc.; and Humana Wisconsin Health Organization Insurance Corporation (collectively, the "Operating Subsidiaries"). The Operating Subsidiaries have assigned the claims asserted here to plaintiff. Humana Inc. and the Operating Subsidiaries are referred to collectively as "Humana."

11. St. Jude Medical, Inc. was a corporation organized and existing under the laws of the State of Minnesota. St. Jude Medical, Inc. did business throughout the world and throughout the United States, including in the State of Florida.

12. Defendant Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Abbott does business throughout the world and throughout the United States, including in the State of Florida.

13. Abbott completed its acquisition of St. Jude Medical, Inc. through two mergers. First, Vault Merger Sub, Inc., a wholly owned subsidiary of Abbott, was merged with and into St. Jude Medical, Inc., with St. Jude Medical, Inc. surviving the merger. Second, St. Jude Medical,

Inc. was merged with and into Vault Merger Sub, LLC, with Vault Merger Sub, LLC surviving the merger. Following completion of the second merger, Vault Merger Sub, LLC was renamed St. Jude Medical, LLC.

14. Pursuant to the terms and effect of the Agreement and Plan of Merger, dated April 27, 2016, executed by and among Abbott Laboratories, St. Jude Medical, Inc., and two wholly owned subsidiaries of Abbott named Vault Merger Sub, Inc. and Vault Merger Sub, LLC, St. Jude Medical, LLC is liable as the successor in interest to St. Jude Medical, Inc., and is responsible for the conduct of St. Jude Medical, Inc. as its predecessor in interest.

15. Defendant St. Jude Medical, LLC is a limited-liability corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Saint Paul, Minnesota, where it purports to operate its global headquarters. St. Jude does business throughout the world and throughout the United States, including in the State of Florida.

16. Abbott is St. Jude's parent corporation. Upon information and belief, Abbott is the successor in interest to all of the debts and obligations of St. Jude Medical, Inc., to the extent that those were not assumed by St. Jude, either as de facto successor or as alter ego.

17. Successor. Upon information and belief, Abbott is a de facto successor to St. Jude Medical, Inc. as Abbott is engaged in a substantial continuation of St. Jude Medical, Inc.'s business. There is a continuity of the business enterprise between St. Jude Medical, Inc. and Abbott, including the continuity of management, employees, business location, and assets. There is a continuity of shareholders between Abbott and St. Jude Medical, Inc., as St. Jude Medical, Inc. shareholders became Abbott shareholders at the completion of Abbott's acquisition of St. Jude Medical, Inc. Additionally, St. Jude Medical, Inc. has ceased all operations. Upon information and belief, Abbott has assumed those liabilities and obligations necessary for the uninterrupted

continuation of St. Jude Medical, Inc.'s business operations, including the manufacture, sale, and distribution of ICD and CRT-D devices and communications with the FDA regarding those devices.

18. Alter Ego. Since completion of the Mergers on January 4, 2017, St. Jude has operated and continues to operate as a mere alter ego and instrumentality of Abbott. Abbott exercised and continues to exercise complete dominion and control over its wholly-owned subsidiary St. Jude. Because of the manner in which St. Jude and Abbott operate as a single, unified enterprise, the distinction between St. Jude must be disregarded and Abbott held liable for the acts complained of here. In addition, upon information and belief, between execution of the Merger Agreement and completion of the Mergers, Abbott exercised dominion and control over St. Jude's predecessor in interest, St. Jude Medical, Inc., in its device recall efforts, and operated as a mere alter ego and instrumentality with respect to decisions affecting the recall efforts such that, for these reasons, corporate separateness must be disregarded.

19. It would be offensive to the interests of justice to allow Abbott, who, upon information and belief, played a role in directing the investigation and recall of St. Jude Medical, Inc.'s defective ICD and CRT-D devices, and who has acted for and controlled St. Jude with respect to the management of its defective ICD and CRT-D device recall efforts and interactions with the FDA, to shift all liability to St. Jude Medical, LLC.

20. The unity between Abbott and St. Jude is evidenced by several facts. For example:

a. St. Jude's and Abbott's websites both state that "St. Jude Medical is now Abbott."

b. Upon information and belief, Abbott and St. Jude Medical, LLC share substantially identical officers, management, business operations, and facilities.

c. Upon completion of the merger, several of St. Jude Medical's executives became

employees and executives of Abbott, including Michael Rousseau. Mr. Rousseau, formerly St. Jude Medical's CEO, became the President of the Cardiovascular & Neuromodulation Division of Abbott.

d. Upon information and belief, Abbott and/or Abbott's Cardiovascular & Neuromodulation Division, which operates out of the Sylmar, California facility, exercises control over St. Jude Medical, LLC's operations in all meaningful ways.

e. Abbott acted and has continued to act as the sole voice for "St. Jude Medical" with the FDA, and exercised complete dominion and control over St. Jude Medical, LLC in directing its response to FDA investigations into St. Jude Medical, Inc.'s actions with respect to the recalled devices.

f. Abbott has also publicly assumed control over the recall. For example, an August 29, 2017 Reuters article entitled *Abbott Releases New Round of Cyber Updates for St. Jude Pacemakers* quotes Abbott spokesperson Candace Steele Flippin as saying "Abbott is resolving all old St. Jude Medical issues." That same month, Abbott announced on Abbott letterhead that it was releasing the Abbott Battery Performance Alert Update, which referred to the battery performance of the St. Jude devices. In the Patient's Guide to the Abbott Battery Performance Alert Update, Abbott stated: "In October 2016, Abbott notified physicians and patients that a subset of ICDs and cardiac resynchronization therapy defibrillator (CRT-D) devices manufactured between January 2010 and May 2015 could potentially experience premature battery depletion." This Patient's Guide directs those with further questions about the Battery Performance Alert to "please contact our dedicated hotline . . . or visit our website at sjm.com/batteryupdate."

21. Upon information and belief, at all times herein mentioned, defendants' employees, subsidiaries, affiliates, and other related entities, as well as the employees of each of defendants' 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 defendants, such designation 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.

Jurisdiction and Venue

22. This Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1331, in that this is a civil action arising under the Medicare Secondary Payer Act, 42 U.S.C. § 1395y(b).

23. This Court has diversity subject-matter jurisdiction over this action under 28 U.S.C. § 1332(a) because Humana is completely diverse from defendants and the amount in controversy on Humana's claims exceeds $75,000, exclusive of costs.

24. This Court has personal jurisdiction over defendants because they systematically and continually conduct business throughout the State of Florida, including marketing, advertising, and selling medical devices.

25. Venue is proper in this Court (1) under 28 U.S.C. § 1391(c) because defendants do business in, and thus resides in, this judicial district; and/or (2) under 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to this action occurred in this judicial district.

26. Humana has more than 650,000 Medicare Advantage insureds in the state of Florida and insures nearly 1.4 million Floridians in total. Humana's operating subsidiary in Florida, Humana Health Insurance Company of Florida, is located at 3501 Southwest 160th Avenue,

Miramar, Florida 33027, in this District. Furthermore, the Humana members discussed below as Patient 1 and Patient 4 had defective St. Jude devices replaced at Westside Regional Medical Center in Plantation, Florida, in this District.

Legal Background

27. Title XVIII of the Social Security Act ("Medicare Act") creates the Medicare Program. 42 U.S.C. § 1395, *et seq.* Medicare is a system of federally funded health insurance for people 65 and older, certain disabled persons, and persons with end-stage renal disease.

28. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS"), acting under authority delegated by the Secretary of the U.S. Department of Health and Human Services ("HHS").

29. Part A of the Medicare Act, 42 U.S.C. § 1395c, *et seq.*, provides insurance for costs of inpatient hospital services and certain other services. Part A is available without payment of premiums to most persons who paid Medicare payroll taxes before becoming Medicare-eligible. Part A generally pays 100% of the cost of covered services after deductibles and coinsurance, up to Medicare coverage limits. Private contractors, mainly insurance companies, administer Part A benefits under contracts with CMS. Those contractors were formerly known as Fiscal Intermediaries and are now known as Medicare Administrative Contractors.

30. Part B of the Medicare Act, 42 U.S.C. § 1395j, *et seq.*, is a voluntary program in which the beneficiary pays premiums to Medicare, and in return Medicare pays the costs of his or her medically necessary outpatient services, such as doctors' office visits and home health care. Generally, Part B covers 80% of the cost of such services after exhaustion of deductibles. Private contractors, mainly insurance companies, administer Part B benefits under contracts with CMS. Those contractors were formerly known as Carriers and are now also known as Medicare Administrative Contractors.

31. With the exception of certain persons with end-stage renal disease, each individual eligible for Medicare is entitled to elect to receive benefits under the Medicare program through the original Medicare program under Parts A and B, or through enrollment in a Medicare Advantage plan under Medicare Part C. In the Medicare Part C or Medicare Advantage program, private contractors, mainly health-maintenance organizations and insurance companies, administer Medicare benefits under contracts with CMS. Those contractors were formerly known as Medicare + Choice organizations and are now also known as Medicare Advantage Organizations, or MAOs. *See* 42 U.S.C. § 1395w-21(a)(1).

32. No matter which option beneficiaries choose, Medicare Parts A and B or Medicare Part C, the benefits provided are Medicare benefits, governed by Title XVIII and the Medicare regulations promulgated thereunder by CMS. Medicare pharmacy benefits are available through Medicare Part D.

33. To qualify to become a Medicare Advantage plan, a MAO must meet strict qualifying standards and contract with CMS to provide Medicare benefits to those Medicare beneficiaries who elect to enroll in their plans. Medicare Advantage plans must provide all Medicare benefits offered under Parts A and B. They generally also provide additional or "supplemental" benefits. *See* 42 U.S.C. §§ 1395w-21–1395w-29.

34. CMS funds MAOs and delegates to them the obligation to administer, pay, and assume Medicare's economic risk for the Medicare benefits provided to Part C enrollees, all pursuant to the requirements of Title XVIII and CMS Medicare regulations.

35. The funds for Medicare Advantage benefits come from the Medicare Trust Funds. *See* 42 U.S.C. § 1395w-23(f).

36. When Medicare Advantage plans recover reimbursement from primary plans or

other liable parties pursuant to the MSP Act, those recoveries help reduce Medicare expenditures by the Medicare Trust Funds. Thus, recoveries by MAOs fulfill the essential purpose of the MSP Act: shifting expense from the Medicare program to primary payers.

37. Currently, there are over 20 million people (about 34% of all Medicare beneficiaries) enrolled in the thousands of Medicare Advantage plans offered nationally by more than 400 MAOs. Humana is a MAO and offers Medicare Advantage plans to over 3.5 million members, including more than 650,000 in the state of Florida.

38. From its inception through 1980, Medicare generally paid for medical services regardless of whether the recipient was also covered by another health-insurance plan.

39. In response to skyrocketing costs in 1980, Congress began enacting the statutes that now comprise the MSP Act, 42 U.S.C. § 1935y(b). By its terms, the MSP Act applies to payments under Title XVIII of the Social Security Act, i.e., to the whole Medicare program.

40. The MSP Act provides that when Medicare pays for treatment of an enrollee, and there is also a "primary plan," Medicare's payment is a conditional plan. The primary plan, and any entity that receives payment from a primary plan, must reimburse Medicare for the payment it made. 42 U.S.C. § 1395y(b)(2).

41. The MSP Act defines a "primary plan" to include a "self-insured plan." 42 U.S.C. § 1395y(b)(2)(A)(ii). The Act further states: "An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part." *Id.*

42. By regulation, a Medicare beneficiary who receives payment from a primary payer is required to reimburse Medicare within sixty days, or else "the primary payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party." 42 C.F.R.

§ 411.24(h).

43. A primary plan's responsibility for such payment "may be demonstrated by . . . a payment conditioned upon the receipt's compromise, waiver, or release (whether or not there is a determination of admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means." 42 U.S.C. § 1395y(b)(2)(B)(ii); *see also* 42 C.F.R. § 411.22(b).

44. In the event that a primary plan fails to reimburse Medicare for its conditional payments made in the secondary position, the MSP Act authorizes a private cause of action to recover double damages from the primary plan. 42 U.S.C. § 1395y(b)(3)(A). This includes a statutory right of subrogation. 42 U.S.C. § 1395y(b)(2)(B).

45. Humana, as a Medicare secondary payer, has standing under 42 U.S.C. § 1395y(b)(3) to bring this private cause of action to recover damages from St. Jude, as the primary payer, because Humana made conditional payments on behalf of its Medicare Advantage enrollees for which St. Jude was primarily liable and for which it did not reimburse Humana.

Factual Background

St. Jude's Cardiac Devices

46. St. Jude Medical, Inc. manufactured a variety of medical devices designed to treat cardiac conditions, including Implantable Cardiac Defibrillator ("ICD") and Cardiac Resynchronization Therapy Defibrillator ("CRT-D") devices. ICD and CRT-D devices provide pacing therapy to support slow heart rhythms, and electrical-shock or pacing therapy to treat fast heart rhythms.

47. An ICD is a small device that is surgically placed into 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.

48. 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. The device then emits tiny pulses of electricity to correct any irregularities.

49. St. Jude Medical, Inc. received approval from the Food and Drug Administration ("FDA") to manufacture, market, and sell several models of ICDs and CRT-Ds. These models of St. Jude Medical, Inc.'s ICDs and CRT-Ds are powered by lithium-based batteries.

50. If the battery unexpectedly runs out on one of the recalled devices due to the defect, the device becomes unable to deliver life-saving pacing or shocks, which could lead to serious health consequences, including death.

St. Jude Learns of a Battery Defect

51. As early as 2011, St. Jude Medical, Inc. received evidence from its battery supplier that a phenomenon known as "lithium cluster bridging" was causing its device batteries to deplete prematurely.

52. Between 2011 and 2014, St. Jude Medical, Inc. reviewed forty-two product reports showing evidence of premature battery depletion due to lithium cluster bridging.

53. By 2014, St. Jude Medical, Inc. had received notice that premature battery depletion of one of its ICDs caused at least one patient's death, and that this device had lithium cluster bridging.

54. In December 2014, a study published in the journal *HeartRhythm* reported cases of battery failure in St. Jude Medical, Inc.'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.

55. On information and belief, St. Jude Medical, Inc. did not advise the FDA, medical

providers, the public, or individuals using their devices of the battery depletion problem from 2011 through 2015. To this point, and despite the evidence of its product reports, St. Jude Medical, Inc. had concluded that the root cause of the battery depletion issue "could not be determined" and that the explanation of lithium cluster bridging was repeatedly "unconfirmed."

56. In late 2015 and continuing through early 2016, Abbott and St. Jude Medical, Inc. conducted discussions about a potential business combination. To that end, Abbott conducted a due diligence review of St. Jude Medical, Inc.

57. In April 2016, after the review, St. Jude Medical, Inc. opened new investigations into the premature battery depletion issue.

58. In August 2016, after this review, St. Jude Medical, Inc. decided to commence a field action to recall the defective devices.

The FDA Issues a Recall, Investigates Defendants, and Determines That Defendants Violated Federal Requirements

59. On October 10, 2016, the FDA issued a Class I recall of certain models of St. Jude Medical, Inc.'s ICDs and CRT-Ds due to a battery defect, which can cause the batteries in those devices to deplete suddenly and prematurely.

60. 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).

61. In particular, the FDA issued a Class I recall of the following devices sold in the United States that St. Jude Medical, Inc. manufactured:

- 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
- Quadra Assura MP: Model No(s). CD3269-40, CD3269-40Q, CD3369-40C

62. The recall implicated hundreds of thousands of devices in St. Jude Medical, Inc.'s ICD and CRT-D lines, including 251,346 devices sold in the United States alone and 398,740 devices sold worldwide.

63. In February 2017, FDA investigators inspected Abbott's facility in Sylmar, California, which formerly belonged to St. Jude Medical, Cardiac Rhythm Management Division. The FDA inspection revealed that St. Jude Medical, Inc. knew of the battery depletion defect as far back as 2011, but failed to report health risks posed by the device, failed to follow reporting requirements, failed to adequately control products that did not conform to specifications, and failed to follow corrective and preventive action procedures ("CAPA"). The FDA detailed these deficiencies and violations in two documents: a Form FDA 483 report directed to St. Jude Medical, Inc., and a Warning Letter directed to Abbott.

64. As a result of its investigation, the FDA concluded that St. Jude Medical, Inc.:

a. Failed to establish and maintain procedures for implementing corrective and preventative actions, as required by 21 C.F.R. § 820.100(a);

b. 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 be based on three factors: severity, probability, and detectability;

c. Violated—and its successor continued to be in violation of—the required Quality Management Review SOP (standard operating procedure);

d. Released ten recalled ICDs from its distribution centers after the October 2016 recall had been issued, resulting in the implantation of seven additional recalled ICDs into U.S. patients; and

e. 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."

65. Consequently, the FDA issued a Form FDA 483 Report to St. Jude Medical, Inc. According to the FDA, a Form 483 is issued to firm management after an inspection when investigators have observed conditions that in their judgment may constitute violations of the Food Drug and Cosmetic Act and related acts, including indications that a device has been adulterated or is being prepared, packed, or held under conditions that may cause it to become adulterated or injurious to health. Among other things, the FDA observed that "[a] correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA."

66. The FDA sent the Form FDA 483 to St. Jude Medical, Inc.'s attention, but a response was sent by Abbott by letter dated March 13, 2017, on Abbott letterhead. This letter was

signed by Vishnu Charan, VP of Operations for Abbott, and Nalin Perera, Sr. Director of Operations Quality for Abbott. Mr. Charan and Ms. Perera were formerly executives of St. Jude Medical, Inc. but then worked for Abbott, holding substantially the same titles. In that letter, Abbott answered on behalf of "St. Jude Medical" but stated its (Abbott's) efforts to continue investigating and correcting the deficiencies cited by the FDA.

67. 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 and requesting remedial action from Abbott. The letter indicated that the recalled devices were adulterated and that St. Jude's general violations included:

a. "Failure to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a)";

b. "Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a)";

c. "Failure to ensure that design verification shall confirm that the design output meets the design input requirements, as required by 21 CFR 820.30(f)"; and

d. "Failure to ensure that design validation shall include risk analysis, where appropriate, as required by 21 CFR 820.30(g)."

68. The Warning Letter details these violations in five pages of single-spaced text.

Defendants Demonstrate Responsibility for the Recalled Devices

69. As part of the recall, defendants posted information to patients with affected ICDs or CRT-Ds on their website. They advised that they would provide replacement devices at no cost to affected patients and would cover up to $2,500 in unreimbursed medical expenses related to the replacement procedure. They also offered to provide payments to U.S. patients for one-time office visits needed to address concerns related to the defect and recall, covering only unreimbursed

medical expenses incurred by the patient such as out-of-pocket expenses and co-pays.

70. On information and belief, there are at least dozens—and potentially hundreds or thousands—of affected patients who took advantage of the recall who were Medicare-enrollee beneficiaries covered under Humana's Medicare Advantage plans.

71. On information and belief, the medical costs relating to the replacement procedures were submitted by hospitals and other medical providers to Humana for reimbursement. Humana was not made aware that the medical costs were incurred for medical procedures related to the recalled devices. In addition, there is no practical way for Humana to determine whether the medical procedure to replace a defibrillator device involves one of defendants' recalled devices. Humana attempted to obtain this information from defendants but has been unable to do so without filing suit.

72. Nevertheless, Humana is aware of several instances of this conduct; on information and belief, there are many more (numbering perhaps in the hundreds or thousands).

73. The first example involved a patient who for privacy reasons is here called "Patient 1." Patient 1 is a Humana MA member who received her original St. Jude device in 2007 or 2008, which was replaced in approximately 2013. After her doctor at Broward Arrhythmia Physicians ("BAP") in Lauderdale Lakes, Florida mentioned a "malfunction" and recall, Patient 1 received a replacement device at Westside Regional Medical Center ("Westside") in Plantation, Florida in 2016. Contrary to her prior experience, Patient 1 did not receive any invoices for the replacement service; to the extent she paid anything, she was reimbursed for it. BAP and Westside submitted claims to Humana for reimbursement for the extraction procedure and associated medical costs in the amount of approximately $23,366, which Humana paid shortly after submission. The submissions were not coded to indicate that the procedures arose from a recall. For example, the

main diagnosis was given as "Other specified complication of cardiac prosthetic devices, implants and grafts, initial encounter," while the primary associated procedure was indicated as "Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; dual lead system." These descriptions do not identify St. Jude as the manufacturer of the device nor do they specify that the device was the subject of defendants' recall.

74. The second example involved a patient who for privacy reasons is here called "Patient 2." Patient 2 is a Humana MA member who received his original St. Jude device in 2006 or 2007, which was replaced in 2013 or 2014 before that one was replaced in approximately 2017 at Manatee Memorial Hospital in Bradenton, Florida. It was actually replaced twice in 2017: the first time was due to the recall and the second time, several months later, was due to something being wrong with the replacement device. Other local providers who provided medical services or equipment included Lakewood Ranch Anesthesia PL, Blue Radiology Services LLC, and Nova Medical Equipment, Inc. Patient 2 was notified that St. Jude would repay $2,500 to the company that his policy was through. His out-of-pocket expense was in the $250-$350 range for his two replacement procedures in 2017. The providers submitted claims to Humana for reimbursement for the extraction procedure and associated medical costs in the total amount of approximately $33,375, which Humana paid shortly after submission. The submissions were not coded to indicate that the procedures arose from a recall. For example, the main diagnosis was given as "Paroxysmal Atrial Fibrillation," while the primary associated procedure was indicated as "Cardioverter-defibrillator, other than single or dual chamber (implantable)." These descriptions do not identify St. Jude as the manufacturer of the device nor do they specify that the device was the subject of defendants' recall.

75. The third example involved a patient who for privacy reasons is here called "Patient

3." Patient 3 is a Humana MA member who received his original St. Jude device in 2012. It was replaced in 2017 at Lakeland Regional Medical Center in Lakeland, Florida by a device not manufactured by defendants. Patient 3 had received notice of the recall from his doctor at Watson Clinic (also in Lakeland) by letter in 2016, and thereafter he started having trouble with the device. Patient 3 got a staph infection as a result of the replacement procedure and he again had to go through an explant procedure to remove the cardiac device. Patient 3 was on an external device for a time until a second device (also not manufactured by defendants) was implanted later in 2017. Patient 3 was advised that because of the recall, St. Jude would pay his costs. St. Jude did not in fact cover certain of Patient 3's out-of-pocket costs. Twenty-two separate providers submitted claims to Humana for reimbursement for the extraction procedure and associated medical costs in the in the total amount of approximately $119,964, which Humana paid shortly after submission. (Lakeland Regional Medical Center submitted approximately $109,100 in claims, accounting for over 90% of the amount submitted from all providers.) The submissions were not coded to indicate that the procedures arose from a recall. For example, the main diagnosis was given as "Ventricular Tachycardia," while the primary associated procedure was indicated as "Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; multiple lead system." These descriptions do not identify St. Jude as the manufacturer of the device nor do they specify that the device was the subject of defendants' recall.

76. The fourth example involved a patient who for privacy reasons is here called "Patient 4." Patient 4 is a Humana member who received her original St. Jude device in 2013. She was advised of the recall by her doctor at BAP, who recommended that it be replaced. She was given a replacement device at Westside in 2016. The providers submitted claims to Humana for reimbursement for the extraction procedure and associated medical costs in the total amount of

approximately $36,225, which Humana paid shortly after submission. The submissions were not coded to indicate that the procedures arose from a recall. For example, the main diagnosis was given as "Encounter for Adjustment and Management of Automatic Implantable Cardiac Defibrillator," while the primary associated procedure was indicated as "Removal of Pacing Cardioverter-Defibrillator Pulse Generator with Replacement of Pacing Cardioverter-Defibrillator Pulse Generator; Multiple Lead System." These descriptions do not identify St. Jude as the manufacturer of the device nor do they specify that the device was the subject of defendants' recall. Patient 4 had no direct communications with defendants, only with her doctor, who advised her to the effect that "the manufacturer will pay most of it and it will happen behind the scenes, [you] won't even know it happened."

77. On information and belief, defendants encouraged or actively misled the foregoing providers to invoice the procedure that way so as to avoid their own liability for payment and to shift these costs to MAOs such as Humana instead. This is evidenced by the fact that the providers' invoices were coded in a way that obscured that these procedures were to replace defendants' recalled devices. Furthermore, by providing the replacement device at no cost and covering the patients' out-of-pocket costs, defendants intended (a) to remove any incentive for the patient to notify MAOs such as Humana of the fact that the costs arose from the recall; and (b) to have the providers present incomplete or misleading information that would induce Humana to reimburse the providers, and thereby obtain the benefit of not reimbursing the providers themselves.

78. Humana relied on this false, misleading, excluded, or incomplete information when reimbursing the providers. Humana paid the invoices for the foregoing providers because it lacked knowledge of the material fact that the procedures were for the purpose of replacing defective devices. If Humana had known all of the material facts, it would have rejected the provider

invoices, sought reimbursement from defendants, or taken some other measure to avoid paying the medical costs arising from the replacement of the recalled devices.

79. Defendants have demonstrated responsibility to make payment for the costs associated with the defect and recall pursuant to 42 U.S.C. § 1395y(b)(2)(B)(ii) by offering replacement devices free of charge and offering up to $2,500 for patients' medical expenses.

80. Defendants have removed the incentive for patients to sue defendants or otherwise assert a claim for expenses associated with the defect and recall. But for defendants' offer to pay their out-of-pocket costs, patients would be financially incentivized to sue to recover their costs arising from the defect and recall. Defendants have thereby circumvented the normal process that would allow for Humana's recovery as a secondary payer.

81. In the alternative, even in the unlikely event that defendants lacked knowledge of other coverage, that would not change the status of Humana's payments as conditional payments or relieve defendants of the obligation to make primary payment. 43 C.F.R. § 411.21 ("Conditional payment means a Medicare payment for services for which another payer is responsible, made either on the bases set forth in subparts C through H of this part, or because the intermediary or carrier did not know that the other coverage existed.").

82. Humana has not received any reimbursement to date for the conditional payments it made on behalf of its Medicare Advantage members in connection with medical costs arising from the recall of defendants' defective products.

Count I

Medicare Secondary Payer – Private Cause of Action
42 U.S.C. § 1395y(b)(3)(A)

83. Humana incorporates by reference the allegations of paragraphs 1 through 82 of the complaint as if fully set forth in this paragraph.

84. Congress has explicitly created a private right of action under the MSP Act where primary payment has not been made. 42 U.S.C. § 1395y(b)(3)(A) states: "There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement)" in accordance with the MSP Act.

85. Humana is a secondary payer under the MSP Act.

86. Defendants are individually or jointly a primary plan under the MSP Act.

87. Defendants were required to, but did not, make appropriate reimbursement to Humana in accordance with the MSP Act and MSP regulations for all costs in connection with, arising out of, or in any way related to the recalled ICD and CRT-D devices manufactured by St. Jude Medical, Inc.

88. Humana paid conditional payments for those costs in an amount exceeding $75,000 and is entitled to recover double damages.

Count II

Medicare Secondary Payer – Right to Charge
42 U.S.C. § 1395w-22(a)(4)

89. Humana incorporates by reference the allegations of paragraphs 1 through 82 of the complaint as if fully set forth in this paragraph.

90. In what is known as the "right-to-charge" provision, Congress explicitly authorized MA organizations (which were originally called "Medicare+Choice" organizations) to charge a primary payer for conditional secondary payments. 42 U.S.C. § 1395w-22(a)(4) states in part:

> Notwithstanding any other provision of law, a Medicare+Choice organization may (in the case of the provision of items and services to an individual under a Medicare+Choice plan under circumstances in which payment under this subchapter is made secondary pursuant to section 1395y(b)(2) of this title) charge . . . in accordance with the charges allowed under a law, plan, or policy described in such section—

> (A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services. . . .

91. Defendants are the entities with primary responsibility for the payment of all costs in connection with, arising out of, or in any way related to the recalled ICD and CRT-D devices manufactured by St. Jude Medical, Inc.

92. Humana paid conditional payments for those costs in an amount exceeding $75,000, has the right to charge defendants for those payments, and is entitled to recover double damages under 42 U.S.C. § 1395y(b)(3)(A).

93. Humana has issued a notice charging defendants for its conditional secondary payments. Defendants are in sole possession of information necessary to quantify the exact amount of the charge, which they have refused to provide despite repeated requests. Defendants have failed to pay the charges.

Count III

Medicare Secondary Payer – Subrogation
42 U.S.C. § 1395y(b)(2)(B)(iii)-(iv)

94. Humana incorporates by reference the allegations of paragraphs 1 through 82 of the complaint as if fully set forth in this paragraph.

95. 42 U.S.C. § 1395y(b)(2)(B)(iii) states in part:

> In order to recover payment made under this subchapter for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity.

96. 42 U.S.C. § 1395y(b)(2)(B)(iv) states: "The United States shall be subrogated (to

the extent of payment made under this subchapter for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan."

97. Humana is entitled to assert such a cause of action. 42 C.F.R. § 422.108 states in part: "The MA organization will exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations in subparts B through D of part 411 of this chapter." Subparts B through D of part 411 of the chapter referred to (Chapter VI) include the right of subrogation. 42 C.F.R. § 411.26.

98. Defendants are the entities required or responsible to make payment with respect to all costs in connection with, arising out of, or in any way related to the recalled ICD and CRT-D devices manufactured by St. Jude Medical, Inc.

99. Humana paid conditional payments for those costs in an amount exceeding $75,000 and is entitled to recover double damages under 42 U.S.C. § 1395y(b)(3)(A).

Count IV

Subrogation

100. Humana incorporates by reference the allegations of paragraphs 1 through 82 of the complaint as if fully set forth in this paragraph.

101. Humana has paid costs, or is subject to the payment of future costs, in connection with, arising out of, or in any way related to ICD and CRT-D devices manufactured by St. Jude Medical, Inc. that were recalled or that may be recalled.

102. Under the terms of its MA coverage, Humana is a subrogee to the enrollees of its MA plans who obtained ICD or CRT-D devices manufactured by St. Jude Medical, Inc. that were recalled or that may be recalled. For example, Patients 1 through 3 have materially identical subrogation provisions in their evidence of coverage documents that state: "If we pay a claim for

you, we have subrogation rights. This is a very common insurance provision that means we have the right to recover the amount we paid for your claim from any third party that is responsible for the medical expenses or benefits related to your injury, illness, or condition. You assign to us your right to take legal action against any responsible third party[.]" Patient 4 has similar subrogation language in her Certificate of Coverage document that states: "As a condition to receiving benefits from us, you agree to transfer to us any rights you may have to make a claim, take legal action or recover any expenses paid under the master group contract. We will be subrogated to your rights to recover from any funds paid or payable as a result of a personal injury claim or any reimbursement of expenses by: Any legally liable person or their carrier, including self-insured entities. . . ."

103. Humana did not in any meaningful sense act as a volunteer in paying these costs, because it was never notified (and still has not been notified) of the identity of these enrollees or what portion of its costs were paid or may yet be paid in connection with, arising out of, or in any way related to ICD and CRT-D devices manufactured by St. Jude Medical, Inc. that were recalled or that may be recalled.

104. Humana is not primarily liable for these costs, since they arose as a result of a defect in defendants' medical devices for which defendants have acknowledged responsibility.

105. On information and belief, to the extent of any debt owed by their enrollees for the provision of their medical costs, Humana has paid off the entire debt.

106. Subrogation will not work any injustice to the rights of a third party.

Count V

Unjust Enrichment

107. Humana incorporates by reference the allegations of paragraphs 1 through 82 of the complaint as if fully set forth in this paragraph.

108. Humana has paid medical costs in connection with, arising out of, or related to recalled ICD and CRT-D devices manufactured by St. Jude Medical, Inc., in an amount exceeding $75,000.

109. By paying those costs, which are properly the responsibility of defendants, Humana has conferred a benefit upon defendants.

110. Defendants have appreciated the benefit by avoiding payment for the costs themselves, and by incentivizing Humana members to avoid notifying Humana that the costs were incurred as a result of the recall.

111. Defendants have accepted and retained this benefit under circumstances that make it inequitable for them to retain the benefit without paying Humana the value of it.

Count VI

Common Law Fraud

112. Humana incorporates by reference the allegations of paragraphs 1 through 82 of the complaint as if fully set forth in this paragraph.

113. Defendants have engaged in a pattern of fraudulent conduct that has occurred over an extended period of time. Because of the nature of the fraud and the number of acts constituting the fraud, Humana lacks detailed knowledge of all the circumstances surrounding the fraud. Nevertheless, Humana has identified certain instances, including those listed in paragraphs 73 through 76 of this complaint, as cases likely involving defendants' wrongful conduct.

114. Defendants schemed to mislead Humana through both false statements and fraudulent omissions. The false statements were in the form of provider invoices suggesting that the medical costs arising out of the recall were for ordinary-course procedures instead of recalls for which defendants were the primary plan responsible for payment. Defendants caused providers to make those false statements to Humana by either actively encouraging providers to file claims

against medical insurers such as Humana, or by omitting material facts regarding their role as a primary plan that was responsible for payment in connection with their recall-related communications with providers.

115. Defendants also failed to notify Humana of the medical costs arising from recall-related procedures. Defendants owed Humana a duty to disclose those facts. That duty arose out of the MSP statutes noted above, including 42 U.S.C. § 1395w-22 and § 1395y, their accompanying regulations, and the Florida insurance-fraud statute, specifically Fla. Stat. § 817.234. On information and belief, Defendants encouraged providers to seek reimbursement from Humana without disclosing material facts or by presenting invoices and other submissions with misleading, omitted, or incomplete information in order to conceal the fact that the medical costs arose from the defendants' recall of their devices.

116. Defendants knew that Humana members would need medical procedures to explant their recalled devices and implant replacement devices, thus incurring medical costs. Defendants further knew that providers typically seek payment for those costs from patients and from their medical insurers. Defendants knew that by providing the replacement devices at no cost to patients, and by covering the patients' out-of-pocket costs, providers would seek the remaining reimbursement from medical insurers such as Humana. On information and belief, defendants knew that providers would either intentionally cooperate in this scheme or unintentionally participate simply by seeking reimbursement in the ordinary course.

117. By failing to cover any cost but the cost of the device and the patients' out-of-pocket costs, defendants intended to induce Humana's reliance on invoices that presented misleading, omitted, or incomplete information, and to cover the remaining costs notwithstanding that those costs arose from defendants' conduct.

118. Humana was damaged by acting in reliance on this false, misleading, omitted, or incomplete information. Defendants gained a benefit by avoiding costs that they otherwise would have borne.

Count VII

Violation of the Florida Deceptive and Unfair Trade Practices Act
Fla. Stat. § 501.204

119. Humana incorporates by reference the allegations of paragraphs 1 through 82 of the complaint as if fully set forth in this paragraph.

120. The Florida Deceptive and Unfair Trade Practices Act (FDUTPA) provides in part: "Unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." Fla. Stat. § 501.204(1).)

121. Florida has an insurance-fraud statute, which provides in part:

> (1)(a) A person commits insurance fraud punishable as provided in subsection (11) if that person, with the intent to injure, defraud, or deceive any insurer:
>
> 1. Presents or causes to be presented any written or oral statement as part of, or in support of, a claim for payment or other benefit pursuant to an insurance policy or a health maintenance organization subscriber or provider contract, knowing that such statement contains any false, incomplete, or misleading information concerning any fact or thing material to such claim;
>
> 2. Prepares or makes any written or oral statement that is intended to be presented to any insurer in connection with, or in support of, any claim for payment or other benefit pursuant to an insurance policy or a health maintenance organization subscriber or provider contract, knowing that such statement contains any false, incomplete, or misleading information concerning any fact or thing material to such claim;

Fla. Stat. § 817.234.

122. This statute proscribes unconscionable, deceptive, or unfair acts or practices, and may serve as a predicate offense under the FDUTPA.

123. Defendants caused Humana to be presented with statements in support of claims for payment knowing that those statements contained false, incomplete, or misleading information about the fact that the claimed medical costs arose out of defendants' recall.

124. The purpose of the statements submitted to Humana, and in particular the omission or obscuring of facts that would have notified Humana that the claimed medical costs arose from defendants' recall, were material to the claim for such costs.

125. Defendants insurance fraud constitutes a *per se* violation of the FDUTPA. In the alternative, defendants' conduct also constitutes an unfair or deceptive trade practice under FDUTPA without reference to their violations of the insurance fraud statute.

126. Defendants misled and deceived MAOs such as Humana by removing the incentive for patients and providers to notify health insurers of the true costs arising from the recall, and by orchestrating submissions to MAOs such as Humana that concealed or obscured information that would have provided notice of the true costs arising from the recall. This constituted a deceptive act or unfair practice.

127. Defendants' scheme caused Humana to make payments for the cost of medical procedures arising from the recall that were caused by, and were the responsibility of, defendants.

128. Humana has suffered actual damages in an amount exceeding $75,000.

Prayer for Relief

129. Based on the foregoing, Humana requests that the Court enter an order that:

a. Enters judgment in favor of Humana and against defendants St. Jude and Abbott;

b. Requires defendants to reimburse Humana for all conditional payments made by Humana in connection with, arising out of, or in any way related to the recalled ICD and CRT-D devices manufactured by St. Jude;

c. Awards Humana double damages under 42 U.S.C. § 1395y(b)(3)(A);

d. Declares and permanently enjoins defendants that, to the extent that any and all future costs in connection with, arising out of, or in any way related to the recalled ICD and CRT-D devices manufactured by defendants would otherwise have been conditionally paid by Humana for its Medicare-enrollee beneficiaries, such costs shall instead be borne by defendants and shall not be paid by Humana;

e. Permanently enjoins and requires defendants to notify hospitals and any other provider that any and all future costs in connection with, arising out of, or in any way related to the recalled ICD and CRT-D devices manufactured by defendants and that would otherwise have been conditionally paid by Humana for its Medicare-enrollee beneficiaries, shall instead be borne by defendants and shall not be paid by Humana or submitted to Humana for reimbursement;

f. Awards Humana pre-and post-judgment interest;

g. Awards Humana its attorneys' fees and costs; and

h. Provides any other relief that the Court deems proper.

Jury Demand

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Humana demands a trial by jury for all issues so triable.

Dated: July 26, 2019

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