

## 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”) (collectively the “United States”), St. Jude Medical, Inc. (“St. Jude”), and Charles Donigian (hereafter collectively referred to as “the Parties”), through their authorized representatives.

### RECITALS

A. St. Jude is a medical device manufacturer headquartered in St. Paul, Minnesota. Its primary business is the manufacture and sale of cardiovascular medical products, including pacemakers and implantable cardioverter defibrillators (“ICDs”).

B. On July 6, 2006, Charles Donigian (the “Relator”) filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned *United States ex rel. Donigian v. St. Jude Medical, Inc.*, No. 06cv11166, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). On January 19, 2010, the Relator filed a Third Amended Complaint in the Civil Action. The Relator alleged, *inter alia*, that St. Jude used certain post-market clinical trials and data collection registries as vehicles to pay kickbacks to induce participating physicians to implant St. Jude pacemakers and ICDs in their patients. The United States intervened in part in the Civil Action on August 5, 2010.

C. The United States contends that it has certain civil claims against St. Jude for the following conduct during the years 2003 through 2008 (hereinafter referred to as the “Covered Conduct”): St. Jude, acting through certain of its employees, used three post-market studies known as “AWARE,” “ASSIST,” and “HOUSECALL PLUS,” and a registry known as “ACT” (together, the “Subject Studies and Registry”) in part as vehicles to pay participating physicians

kickbacks to implant St. Jude pacemakers and ICDs. Although St. Jude collected data and information from participating physicians, it knowingly and intentionally used the Subject Studies and Registry as a means of increasing device sales by paying certain physicians to select St. Jude pacemakers and ICDs to implant in their patients. Each of the Subject Studies and Registry required the implant of a St. Jude CRM device in each patient and the submission of data regarding each patient. In each case, St. Jude paid each participating physician a fee that ranged up to \$1,000 to \$2,000 per patient. St. Jude, acting through its employees, solicited physicians for the studies in order to retain their business and/or convert their business from a competitor's product.

D. The United States contends that, as a result of the foregoing conduct, St. Jude submitted or caused to be submitted false claims for payment to the Medicare Program ("Medicare"), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh.

E. The United States also contends that it has certain administrative claims against SJM for engaging in the Covered Conduct.

F. 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, and to damages for retaliation and wrongful discharge.

G. This Settlement Agreement is neither an admission of liability by St. Jude nor a concession by the United States that its claims are not well founded.

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:

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TERMS AND CONDITIONS

1. St. Jude shall pay to the United States sixteen million dollars (\$16,000,000) and interest thereon at a rate of 2.0% beginning August 24, 2010, and continuing through the day before full payment is made (the "Settlement Amount"), by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts, no later than seven days after the Effective Date of this Agreement.

2. Conditioned upon the United States receiving the Settlement Amount from St. Jude and as soon as feasible after receipt, the United States shall pay \$2,640,000, plus a proportionate share of the interest on the Settlement Amount, to Relator by electronic funds transfer.

3. St. Jude agrees to pay Relator for expenses, and attorney's fees and costs, and for Relator's claims of retaliation and wrongful discharge pursuant to a confidential separate settlement agreement, to be entered into between St. Jude and Relator simultaneously, with the execution of this settlement agreement.

4. Subject to the exceptions in Paragraph 7 (concerning excluded claims) below, in consideration of the obligations of St. Jude in this Agreement and conditioned upon St. Jude's full payment of the Settlement Amount, the United States releases St. Jude, together with its predecessors, successors, subsidiaries, and its present and former directors, officers, and employees, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12; or the common law theories of payment by mistake, unjust enrichment, and fraud.

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5. Subject to the exceptions in Paragraph 7 below, in consideration of the obligations of SJM in the Agreement and conditioned upon SJM's full payment of the Settlement Amount, and the agreed upon Relator's attorney's fees, costs and expenses, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases SJM together with its predecessors, successors, subsidiaries, affiliates, and its present and former directors, officers, shareholders, members, employees, administrators, partners, agents, attorneys, and accountants, both individually and in their capacities as directors, officers, shareholders, members, employees, administrators, partners, agents, attorneys, and accountants (collectively "the Releasees") from (a) any and all claims, whether disclosed or undisclosed, which Relator has asserted, could have asserted, or may assert now or in the future against the Releasees related to the Civil Action, the Covered Conduct and the Relator's investigation and prosecution thereof, including but not limited to any civil monetary claim the Relator or the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33, any claim for attorney's fees, expenses or costs under 31 U.S.C. § 3730(d), and his employment with SJM, including but not limited to any claim for retaliation under 31 U.S.C. § 3730(h), and (b) any and all claims (including attorney's fees, costs, and expense of every kind and however denominated), whether disclosed or undisclosed, which Relator has asserted, could assert, or may assert now or in the future against Releasees under federal or state law, regulation, rule or ordinance, and/or public policy, common law contract, or tort claim, including any claims arising out of or in any way connected with the Civil Action, Covered Conduct or Relator's employment or cessation of employment.

6. OIG-HHS expressly reserves all rights to institute, direct, or maintain any administrative action seeking exclusion against St. Jude (and/or its officers, directors, and

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employees) from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7a (the Civil Monetary Penalties Law), 42 U.S.C. § 1320a-7(a) (mandatory exclusion), and/or 42 U.S.C. § 1320a-7(b) (permissive exclusion).

7. Notwithstanding the releases given in paragraphs 4 and 5 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, United States Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory 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 for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for failure to deliver goods or services due; or
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

8. Relator and his 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). Conditioned upon Relator's receipt of the payment described in Paragraph 2, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its officers, agents, and employees, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

9. St. Jude waives and shall not assert any defenses St. Jude 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. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

10. St. Jude fully and finally releases the United States, and its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that St. Jude has asserted, could have asserted, or may assert in the future against the United States, and its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

11. SJM fully and finally releases the Relator from any claims (including attorney's fees, costs and expenses of every kind and however denominated) that SJM has asserted, could have asserted, or may assert in the future against the Relator, related to the allegations in the Civil Action and the Relator's investigation and prosecution thereof.

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12. 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 carrier or intermediary or any state payer, related to the Covered Conduct; and St. Jude agrees not to resubmit to any Medicare carrier or intermediary or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

13. 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. §§ 1395-1395hhh and 1396-1396v; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of St. Jude, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' investigation of the matters covered by this Agreement;
- (3) St. Jude's investigation, defense, and corrective actions undertaken in response to the United States' investigation in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment St. Jude makes to the United States pursuant to this Agreement and any payments that St. Jude may make to Relator, including costs and attorneys fees,

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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, and St. Jude 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 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 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 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 agrees that the United States, at a minimum, shall be entitled to recoup from St. Jude 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.

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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 or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on St. Jude 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's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

14. 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 Paragraph 15 (waiver for beneficiaries paragraph), below.

15. St. Jude agrees that it waives 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 payers based upon the claims defined as Covered Conduct.

16. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1) in the form of the Joint Stipulation of Dismissal and Proposed Order of Dismissal attached hereto as Attachment 1. The dismissal shall be with prejudice to the United States and to the Relator as to the Covered Conduct and with prejudice to the Relator and without prejudice to the United States as to all other claims in the Civil Action. If the Court enters an Order of Dismissal that differs from the proposed Order of Dismissal attached hereto as

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Attachment 1, the Parties agree to take all reasonable and necessary steps to seek modification of the entered Order to conform it to the attached Order of Dismissal.

17. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

19. 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 Massachusetts. 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.

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

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

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

23. This Agreement is binding on St. Jude's successors, transferees, heirs, and assigns.

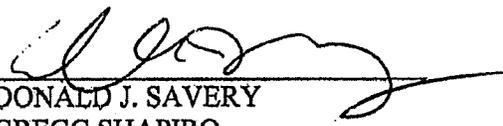
24. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

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

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

THE UNITED STATES OF AMERICA

DATED: 1/19/11

BY:   
DONALD J. SAVERY  
GREGG SHAPIRO  
Assistant United States Attorneys  
District of Massachusetts

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
A. THOMAS MORRIS  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: 1/19/11

BY:   
GREGORY E. DEMSKE  
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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DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
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GREGG SHAPIRO  
Assistant United States Attorneys  
District of Massachusetts

DATED: 1/20/11

BY:   
A. THOMAS MORRIS  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
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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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BY: \_\_\_\_\_

DONALD J. SAVERY  
GREGG SHAPIRO  
Assistant United States Attorneys  
District of Massachusetts

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

A. THOMAS MORRIS  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: \_\_\_\_\_

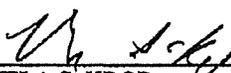
BY: \_\_\_\_\_

GREGORY E. DEMSKE  
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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ST. JUDE MEDICAL, INC. - DEFENDANT

DATED: 1/19/11

BY:   
PAMELA S. KROP  
Vice President and General Counsel  
St. Jude Medical, Inc.

DATED: 1/19/11

BY:   
ERIC A. DUBELIER  
KATHERINE J. SEIKALY  
Reed Smith LLP  
Counsel for St. Jude Medical, Inc.

DATED: 1/19/11

BY:   
MARK SELTZER  
Nixon Peabody LLP  
Counsel for St. Jude Medical, Inc.

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CHARLES DONIGIAN - RELATOR

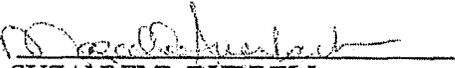
DATED: 1/19/11

BY:   
CHARLES DONIGIAN

DATED: 1/19/11

BY:   
KENNETH J. NOLAN  
MARCELLA AUERBACH  
Nolan & Auerbach, P.A.  
Counsel for Charles Donigian

DATED: 1/19/11

BY:   
SUZANNE E. DURRELL  
Durrell Law Office  
Counsel for Charles Donigian

CHARLES DONIGIAN - RELATOR

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
CHARLES DONIGIAN

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
KENNETH J. NOLAN  
MARCELLA AUERBACH  
Nolan & Auerbach, P.A.  
Counsel for Charles Donigian

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
SUZANNE E. DURRELL  
Durrell Law Office  
Counsel for Charles Donigian

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