SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"), the Defense Health Agency ("DHA"), acting on behalf of the TRICARE Program; and the Office of Personnel Management ("OPM"), which administers the Federal Employees Health Benefits Program ("FEHBP") (collectively, the "United States"), St. Jude Medical, Inc. and St. Jude Medical LLC (together, "St. Jude Medical"), and Debbie Burke ("Relator"), through their authorized representatives.

RECITALS

A. St. Jude Medical, Inc. ("SJM") developed and manufactured implantable cardioverter defibrillators ("ICDs") and implantable cardiac resynchronization therapy defibrillators ("CRT-Ds"), including the Fortify, Unify, Assura (including Quadra) devices.

B. On November 2, 2016, Relator filed a *qui tam* action in the United States District Court for the District of Maryland captioned *United States ex rel. Burke v. St. Jude Medical, Inc.*, SAG 16-CV-361 (D. Md.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil Action).

C. In January 2017, Abbott Laboratories ("Abbott") acquired SJM. All of the conduct at issue in this Agreement occurred before the acquisition. Following the acquisition, St. Jude Medical, Inc. became St. Jude Medical LLC. Abbott agrees to act as the guarantor of the payment obligations of St. Jude Medical as set forth in paragraphs 1 and 2 of this Agreement. The United States, St. Jude Medical, Relator, and Abbott are collectively hereinafter referred to as "the Parties".

D. The United States contends that SJM submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare"), the TRICARE Program, 10 U.S.C. §§ 1071-1110b ("TRICARE"), and the FEHBP, 5 U.S.C. §§ 8901-8914.

E. The United States contends that it has certain civil claims against SJM relating to the following alleged conduct (hereinafter referred to as the "Covered Conduct"):

i. During the period November 20, 2014, through October 10, 2016, SJM developed, manufactured, and sold the ICDs and CRT-Ds, including the Fortify, Unify, Assura (including Quadra) devices. ICDs and CRT-Ds are implanted in the chest by physicians and are designed to detect and convert potentially fatal heart arrhythmias by delivering an electric shock to the heart.

ii. The ICDs and CRT-Ds at issue contain lithium batteries.[1] The use of these batteries can lead to a "lithium cluster," which is a well-known and unavoidable byproduct of lithium batteries. The clusters can move after formation, typically due to movement of the device. In most instances, these clusters are harmless. However, if the clusters form a bridge between the cathode and the anode surfaces of the battery or other parts of the ICD or CRT-D, they can conduct electric current leading to a battery short, which can prematurely drain the battery of power (known as Premature Battery Depletion, or "PBD"). It was not possible to determine whether a lithium cluster had bridged the anode and cathode surfaces without first explanting the device.

iii. In 2013, SJM engineers, along with the battery manufacturer, began developing an improvement to the battery of its ICD and CRT-D devices to prevent lithium clusters from causing PBD. The fix would add an upward-facing cup around the existing downward-facing cup, forming a seal that would fully prevent clusters from bridging the battery to the ICD and CRT-D. On August 21, 2014 SJM submitted a Real Time Review ("RTR") request to the FDA in order to seek permission to make the design change to the batteries of its ICD and CRT-D devices. A Real Time Review Pre-Market Approval Supplement ("PAS") is a process that permits manufacturers of devices to obtain expedited consideration from the FDA for minor changes to already approved devices.

iv. In SJM's RTR submission to the FDA, SJM disclosed that there had been lithium clusters and PBD, but also represented that "no serious injury, permanent harm or deaths have been reported associated with this complaint". The United States contends that SJM knew this statement was false and misleading. At the time of the RTR submission, SJM was aware of two reported serious injuries and one death associated

[1] The specific models of ICDs at issue are those identified in the FDA's safety communication, dated on or about October 11, 2016, titled "Premature Battery Depletion of St. Jude Medical ICD and CRT-D Devices."

with PBD with lithium clusters present in SJM explanted devices. The United States further contends that, during an October 29, 2014, conversation among a SJM regulatory official, SJM engineers, and FDA personnel related to SJM's RTR request, SJM again falsely stated that "no serious injury, permanent harm, or deaths have been reported associated with this complaint." Based on the information SJM provided to FDA, the FDA approved SJM's RTR PAS on November 20, 2014.

v. The United States contends that, had SJM been truthful with the FDA about the serious injuries and death associated with the lithium cluster short and PBD problem at the time of the RTR submission, the FDA would have requested that SJM initiate a voluntary recall of the ICD and CRT-D devices that had been manufactured prior to the new design.

vi. SJM continued to distribute devices that had been manufactured without the new design. Such devices were implanted into Medicare, TriCare, and FEHBP patients even after November 20, 2014, and until October 10, 2016.

vii. After the RTR PAS approval, SJM continued to receive reports about lithium cluster shorts and PBD in the older devices, which it continued to sell and which it knew were being implanted. In August 2016, SJM contacted the FDA and informed it that the number of PBD events had increased to 729, including two deaths and 29 events associated with loss of pacing.

viii. On October 10, 2016, SJM issued a medical advisory regarding the PBD caused by lithium cluster shorts, which FDA classified as a Class I recall. A Class I recall is one in which there is a reasonable probability that "violative" products "will cause serious adverse health consequences, including death."

ix. After the recall, SJM no longer sold the older devices, but thousands of them had been implanted into patients between November 20, 2014 and October 10, 2016.

As a result of the foregoing conduct, the United States alleges that between November 20, 2014, and October 10, 2016, SJM knowingly submitted or caused false or fraudulent claims for the Fortify, Unify, and Assura (including Quadra) devices to be submitted to, or caused purchases by, Medicare, TRICARE, and FEHBP.

F. This Settlement Agreement is neither an admission of liability by St. Jude Medical nor a concession by the United States that its claims are not well founded. St. Jude Medical denies the United States' allegations in Paragraph E and the Relator's allegations as set forth in the Civil Action.

G. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. St. Jude Medical, with Abbott as guarantor, shall pay to the United States $27,000,000 (Settlement Amount) plus accrued interest thereon at the rate of 0.875 percent from January 25, 2021, to the date of payment, of which $13,500,000 is restitution, no later than fourteen (14) days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. St. Jude Medical, with Abbott as guarantor, shall pay to Relator $64,467.91 in satisfaction of any claims Relator may have for fees and costs under 31 U.S.C. § 3730(d).

3. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, plus interest due under Paragraph 1, the United States releases St. Jude Medical, together with its current and former parent corporations, including Abbott (and all of its subsidiaries); subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors, transferees, heirs, and assigns of any of them (collectively, the "SJM Released Parties") from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. §

1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, disgorgement, unjust enrichment, and fraud.

4. Upon the United States' receipt of the Settlement Amount, plus accrued interest, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases all SJM Released Parties and any former or current St. Jude Medical or Abbott director, officer, or employee from all liability, claims, demands, actions, or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that Relator, her heirs, successors, attorneys, agents and assigns otherwise would have standing to bring as of the date of this Agreement, including any liability to Relator arising from or relating to the claims Relator asserted or could have asserted in the Civil Action.

5. Notwithstanding the release given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

6. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). In connection with this Agreement and this Civil Action, Relator and her heirs, successors, attorneys, agents, and assigns agree that neither this Agreement, any intervention by the United States in the Civil Action in order to dismiss the Civil Action, nor any dismissal of the Civil Action, shall waive or otherwise affect the ability of the United States to contend that provisions in the False Claims Act, including 31 U.S.C. §§ 3730(d)(3) and 3730(e), bar Relator from sharing in the proceeds of this Agreement. Moreover, the United States and Relator and her heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the False Claims Act on the issue of the share percentage, if any, that Relator should receive of any proceeds of the settlement of her claim(s).

7. Relator, for herself, and for her heirs, successors, attorneys, agents, and assigns, releases all SJM Released Parties, and their directors, officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

8. The SJM Released Parties waive and shall not assert any defenses the SJM Released Parties may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double

Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

9. The SJM Released Parties fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that SJM Released Parties have asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.

10. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE, FEHBP, or any state payer, related to the Covered Conduct; and St. Jude Medical agrees not to resubmit to any Medicare contractor, TRICARE, FEHBP, or state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

11. St. Jude Medical agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of St. Jude Medical, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

(2) the United States' audit(s) and civil and criminal investigations of the matters covered by this Agreement;

(3) St. Jude Medical's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and criminal investigations in connection with the matters covered by this Agreement (including attorneys' fees);

(4) the negotiation and performance of this Agreement; and

(5) the payment St. Jude Medical makes to the United States pursuant to this Agreement and any payments that St. Jude Medical may make to Relator, including costs and attorney's fees;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by St. Jude Medical, and St. Jude Medical shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by St. Jude Medical or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: St. Jude Medical further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this paragraph)

included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by St. Jude Medical or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. St. Jude Medical agrees that the United States, at a minimum, shall be entitled to recoup from St. Jude Medical any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by St. Jude Medical or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on St. Jude Medical or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine St. Jude Medical's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

12. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 3, 4, 7, 9, and Paragraph 13 (waiver for beneficiaries paragraph), below.

13. The SJM Released Parties agree that they waive and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or

their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

14. Upon receipt of the payment described in Paragraphs 1 and 2, above, the United States and Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1). The stipulation shall be: (a) with prejudice to the United States and Relator as to the Covered Conduct; and (b) with prejudice to the Relator and without prejudice to the United States as to all conduct other than the Covered Conduct. The stipulation will not affect any claim by Relator for a relator share of the settlement proceeds under 31 U.S.C. § 3730(d).

15. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

16. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

17. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Maryland. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

18. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

19. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

20. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

21. This Agreement is binding on St. Jude Medical successors, transferees, heirs, and assigns.

22. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

23. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

24. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

UNITED STATES OF AMERICA

DATED: 7/7/2021 BY: Jane E. Andersen
THOMAS F. CORCORAN
JANE E. ANDERSEN
Assistant United States Attorneys
District of Maryland

DATED: _____ BY: _____
JONATHAN GOLD
Trial Attorney
Commercial Litigation Branch, Civil Division
Department of Justice

DATED: _____ BY: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____ BY: _____
LEIGH A. BRADLEY
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____ BY: _____
EDWARD M. DEHARDE
Assistant Director
Federal Employee Insurance Operations,
Healthcare and Insurance
United States Office of Personnel Management

DATED: _____ BY: _____
PAUL ST. HILLAIRE
Assistant Inspector General for Legal
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Assistant United States Attorneys
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Office of Counsel to the Inspector General
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United States Department of Health and Human Services

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JANE E. ANDERSEN
Assistant United States Attorneys
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DATED: _____ BY: _____
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Trial Attorney
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DATED: _____ BY: GREGORY DEMSKE Digitally signed by GREGORY DEMSKE Date: 2021.07.01 17:49:06 -04'00'
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

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LEIGH A. BRADLEY
General Counsel
Defense Health Agency
United States Department of Defense

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United States Office of Personnel Management

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JANE E. ANDERSEN
Assistant United States Attorneys
District of Maryland

DATED: _____ BY: _____
JONATHAN GOLD
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Commercial Litigation Branch, Civil Division
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LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: 07/06/2021 BY: Paul N. Bley
SALVATORE M. MAIDA
for General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____ BY: _____
SHIRLEY R. PATTERSON
Acting Deputy Associate Director
Insurance Operations
United States Office of Personnel Management

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J. DAVID COPE
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

UNITED STATES OF AMERICA

DATED: _____ BY: _____
THOMAS F. CORCORAN
JANE E. ANDERSEN
Assistant United States Attorneys
District of Maryland

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DATED: _____ BY: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____ BY: _____
LEIGH A. BRADLEY
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____ BY: EDWARD DEHARDE Digitally signed by EDWARD DEHARDE Date: 2021.07.07 14:13:25 -04'00'
EDWARD M. DEHARDE
Assistant Director
Federal Employee Insurance Operations,
Healthcare and Insurance
United States Office of Personnel Management

DATED: _____ BY: PAUL ST HILLAIRE Digitally signed by PAUL ST HILLAIRE DN: c=US, o=U.S. Government, ou=Office of Personnel Management, cn=PAUL ST HILLAIRE, 0.9.2342.19200300.100.1.1=24001000034787 Date: 2021.07.07 07:52:14 -04'00'
PAUL ST. HILLAIRE
Assistant Inspector General for Legal
and Legislative Affairs
United States Office of Personnel Management

ST. JUDE MEDICAL, INC., ST. JUDE MEDICAL LLC, AND ABBOTT LABORATORIES

DATED: 7/6/21 BY: _____

DAVID E. MENDELSON
Abbott Laboratories Divisional Vice President and Associate General Counsel, Litigation
St. Jude Medical, Inc., St. Jude Medical LLC (as successor in interest to St. Jude Medical, Inc.), and Abbott Laboratories

DATED: 7/6/21 BY: _____

BRIGHAM Q. CANNON
NICOLAS W. THOMPSON
ELIZABETH S. HESS
HENRY J. DEPIPPO
Kirkland & Ellis LLP
Counsel for St. Jude Medical, Inc., St. Jude Medical LLC (as successor in interest to St. Jude Medical, Inc.), and Abbott Laboratories

DEBBIE BURKE – RELATOR

DATED: 7/2/21 BY: Debbie P. Burke
Debbie Burke, Relator

DATED: 7/2/21 BY:
Nathan Peak
Counsel for Relator, Debbie Burke