IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex rel.* CHARLES DONIGIAN, Plaintiff, v. ST. JUDE MEDICAL, INC., Defendant.	CIVIL ACTION NO. 06 CA 11166-DPW **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** **JURY TRIAL DEMANDED**

THIRD AMENDED FALSE CLAIMS ACT COMPLAINT

INTRODUCTION

1. CHARLES DONIGIAN ("Relator") brings this action on behalf of the UNITED STATES OF AMERICA against ST. JUDE MEDICAL, INC. (hereinafter "SJM" or "DEFENDANT") for treble damages and civil penalties arising from the DEFENDANT'S conduct in violation of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("FCA"). The violations arise out of requests for payment made to Medicare, Medicaid, TRICARE, and other government agencies and programs (hereinafter, collectively the "Government Healthcare Programs") based on false or fraudulent claims, false statements, and illegal inducements and kickbacks. He also brings personal claims alleging that DEFENDANT unlawfully retaliated against him in his employment in violation of the Federal FCA and wrongfully discharged him in violation of the laws of the State of Missouri where he resides.[1]

[1]Prior to serving this Third Amended Complaint on Defendant, the Relator intends to move for a voluntarily dismissal with prejudice of the claims under certain State FCAs that are contained in his Second Amended

2. This Complaint describes kickbacks provided by DEFENDANT to physicians, hospitals and other healthcare providers (hereinafter sometimes collectively referred to as "providers"), to induce them to prescribe certain medical products manufactured and sold by DEFENDANT, and also causing the providers to submit requests for payment for such products to Government Healthcare Programs. These kickbacks took many forms including: (1) payments ostensibly for physician's collection of data and provision of services in connection with DEFENDANT'S post-market clinical studies which DEFENDANT knowingly and intentionally designed and used as a means of increasing sales of its devices over competitors, not as *bona fide* scientific research; and (2) payments for entertainment, travel,. conferences at luxury resorts, tickets to sporting events, and other gifts and benefits.

3. The kickbacks achieved SJM's intended purpose. Relator is aware of cases where physicians prescribed SJM devices because they were receiving kickbacks. For a substantial portion of these patients and procedures, the physician or hospital then submitted reimbursement claims to Medicare and other Government Health Care Programs.

4. Relator is informed and believes that the pervasive kickbacks, false statements and false or fraudulent claims described herein began at least six (6) years before the filing of this lawsuit.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this case pursuant to 31 U.S.C. § 3732(a) and 3730, as well as under 28 U.S.C. §§ 1331 and 1345, because SJM does business in the District of Massachusetts. This Court has supplemental jurisdiction over the state law claim brought on behalf

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Complaint. However, pursuant to state laws, dismissal of some or all of those claims will require the approval of this Court and/or the State(s).

of the Relator for wrongful discharge under Missouri law pursuant to 28 U.S.C. § 1367.

6. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) and (c), because SJM transacts business in this District.

PARTIES

7. Relator, CHARLES DONIGIAN is a resident of Missouri. He was employed by SJM as a Technical Service Specialist ("TSS") from Fall 2004 through Spring 2007, covering the St. Louis and mid-Missouri area. As a TSS for SJM, Relator was responsible for assisting with the marketing, sale and distribution of cardiovascular medical devices which included managing the completion of any required paperwork and patient enrollment documents related to post-market studies being conducted by SJM. His territory was part of SJM's West Central West ("WCW") area comprised of North Dakota, South Dakota, Minnesota, Illinois, Missouri, Iowa, Wisconsin and Nebraska.

8. Relator brings this action based on his direct, personal, independent, and unique knowledge obtained during the period of his employment with DEFENDANT, and also on information and belief. As characterized by the Federal False Claims Act, Plaintiff may be referred to as "Relator" hereafter. Most if not all of the actionable allegations set forth in this Complaint are not based on a public disclosure as set forth in 31 U.S.C. § 3730(e)(4). Notwithstanding same, Relator is an "original source" of the facts alleged in this Amended Complaint and in prior Complaints and has voluntarily provided this information to the United States prior to filing of this action and the original Complaint.

9. SJM, together with its subsidiaries, engages in the development, manufacture and distribution of cardiovascular medical devices and implantable neuromodulation devices for the

global cardiac rhythm management, cardiac surgery, cardiology, and atrial fibrillation therapy areas. SJM markets and sells its products through a direct sales force and independent distributors in the United States and other countries. SJM's headquarters are located in St. Paul, Minnesota.

10. At all times relevant hereto, SJM acted through its agents and employees, and the acts of said DEFENDANT'S agents and employees were within the scope of their agency and employment. The policies and practices alleged in this Complaint were, on information and belief, set or ratified at the highest corporate levels of SJM.

THE MEDICAL DEVICES AT ISSUE MANUFACTURED BY DEFENDANT SJM

11. This Complaint involves two types of medical devices, pacemakers and implantable cardioverter defibrillators (ICDs), both of which have been the subject of multiple SJM post-market clinical trial studies. Post-market studies are studies that ostensibly assess the clinical performance of a medical device or drug after that device or drug has been approved by the United States Food and Drug Administration ("FDA").

12. Pacemakers are battery-powered implantable devices that function to electrically stimulate the heart to contract and thus to pump blood throughout the body. Pacemakers consist of a pager-sized housing device which contains a battery and the electronic circuitry that runs the pacemaker, and one or two long thin wires that travel through a vein in the chest to the heart. Pacemakers are usually implanted in patients in whom the heart's own "spark plug" or electrical system is no longer functioning normally.

13. An implantable cardioverter defibrillator (ICD) is a small implantable device that looks similar to a pacemaker. While pacemakers can speed up a slow heart rate, ICDs were designed to slow down a fast heart rate. In addition, many ICDs also contain a built-in full-featured

pacemaker. The ICD detects arrhythmias (both Brady arrhythmia and tachyarrhythmia) and delivers electrical therapy-pacing pulses or defibrillation therapy as necessary. When not needed, the ICD merely monitors the heart without delivering any electrical energy.

14. Medical device companies such as SJM sell products directly to healthcare providers (e.g., hospitals and skilled nursing facilities). Government Healthcare Programs end up paying for these devices either under a bundled rate (which not only includes the cost of the devices, but also includes the cost of the implant procedures), or unbundled (paying for the devices themselves), depending upon the particular Government Healthcare Program's reimbursement plan. After implantation, there are follow up visits.

GOVERNMENT HEALTHCARE PROGRAMS

15. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare Program, to pay for the costs of certain healthcare services. The program is overseen by the United States Department of Health and Human Services through the Centers for Medicare and Medicaid Services ("CMS"). Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age and others that qualify under the terms and conditions of the Medicare Program based on disability or affliction with certain diseases. *See* 42 U.S.C. §§ 1395 to 1395ccc. For purposes of this case, there are two general components to the Medicare program, Part A and Part B. A physician or provider is paid for device implantation under Part A, while device follow up and interrogation is reimbursed through Medicare Part B. SJM provides the programmer and technical support, and gives the doctor money if patient was in a registry or study.

16. Part A of the Medicare Program, set forth in Title XVIII of the Social Security Act,

authorizes payment for institutional care, including inpatient hospital care and related services. *See* 42 U.S.C. §§ 1395c-1395i-5. To assist in the administration of Medicare Part A, CMS contracts with "fiscal intermediaries", typically insurance companies, who are responsible for processing and paying claims and auditing cost reports. *See* 42 U.S.C. § 1395h. In the case of Part B, CMS contracts with "carriers" who have the same or similar functions as the fiscal intermediaries on the Part A side. *See* 42 U.S.C. § 1395u

17. HHS issues a Hospital Manual, which is distributed to all Medicare providers, to inform them of its reimbursement policies and procedures. Similar manuals are provided to the fiscal intermediaries (the "Intermediary Manual") and to the carriers. These manuals are an essential source of information to Medicare providers and intermediaries regarding Medicare coverage policies for Part A and Part B, respectively.

18. Upon discharge of a Medicare beneficiary from the hospital, the hospital submits an interim reimbursement claim for items and services provided to that patient. These claims are submitted on a standard form (HCFA-1450)(UB-92). For Part B services, the health care provider submits a claim for reimbursement using a Form CMS-1500.

19. CMS issued a Medicare National Coverage determination in 1986 providing limited coverage of implantable defibrillators (ICDs). The policy has expanded over the years with revisions in 1991, 1999, and 2003, and ultimately a Medicare National Coverage decision memo for implantable defibrillators (CAG-00157R3) dated January 27, 2005 which considerably expanded Medicare coverage for ICDs. The benefit category for ICDs is the prosthetic devices category.

20. The Medicaid program, as enacted under Title XIX of the Social Security Act of 1965, 42 U.S.C. §§ 1396, *et seq.*, is a system of medical assistance for indigent individuals. Though

federally created, the Medicaid program is a joint federal-state program in which the United States provides a significant share of the funding for the program. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50 percent and is as high as 83 percent. The Medicaid Program is overseen by the United States Department of Health and Human Services through CMS. The States directly pay providers, with the States obtaining the federal share of the payment from accounts which draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994). Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid.

21. By enrolling in a state's Medicaid program, all health care providers agree to abide by the state's Medicaid manual. The Medicaid manuals for individual states typically incorporate the anti-fraud provisions of the Medicare Program (see discussion infra).

22. Among the rules and regulations which enrolled providers in both the Medicare and Medicaid program agree to follow are to: (a) bill for only those covered services which are medically necessary; (b) neither bill for any services which were not performed or delivered in accordance with all applicable policies, nor submit false or inaccurate information relating to provider costs or services; (c) not engage in any act or omission that constitutes or results in over utilization of services; (d) be fully licensed and/or certified under all applicable state and federal laws to perform the services provided; (e) comply with the applicable state and federal statutes, policies and regulations; and (f) not engage in any illegal activities related to the furnishing of services or products.

23. Provider hospitals participating in the Medicaid program are required to file annual cost reports with the state agencies administering that particular state's Medicaid program and are required to submit claim forms identical to those used in the Medicare program.

24. TRICARE Management Activity, formerly known as CHAMPUS, is a program of the Department of Defense that helps pay for covered civilian health care obtained by military beneficiaries, including retirees, their dependents, and dependents of active-duty personnel. *See* 10 U.S.C. §§ 1079, 1086; 32 C.F.R. Part 199. TRICARE contracts with fiscal intermediaries and managed care contractors to review and pay claims, including claims submitted by DEFENDANT under the TRICARE program. The federal government, through its Departments of Defense and Veterans Affairs, also maintains and operates medical facilities including hospitals.

25. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. (Together these programs described in the preceding paragraphs shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs").

26. Reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement. The most basic requirement for reimbursement eligibility under Medicare, Medicaid and other Government Health Care Programs is that the service provided must be reasonable and medically necessary. See, e.g., 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1396, *et seq.*; 42 C.F.R. § 410.50. Medical providers are not permitted to bill the government for medically unnecessary services or procedures performed solely for the profit of the provider. See id.

27. As described further below, each of the Government Health Care Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the federal Anti-Kickback Statute (discussed infra) and with other federal laws governing the provision of health care services in the United States. For example, physicians and hospitals enter into Provider Agreements with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which the hospitals and physicians may not seek reimbursement from Federal Health Care Programs, the provider must sign the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Form CMS-855A; Form CMS-8551 (effective 2001). In addition, the claims themselves as submitted contain a similar certification. *See, e.g.,* Form CMS-1500.

28. When a provider submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law, to include without limitation the Anti-Kickback Statue. In the case of Medicaid, each State's Medicaid Program's applicable certifications also incorporate relevant state law.

29. DEFENDANT SJM sells the medical devices at issue in this case to hospitals and other institutional healthcare providers (hereafter "Health Care Professionals" or "HCPs"). These

same HCPs received millions of dollars in Medicare, Medicaid, TRICARE and other Government Healthcare Program reimbursements and monies for these devices. In turn, the physicians and other HCP's who purchased and prescribed such devices while participating in the phony trials and registries described herein and receiving the unlawful inducements described herein, have received millions of dollars for their services, in addition to the phony trial/registry payments, and unlawful inducements.

30. Services for these patients at issue in this case would be billed under the numerous CPT codes that apply to the implantation of a device in a hospital setting. Attached hereto as Exhibit 1 is a true copy of a SJM explanation of the applicable CPT codes. For follow up visits in the office setting the CPT codes are: 93741-94744 (for ICD follow up); and 93731-93735 (for Pacemaker follow up).

LEGAL BACKGROUND

31. The Federal FCA provides, in pertinent part that any person who :

> (a) (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; ...or
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; ...
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, ... plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729. On May 20, 2009, the False Claims Act was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"). Section 3729(a)(1)(B) was

formerly § 3729(a)(2), and is applicable to this case by virtue of § 4(f) of FERA, while § 3279(a)(1) of the statute prior to FERA, and as amended in 1986, remains applicable here.

32. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the False Claims Act civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

For purposes of the FCA,

> The terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts n reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required..

31 U.S.C. § 3729(b).

33. The Federal FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. 31 U.S.C. § 3729(b)(2).

34. In addition, the Federal FCA, 31 U.S.C. § 3730(h), provides relief to employees who have been retaliated against in their employment because of lawful acts done by the employee in furtherance of efforts to stop one or more violations of the FCA. Such retaliation may include discharge, demotion, suspension, threats, harassment or any other type of discrimination in the terms and conditions of employment. The employee is entitled to all relief

necessary to make that employee whole, including reinstatement, two times back pay, interest on the back pay, and compensation for any special damages, including litigation costs and reasonable attorney's fees.

35. The Medicare and Medicaid Patient Protection Act, also known as the federal Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b) ("AKA"), prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical items or services, including items or services provided under the Medicare, Medicaid, and TRICARE programs. In pertinent part, the AKA states:

> Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony.

42 U.S.C. § 1320a-7b(b).

36. The AKA seeks to prohibit such activities in order to secure proper medical treatment and referrals, and to limit the possibility of a patient having to undergo unnecessary treatments or having to accept specific items or services which are based not on the needs of the patient, but on the incentives given to others, thereby limiting the patient's right to choose proper medical care and services.

37. The AKA arose out of congressional concern that the remuneration and gifts

given to those who can influence health care decisions corrupts medical decision-making and could result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of the federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The AKA was enacted in 1972 "to provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful . . . and which contribute appreciably to the cost of the Medicare and Medicaid programs." H.R. Rep. No. 92-231, 92d Cong., 1st Sess. 108 (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

38. The AKA was strengthened by amendments in 1977 and 1987 which, *inter alia*, increased the criminal penalties from a misdemeanor to a felony and subjected the perpetrator to exclusion from participation in federal health care programs (42 U.S.C. § 1320a-7(b)(7)), civil monetary penalties of $50,000 per violation (42 U.S.C. § 1320a-7a(a)(7)), and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose. 42 U.S.C. § 1320a-7a(a).

39. Concern about improper marketing practices prompted the Inspector General of the Department of Health and Human Services to issue a series of Special Fraud Alerts in 1994 concerning various practices that could run afoul of the AKA. *See* Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 29, 1994); see also Fed. Reg. Dec. 19, 2004. In one Fraud Alert issued in October 1994 (and contained in the above), the OIG stated, *inter alia*,

> Generally, a payment or gift may be considered improper ...if it is:
>
> • Made to a person in a position to generate business for the paying party;

- Related to the volume of business generated; and
- More than nominal in value and/or exceeds fair market value of any legitimate service rendered to the payer, or is unrelated to any service at all other than referral of patients.

OIG scrutiny may be warranted for example for:

> Grants to physicians and clinicians for studies of prescription products when the studies are of questionable scientific value and require little or no actual scientific pursuit. The grants may nonetheless offer substantial benefits based on, or related to, use of the product.

40. In May 2003, the Inspector General of HHS published further guidance on marketing practices which may constitute kickbacks known as the "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," 68 Fed. Reg. 23731 (May 5, 2003) (the "OIG Guidelines"). In those Guidelines, the OIG further addressed "Research Funding" as follows:

> Manufacturers often contract with purchasers of their products to conduct research activities on behalf of the manufacturer on a fee-for-service basis. These contracts should be structured to fit in the personal services safe harbor whenever possible. Payments for research services should be fair market value for legitimate, reasonable, and necessary services. *Post marketing research activities should be especially scrutinized to ensure that they are legitimate and not simply a pretext to general prescriptions of a drug. Prudent manufacturers will develop contracting procedures that clearly separate the awarding of research contracts from marketing. Research contracts that originate through the sales or marketing functions-or that are offered to purchasers in connection with sales contracts—are particularly suspect.*

Id. at 23735-36 (emphasis added).

41. As described above, compliance with the AKA is a precondition to participation as a health care provider under a Government Health Care Program, including Medicare and the state Medicaid programs. Moreover, compliance with the AKA is a *condition of payment*. As noted above, reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement, and each of the Government

Health Care Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the AKA and with other federal laws governing the provision of health care services in the United States. In other words, if a provider tells CMS or its agent that it provided services in violation of the AKA (or another relevant law), CMS will not pay the claim. Provider agreements as well as the claims themselves contain a certification of compliance with all Medicare laws, regulations, and program instructions including the AKA. *Se, e.g.*, Form CMS-855A; Form CMS-8551 (effective 2001); Form CMS-1500.

42. When a provider submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law, to include without limitation the AKA. In the case of Medicaid, each State's Medicaid Program's applicable certifications also incorporate relevant state law.

DEFENDANT SJM'S UNDERSTANDING OF THE ANTI-KICKBACK ACT

43. DEFENDANT SJM and its employees were aware of the obligations of the AKA. They understood that it was a violation of the AKA to offer or to pay remuneration, by whatever means, to induce a customer like a hospital or doctor to purchase or to recommend the purchase of SJM's devices.

44. For example, after the OIG Guidance was published, the Advanced Medical Technology Association ("AdvaMed") adopted in September 2003 (effective January 1, 2004), a voluntary "Code of Ethics on Interactions with Health Care Professionals" ("the Code" or "the AdvaMed Code") purportedly to guide its members on compliance with the AKA. At that time,

AdvaMed was the trade organization for approximately 1,100 manufacturers of medical devices, diagnostic products, and medical information systems, including DEFENDANT SJM, Medtronic, Guidant, Johnson & Johnson, and Biotronik. These members manufactured 90 percent of the $71 billion of health care technology purchased in the United States each year.

45. The AdvaMed Code addressed, *inter alia*, member -sponsored product training and education, supporting third party educational conferences (through grants, meals, hospitality and expenses), sales and promotional meetings, arrangements with consultants including for research, gifts, providing reimbursement and other economic information, grants and other charitable donations. The Code expressed that research and consulting services should be for *bona fide* consulting services with compensation consistent with fair market value and the payments must be to support "genuine medical research" with 'scientific merit".

46. AdvaMed expected that: "Members will communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code." However, AdvaMed also cautioned that : "All Members have an independent obligation to ascertain that their interactions with Health Care Professionals comply with all applicable laws and regulations. The information provided by the Department of Health and Human Service Office of Inspector General, as well as applicable laws or regulations, may provide more specificity than this Code, and Members should address any additional questions to their own attorneys." AdvaMed Code pp. 5-6 (September 3, 2003).[2]

47. DEFENDANT SJM adopted the AdvaMed Code in September 2003, effective January 1, 2004, and undertook training of its employees regarding the Code. The Code is

[2]Relator has a copy of this Code and will supply it as needed as part of his Fed. R. Civ. P. 26 Initial Disclosures.

incorporated in DEFENDANT SJM's "USSD Policies, Procedures and Guidelines Manual" effective January 1, 2004, of which Relator possesses a copy. DEFENDANT clearly recognized that its actions were governed by the AKA. For example, that Manual states:

> St. Jude Medical has adopted the AdvaMed Code of Ethics on Interactions with Health Care Professionals (the AdvaMed Code). In addition to the AdvaMed Code, the St. Jude Medical Code of Business Conduct dealing explicitly with "Relationships with Physician and Customers" and the Medicare Anti-kickback Law also govern this area.

48. Relator was trained after he was hired by DEFENDANT in November 2004. These trainings consisted of: (1) his reading the employee handbook (including the AdvaMed guidelines), signing, and mailing back the completed signature page to General Counsel, St. Jude Medical, One Lillehei Plaza, St. Paul, MN, USA 55117; (2) his responding to an email in November 2005 which required Relator to reread the compliance material and confirm he had; and (3) his viewing a "Legal Minefield" webcast, also in November 2005.

49. As this Complaint alleges, notwithstanding SJM's understanding of the AKA, and Relator's alerting company officials to the ongoing misconduct on several occasions in 2005-2007, SJM repeatedly violated the AKA in its relationships with Health Care Professionals by paying them sham fees for phony post-market clinical research studies, and by paying for or providing them (and in some cases their spouses) entertainment, gifts, travel, vacations, temporary staff, tickets to sporting events, "educational" events at luxury resorts, and other illegal inducements. These payments had the intended effect of causing HCPs to order or prescribe SJM products and devices instead of a competitor's.

DEFENDANT SJM's KICKBACKS TO HEALTH CARE PROFESSIONALS

50. Relator worked as a TSS in the Cardiac Rhythm Management Division

("CRMD") of SJM. The CRMD was part of the United States Sales Division, which division offers cardiac resynchronization therapy devices, implantable cardio-defibrillators, pacemaker leads, introducer systems, and device programs used to treat certain cardiac arrhythmias. There are over 1,000 sales representatives and about 300-500 TSS's in the CRMD division. The CRMD is one of 5 product category corporate divisions. Relator was part of West Central West ("WCW") , which comprises the states North Dakota, South Dakota, Minnesota, Illinois, Missouri, Iowa, Wisconsin, and Nebraska. WCW is broken down into 6 regions, "WCW1 through WCW5 and WCW-AF," of which Relator was in WCW2, the St. Louis and mid-Missouri areas. The Senior Regional Director of these 6 regions was Doug Helm; below him were about 8-10 sales representatives; below them are approximately 14 TSS's, one of whom was Relator.

51. The DEFENDANT'S entire United States' sales force (consisting of between 1,300-1,500 people) was given unlimited budgets for marketing while Relator worked there. For example, Relator knows of one person in his area who had a weekly expense account of about $5,000 (i.e. over $250,000/year). This allowed the sales force to provide various types of incentives to physicians to order pacemakers and ICDs and to enroll patients in and participate in studies/registries, and to reward physicians for doing so, no questions asked. In addition, the Relator is aware of many examples of lavish entertainment, including but are not limited to, payment of airline tickets, conference fees, baseball tickets, gourmet wine, lavish meals, trips, and vacations.

Phony Post-Market Registries, Studies and Trials As Kickbacks

52. The Scientific Studies Organization (SSO) is a department of SJM. It is located at 15900 Valley View Court, Sylmar, CA 91342. SSO on the surface conducted the post-market clinical studies described below. Each territory is assigned a "Field Clinical Engineer" (FCE) from SSO, to maintain contact with the physicians concerning the studies/clinical trials. In practice, the SJM sales force maintained the contact with the physicians too - in fact, the sales force often filled out the phony trial paperwork, with the physician having no involvement in data input, all as more fully described below.

53. The FCE's were integrally involved with sales, not science. The FCE's actively supported and worked with the sales force to have as many targeted physicians as possible involved in clinical trials/studies. A May 8, 2004 email to the Relator (and others) from management, is illustrative:

> FCE Utilization
>
> We demonstrated an excellent working relationship with the FCE Team throughout the RHYTHM ICD clinical trial. This is substantiated by the North Midwest Area's top position nationally in total implants for the study. I feel that the communication level between the CRM Team and FCE Team... and our ability to function as an integrated Team... are at the highest levels.

54. The clinical trials described herein were clearly designed and implemented for the purpose of paying physicians to prescribe DEFENDANT'S products, not for *bona fide* scientific research. The sales force handling the sham studies earned more money the more clinical trial patients were enrolled. This is confirmed in writing, for instance, in a May 8, 2004 management e-mail to the Relator:

> [C]linical trial devices will count toward the tier level. Pricing of

clinical trial devices will be priced separately outside of this agreement.

55. Although the sales force earned commissions, sales of devices that were associated with a phony trial meant that the sales representative would have his commission reduced by approximately 20% of the cost of the study, to offset the payments made by DEFENDANT to physicians. For example, if a payment was made to a physician in the amount of $1,500, then the sales representative was responsible for $300 of the cost of the study, through commission reduction.

56. Not only would physicians prescribe the SJM devices for patients who did not previously have a pacemaker, they also prescribed the SJM devices as replacements for the competitor (e.g., Guidant, Medtronic) pacemakers. Once the patient's device reached its "elective replacement indicator", the switch was made to the SJM product. This was done by doctors in order to receive study money.

57. Certain cardiologists selected SJM devices based upon the existence of a trial/study, so that if they could use a device which was the subject of a trial/study/registry, they would receive additional payment from DEFENDANT, in addition to professional fees. Examples of such doctors are Drs. AH, MK, and TMcD.

58. Certain cardiologists also billed Medicare and other insurers for the SJM study visits even though they did not perform any work required by the study protocol as described below. Examples of such doctors are Drs. MK and TMcD. These same doctors instructed SJM employees in preparing "superbills" so the doctors could submit claims to Medicare/Medicaid, and SJM employees would prepare such superbills despite the SJM Code of Conduct seemingly prohibiting them from assisting with reimbursement or billing paperwork.

59. Certain cardiologists also failed to fill out the proper paperwork and/or to perform the required services despite what they agreed to as part of the research study agreement, the investigator's agreement, or the protocol. Instead, certain members of the SJM sales force did this for the doctors despite the fact that doing so puts the integrity of the study data at risk. Examples of such doctors are Drs. AH, MK, and TMcD.

60. Relator's supervisor, Doug Helm, was the Senior Regional Director for WCW; with responsibility over Missouri, Illinois, Kansas and Nebraska, permitted or even required the sales force under his supervision to engage in this misconduct. The conduct Relator was personally aware of in his area, was also ongoing in the rest of Mr. Helm's region. As described below, SJM management was aware of the misconduct, but did not take adequate steps to stop, correct, or prevent the misconduct.

61. Unlike the phony trials described herein, SJM has legitimate clinical trials; in fact, the Relator had direct involvement with the "Optimal Lead Place" and ASPEN Studies.

AWARE Trial-(Analysis Of A New AT/AF Detection Algorithm In Patients With Atrial Arrhythmias)

62. AWARE stands for "Analysis of a New AT/AF Detection Algorithm in Patients with Atrial Arrhythmias." The AWARE Trial involved 2 pacemaker models: (1) Identity ADx DR 5380, advertised as the world's smallest dual-chamber, rate-responsive pacemaker;" and (2) Identity ADx XL DR 5386, advertised as "dual-chamber, rate responsive, extended longevity pacemaker." A true copy of the AWARE Trial "Scientific Study Plan" is attached as Exhibit 2. Among other things, it notes that the patient's "insurance company will be billed for all procedures or tests that are standard medical treatment for your condition."

63. For the AWARE Trial, physicians receive $700 for the initial implant of the pacemaker, and $100 for each follow-up visit for the pacemaker, usually done at 1, 3, and 6 months. The trial is a sham, designed to induce physicians to prescribe the above pacemakers and millions of dollars were paid to physicians across the country.

64. The inclusion criteria (see § 3.3.1 of the Study Plan) are not adhered to. About 30% of the patients had no history of Atrial Tachy cardia (AT) or Atrial Fibrillation (AF), inclusion criteria. Instead, they had a diagnosis of AV nodal block (Heart block 1st, 2nd, and 3rd degree) and were enrolled in the studies on that basis alone.

65. Similarly, the exclusion criteria (see § 3.3.2 of the Study Plan) are not adhered to. Patients having terminal cancer and who were expected to live only a few months at best were implanted with pacemakers and put into the trial.

66. At no time did the Relator receive notice from SSO that any patient did not qualify and/or was rejected from the AWARE trial. There is no integrity of the study because it is the sales representative making the call as to whether the patient qualified for the trial.

67. The AWARE trial expressly contemplates physicians' diagnosis and treatment for the "study" subjects. For instance, at § 3.1 of the Study Plan, it states that "The *physician* will provide a clinical diagnosis for all documented episodes on the case report form at *each* visit based on any of the following sources: stored electrograms, surface E.C.G.'s, and/or device diagnostics." (emphasis added). Physicians, however, had little to no involvement or participation in the "study."

68. The articulated "purpose of study" set forth in § 1.2 of the Study Plan, "is to evaluate the incidence of AT/AF and inappropriate detection of AT/AF events in patients with a history of AT

or AF. The AT/AF detection algorithm data and AT/AF detection triggered stored EGMs will be compared with the *physician's* clinical diagnoses." (emphasis added). Yet, the paperwork for the trial was filled out by the SJM sales force. If not accessible to the sales force, which was often the case, data was made up. For instance, at implant, one question concerns what medications the patient is taking. To answer, the sales force would look at the patient surgical chart from implantation and copy the medications written in the chart. For the 1, 3, and 6 month follow-up, they would copy what was written on the enrollment form because they did not have access to the charts in the doctors' offices. There are instances where the medications had changed, but were improperly noted on the paperwork.

69. The sales force would also sign the doctor's signature on the forms or obtain the doctor's signature on a blank form. After the data was filled in by the sales force, a copy of the study paperwork was to be shipped via FedEx to SSO in Sylmar, California, with a copy also kept on file in the physician's office. Relator is aware of at least one instance where the study paperwork was still not returned to the SSO some 6 months after the patient's visit.

70. AWARE enrollments stopped in December 2005. The Relator was told that the quota was met. Although SJM's internal records in 2006 showed a Registry with a number of 1,200 patients in the AWARE Trial (due to a cap), Relator at one point observed records indicating 1,500 or more in the trial. SJM funded this kickback program with at least 1.5 million dollars in payments to physicians.

71. Relator is aware of numerous patients affected by the above-described misconduct who were treated by Drs. MK, AH and TMcD. These doctors were never present for the 1, 3, or 6

month follow-up visit; instead Relator was expected to meet with the patients and fill out the paperwork. Examples of these patients (with names redacted for privacy) are attached hereto in Exhibit 3. All or virtually all of these patients were covered by Medicare by virtue of their age, or by another Government Healthcare Program. Doctors also instructed SJM sales force to fill our "superbills" for their patients' study visits in order to obtain reimbursement from Government Healthcare Programs. For example, Drs. MK and TMcD instructed Relator to do so and he did.

ACT Registry (ADVANCEMENT IN ICD THERAPY)

72. The ACT Registry is a data collection "registry," not a clinical trial. A true copy of the ACT "Registry Plan" is attached hereto as Exhibit 4. According to the "Registry Plan," "[a]ny patient that receives an FDA-approved SJM ICD or CRT-D is eligible for enrollment into the registry." Patients were supposed to be followed for a period of 24 months after implant, with data collected at enrollment, and also at 6, 12, 18, 24 months and at any unscheduled follow-up visits. During the follow-up visits, arrhythmic episode diagnoses, device data and stored electrograms are collected. § 3.2 of the Registry Plan provides that 5,000 patients would be enrolled.

73. Physicians received a total of $2,000 ($500 each for enrollment and $375 each for the follow-up visits, scheduled at 6, 12, 18, and 24 months), and millions of dollars were paid to physicians across the country. Although the stated purpose for the physician payments are "for the legitimate reimbursement of time, effort, and oversight by the Investigator and the professional staff", it was the SJM employee who performed these tasks. For example:

> On or about September 16, 2006, an FCE from SSO was in the office of Dr. MK with Relator. The FCE had Dr. MK sign blank case report forms that were later filled out by the Relator and the FCE from patient charts.
>
> On or about September 19, 2005, a SJM TSS filled out a study form for a patient identified

as "COLLAW" (to protect patient privacy, the study forms identified patients by a "name" that was comprised of the first 3 letter of the patient's last name and the first 3 letters of the patient's first name), an 81 year old male implanted with an ICD on or about March 2, 2005. The TSS also rubber stamped the signature of Dr. MK. On the form, the "Current Drug Therapy" section was not filled in and section number 5, "Clinical Diagnoses" was not answered. Dr. MK was paid $500 by SJM for the submission of this form in addition to what she was reimbursed by Medicare.

On or about March 21, 2006, the follow up form was filled out by an FCE from SSO and also rubber stamped with Dr. MK's signature. Dr. MK was paid $375 by SJM for this follow up visit in addition to what she was reimbursed by Medicare.

Another follow up data form for patient COLLAW was filled out by the FCE from SSO on or about October 17, 2006. The FCE had Dr. MK sign a blank form before the patient came in. The form as filled out later by the FCE listed the patient on two drugs, Lasix and Coreg, and then in the number 3 section "Drug Therapy adjusted" box was marked "no". However, it should have been marked "yes' because the prior visit forms listed no drugs for this patient. Again, Dr. MK was paid $375 by SJM for this follow up visit in addition to what she was reimbursed by Medicare.

Similar misconduct occurred with respect to a patient known as "LUTWIL", a 78 year old male who had an ICD implanted on or about March 23, 2005. The enrollment form was incomplete and inaccurate and the signature may not be that of Dr. MK. Dr. MK was paid $500 by SJM for the enrollment of this patient and also billed Medicare.

At the follow up on or about October 17, 2005, an SJM TSS filled in the data which inaccurately stated that there was no drug adjustment, and rubber stamped the doctor's signature. Dr. MK was paid $375 by SJM for this follow up visit in addition to what she was reimbursed by Medicare.

Patient LUTWIL's follow up on or about April 18, 2006 was done by an SJM FCE from SSO, but again, Dr. MK was paid and billed Medicare.

The patient's follow up on or about October 17, 2006 was also done by the FCE. Dr. MK signed a blank follow up data form prior to the patient visiting. The FCE incorrectly marked the number 6 box (which asked for any changes at the previous follow up visit) "no" even though the prior visit forms showed on line number 6 that the device had been reprogrammed and changes *were* made to the tachycardia parameters. Dr. MK was paid $375 by SJM for this follow up visit and billed Medicare for the ICD follow up.

74. In or about January 2006, CMS established a mandatory ICD registry. *See* "Report of

a New System of Records", 70 FR 72437 (Dec. 5, 2005). The data to be reported is substantially identical to the ACT Registry, which started in January 2004.

75. SJM funded this kickback program with at least $10 million in payments to physicians.

76. Relator is aware of numerous patients affected by the above-described misconduct. In addition, some of the patients were enrolled even though they were outside the specified 45 day window (past the implant date) as required by the protocol. A true copy of a list of ACT Registry patients in WCW2 when Relator was employed at SJM is attached hereto as Exhibit 5 (with patient full names omitted by SJM for privacy reasons). Many of these patients were treated by Drs. MK, AH, and TMcD. All or virtually all of these patients listed on Exhibit 5 were covered by Medicare by virtue of their age, or by another Government Healthcare Program. Doctors also instructed SJM sales force to fill our "superbills" for their patients' study visits in order to obtain reimbursement from Government Healthcare Programs. For example, Drs. MK and TMcD instructed the sales force to do so, and they did; on or about September 19, 2006, Dr. MK instructed Relator on filling out her superbill prior to her billing Medicare/Medicaid. All claims specifically identified for said specifically identified patients from the specifically identified implant date through at least the term of the study are false claims caused by the Defendant.

PROVE Trial - Programming Ventricular Tachycardia Therapy in Patients with a Primary Prevention Implantable Cardioverter-Defibrillator Indication.

77. Patients are eligible for the study once they become scheduled to have an ICD implanted.

78. According to the Study Plan, the articulated purpose of the study "is to determine if

turning ATP therapy "ON" (as part of the VT Therapy) can successfully stop VT episodes before they become VF, which is more serious."(p.2) Relator possesses a true copy of the PROVE Study Information and Consent Form; among other things, it notes that the patient's insurance company will be billed for all procedures or tests that are standard medical treatment, including the costs of the ICD device and implantation procedure, and the follow-up doctor visits.

79. The study is supposed to last for one year after enrollment, with follow-up appointments at 3, 6 and 12 months. Although physicians typically have no involvement with the study, they are paid hundreds of dollars for each patient. Oftentimes, there was no scientific value to the "study" results, among other reasons, because of improper programming at enrollment, and no-shows by patients.

80. The "Research Subject Information and Consent Form" provided to patients misleadingly states: "You do not have to participate in this study to receive treatment for your condition. You can have the standard ICD implantation and programming done without being in the study." (p.3)

81. SJM funded this kickback program with at least $10 million in payments to physicians.

82. Relator is aware of numerous patients affected by the above-described types of misconduct. For example, he is aware of patients "REYLAR" and "MEROLI" who were treated by Dr. MK. Again, Dr. MK signed blank forms (e.g., on or about September 19, 2006) and a TSS and/or an FCE filled in the data on the form. On one occasion, Relator was shown a stack of patient charts by an FCE and told that she (the FCE) had to go through them later. Again, Dr. MK was paid

by SJM.

83. Virtually all of the patients enrolled in PROVE were covered by Medicare by virtue of their age, or by another Government Healthcare Program. Doctors also instructed SJM sales force to fill our "superbills" for their patients' study visits in order to obtain reimbursement from Government Healthcare Programs. For example, Drs. MK and TMcD instructed the sales force to do so, and they did, including on or about September 19, 2006, when Dr. MK instructed Relator on doing so

RARE Trial

84. The RARE trial evaluated the incidence of AF in patients with SSS (Sinus Node Dysfunction) by comparing the Auto Mode Switch (AMS) with the AMS triggered electrograms (EGMs).

85. One of the lead investigators was Dr. AH. The study was ongoing when Relator began working at SJM. The study ended in early 2005. DEFENDANT'S SSO published posters in May 2005. They are: Poster - AB -15-2 and Poster AB9-1. Relator possesses true copies of these Posters. These Posters falsely listed Dr. AH as the author when in fact they were written by SJM and they paid for Dr. AH to go to the annual meeting of the prestigious Hearth Rhythm Society ("HRS") to present the posters. Upon information and belief, nothing further was done with the data.

86. Upon information and belief, physicians including Dr. AH received $1500 per patient enrolled in the study, and millions of dollars were paid in total to physicians across the country. Exhibit 3, *supra* at p. 1 contains examples of patients who were enrolled in the RARE study. On information and belief, in addition to the kickbacks, the other misconduct that afflicted the AWARE

study and the ACT Registry also afflicted the RARE Trial.

RATE Registry (Prevalence of AT/AF in the CRM Device Population)

87. The purpose of the Rate Registry according to the Registry Plan, "is to produce a prospective, outcome-oriented registry to document the prevalence of atrial fibrillation (AF) in the [Cardiac Rhythm Management] CRM population by using the Advanced AT/AF Diagnostics in select SJM devices." Relator possesses a true copy of the RATE "Scientific Registry Plan" and other forms.

88. The study started around October 2006 and it was a prospective, two year data collection registry.

89. Eligible patients are those "that receive a St. Jude Medical (SJM) CRM device with advanced AT/AF diagnostic capabilities (Victory®, Epic®, Atlas® II, or comparable future devices.)"

90. The less expensive SJM devices that also have the advanced AT/AF diagnostic capabilities are not eligible for the study. Further, there is no difference in diagnostics: the Rate Registry ICD devices vibrate and beep, while the less expensive models that do not qualify for the study, only vibrate if an alert indication is met. For example, alert indications include high impedance of the right ventricle lead, or battery voltage at "end of life."

91. Data is supposed to be collected at implant and quarterly, for a total follow-up duration of 24 months.

92. Reimbursement to physicians is $1600 per patient: $400 for enrollment, $200 each for 6, 12, 18, and 24 month follow-up visits, and $100 each for 3, 9, 15 and 21 month follow-up visits,

and millions of dollars were paid to physicians throughout the country. One of the doctors involved in the study was Dr. MK. As with other studies described above, the SJM sales force had doctors such as Dr. MK sign blank patient study related forms.

93. In addition, through this registry, SJM encouraged or required doctors to use a more expensive SJM device (such as Victory, Epic II, Atlas II, or comparable devices coming out in the future) and did not inform doctors of the option of using a less expensive device with the same advanced diagnostic capabilities (e.g., Integrity, Epic, Atlas). As with other studies, SJM personnel had doctors sign blank study forms. For example, on or about October 17, 2006, Dr. MK signed blank forms.

Other Trials As Kickbacks

94. Other phony trials conducted by SSO with the same monetary inducements include but are not limited to: Determine, WBC-MRI, RethinQ, Pas, Freedom, and Response H.F. In December 2007, the Relator became aware that the top 15 enrolling sites across the United States for the Freedom Trial had a total of 159 patients. The top 15 enrollment sites included Long Island Heart Associates in New York, New York; Cardiology and Arrhythmia Consultants in Rochester Hills, Michigan; Jeffrey Goodman in Los Angeles, California; Cardiovascular Associates in Birmingham, Alabama and Sentara-Norfolk General Hospital in Norfolk.

95. For example, Dr. RW enrolled patients at the Veteran's Administration Medical Center in Columbia, Missouri.

Entertainment (And Other Inducements) As Kickbacks

96. As noted above, the DEFENDANT'S entire United States' sales force (consisting of some 1,300-1,500 people) was given unlimited budgets for marketing while Relator worked there. This allowed the sales force to provide incentives to the physicians to order pacemakers and ICDs and to enroll patients in and participate in studies/registries, and to reward physicians for doing so, no questions asked, as described above.

97. In addition, the Relator is aware of many examples of lavish entertainment, including but are not limited to, payment of airline tickets, conference fees, baseball tickets, gourmet wine, lavish meals, payment for seating at the Lake Regional Ball, and fishing trips, including but not limited to a fishing trips to Canada. These kickbacks had the intended effect of influencing physicians to order SJM products. For example:

a. In Spring 2005 (March/April) SJM Senior Sales Representative Jack Conner bought airline tickets for Las Vegas for Dr. MK and his wife. Conner also paid for the HRS Conference fees and hotel. Relator was present when Conner gave Dr. MK an envelope in his office to pay for the trip.

b. On May 19, 2005 SJM Senior Sales Representative Jack Conner purchased St. Louis Cardinals baseball tickets from a broker costing over $200. These tickets were to send Dr. AH's son to the St. Louis at Kansas City baseball game.

c. In August 2005 Dr. JH received St. Louis Cardinal baseball tickets for referring pacer/ICD cases to Dr. AH. SJM Technical Service Representative (TSS) Mel Wyatt purchased the tickets online through the Cardinal Prime Seat Club. Relator was present when Wyatt delivered the tickets to Dr. AH (for Dr. JH). Relator was also present at a lunch when SJM Senior Sales Representative Conner reimbursed Wyatt for the purchase of the tickets.

d. In August 2005 SJM Senior Sales Representative Jack Conner delivered a case of wine to the Moberly Regional Medical Center catheter lab manager, SC. Relator was present in the lab doing an implant when Conner delivered the wine to the break room.

e. On August 24, 2005 SJM Senior Sales Representative Jack Conner and Jason Zitzer arranged for a physician, Dr. BL from Washington University in St. Louis, to come to

the University of Missouri to present at Grand Rounds. Connor left the Grand Cru Steakhouse restaurant his credit card number to purchase dinner for three physicians (the speaker Dr. BL, Dr. RW and Dr. GF) and their wives.

f. In September 2005 SJM Senior Sales Representative Jack Conner purchased a $2,500 fishing trip to Canada for Dr. AH and stated he had done this for the last three years. Conner also stated that he had paid $500 for a table at the Lake Regional Ball for the Lake Regional catheter lab staff.

g. In October 2006 SJM Senior Representative Jack Conner paid $500 for a table at the Lake Regional Ball for Dr. MK's and Dr. TMcD's staff to attend.

98. DEFENDANT also provided or facilitated other kickbacks to induce physicians, including but not limited to providing physicians and other providers with "Grants", and with temporary staff for their offices.

99. DEFENDANT also provided payment to physicians to persuade other physicians to prescribe SJM products, including under the guise of the "HF Referral Program" and the "EP Implanter Program."

100. DEFENDANT also provided kickbacks to physicians in Electrophysiology Fellowship Programs (EP Fellows) around the country. (EP Fellows are physicians who have already completed a Cardiology fellowship who then go on to an electrophysiology). SJM spent or was expected to spend in 2007 a total of $158,172,579 from both the CRM Division and the AF Division, for its Fellows program. SJM indicated in its internal marketing material that a single EP Fellow physician, after graduation, with a conservative utilization of SJM products, will generate $2.7 million annually. (The "Class" of 2007 EP Fellows (100 MDs) $270 million annually - $1.4 billion over five years.)

101. Fellows Symposiums are typically held quarterly by St. Jude, at luxury resorts.

They provide education/marketing, plus help to place the EP Fellows. In order to place the EP Fellows, St. Jude also conducts "core practice searches" for Fellows, helping Fellows to be placed in medical practices. St. Jude "educational department" also furnishes a Board review for the NASPE Exam. The Board review is done in December, prior to the Heart Rhythm Society Meeting which is in April/June. St. Jude even has a "Fellows Manager" who the sales department is supposed to work closely with.

102. Previous Fellows Symposiums include one on February 2, 2007 at the Ritz Carlton in Phoenix, Arizona and another on May 8, 2007 at the Marriott in Denver, Colorado. Also utilized are "CAB Meetings," where St. Jude flies in Fellows for a weekend meeting.

103. It was common practice to supply a hospital with introducers for free and allow the hospitals to bill for them. For example, at Moberly Regional Medical Center, Dr. AH preferred to use TERUMO 7 FR., 10 CM LONG, PINNACLE INTRODUCER SHEATHS,.038" GUIDE WIRE. 10/BOX and TERUMO 9 FR., 10 CM LONG, PINNACLE INTRODUCER SHEATHS,.038" GUIDE WIRE. 10/BOX. The cost to SJM per box was around $75.00. SJM also provided the C Codes needed by the hospital so that they could get reimbursement from Medicare.

104. Also, every time a device was implanted it was common practice to buy lunch or dinner for the staff of the catheter lab. At Moberly Regional Medical Center, Dr. AH also requested that his office get lunch from SJM if one of its devices was implanted at the hospital. Also, anytime a device clinic was done at the doctor's office it was practice to provide lunch to the office staff.

RELATOR'S EFFORTS TO STOP DEFENDANT'S ILLEGAL ACTIVITY

105. As a TSS for SJM, Relator was responsible for assisting with the marketing, sale and distribution of cardiovascular medical devices which included managing the completion of any required paperwork and patient enrollment documents related to the AWARE Trial and ACT Registry and other studies.

106. As noted above, Relator received training from SJM on compliance issues. As a Registered Nurse in the State of Missouri the Relator was held to the Nurse Practice Act which the Board of Nursing can revoke a license if the licensee is found guilty of a crime in which the essential element of fraud or dishonesty is part of the offense.

107. In October 2005, Relator began to question SJM's practice of filling out the study paperwork and signing for doctors to his co-workers. Unbeknownst to Relator at the time, the news media was reporting that on or about October 25, 2005, the United States Attorney's Office for the District of Massachusetts and/or DOJ, had issued subpoenas or was otherwise investigating SJM (and also Guidant, Medtronics and other device makers) regarding various issues relating to implantable cardioverter defibrillators (ICDs) and pacemakers, including: "sales practices," illegal payments or other inducements, possible violations of the Anti-Kickback Act and false claims statutes, relationships with doctors, use of incentives to doctors to use the device maker's products, and making excessive payments to doctors to enroll patients in post marketing evaluation studies of their devices (using product surveys) as a way of increasing sales. At least one article refers to SJM reporting that the subpoenas request documents on "cardiac devices, components, and monitoring equipment and services," as well as "general

industry practices."[3]

108. When his co-workers' advice did not match with Relator's understanding from his company training, Relator contacted Paul Bae, SJM Vice President of Human Resources and Compliance Officer, and spoke with him in late October/early November 2005 to report concerns with the manner in which the AWARE Trial and ACT Registry paperwork and patient enrollment documents were completed. Based on that conversation, Relator understood that it was improper for the sales force to fill in any information except identifiers such as facility name or patient's name on the top of the forms; the physician or his staff needed to fill in the collected data, and the physician was to sign as the investigator.

109. Relator's co-workers disagreed with his understanding. Thereafter, Relator and other members of the sales force attended a presentation called "Legal Minefield". After that presentation, Relator contacted the presenter, Neal Williams, SJM Associate General Counsel, on November 15, 2005. Relator's meeting with Williams did not change his understanding. Relator's understanding remained the same as after his conversation with Mr. Bae: that he should not fill out enrollment and data collection forms even if the study center would sign the form—doing so would put the integrity of the study data at risk. In other words, Relator's understanding was that neither he nor anyone else

[3]Prior to these media reports, there were reports beginning with an article in the New York Times on August 2, 2005, followed by another NYT article on September 27, 2005, and an October 3, 2005 article in Washington Business Information Inc.'s Devices & Diagnostics Letter. These articles focused on Guidant, but also discuss SJM, and as to both allege that they used post marketing evaluation studies to persuade doctors to use their devices. After the October 2005 articles reporting on the subpoenas,, there are later articles; these largely just report on the subpoenas and prior media reports. The last one of these articles pre Mr. Donigian's filing appears to be a March 25, 2006 NYT article; that article refers to allegations the companies use illegal inducements to get doctors to use their products and provided doctors with excessive payments to enroll patients in post-marketing studies of their devices as a way of increasing sales.

who was part of the sales force was to complete the ACT Registry or AWARE Trial patient enrollment documents, data collection forms, or implant information reports.

110. Nevertheless, his supervisor, Doug Helm, SJM's Regional Sales Manager for the WCW area, continued to require Relator to complete the AWARE Trial and ACT Registry patient enrollment documents, data collection forms, and implant information reports. Other co-workers criticized Relator saying he was causing the company harm and saying words to the effect of "DOJ is going to see the e-mail and question what we were doing". Relator responded to the effect that "if what the company was doing was legal then there shouldn't be any issue."

111. In December 2005, one of Relator's co-workers told Relator he was sending him some new forms they could properly fill out for the studies. Upon receipt, Relator noticed that the forms were the same as before, except there was not a place for signature by the physicians. Relator again contacted Mr. Williams. Thereafter, Relator understood that he could not fill out any forms the doctors agreed to submit as part of the research study agreement, the investigator's agreement, or the protocol.

112. During this time Relator responded to an e-mail from Kevin O'Malley (from the SJM General Counsel's office) asking (routinely) if he knew of any SJM Policy violations; Relator checked yes. A reply e-mail said someone from the General Counsel would be in touch with the Relator if they had any questions. When no one followed up with Relator, he called SJM's hotline number and reported numerous of the violations alleged herein.

113. In February 2006, Relator again contacted Mr. Bae to report concerns with the manner in which the AWARE Trial paperwork and patient enrollment documents were completed. At this

time and also in April 2006, Relator also reported incidents of retaliation by co-workers based on Relator's prior reports of compliance violations. In the interim, in March 2006, his supervisor Doug Helm gave him negative marks in his annual performance review because of his communications about the study paperwork and other kickbacks.

114. Relator also reported to management the common use of improper and illegal kickbacks by the SJM sales force including the improprieties concerning the AWARE trial and ACT Registry. This included many of the kickbacks described herein.

115. In May 2006, attorneys for AdvaMed (Reed & Smith) met with one of Relator's co-workers to discuss Relator's reported violations.

116. While employed by DEFENDANT SJM, Relator repeatedly questioned, investigated, and reported internally and subsequently to appropriate Government officials (prior to filing this action), SJM's illegal practices.

117. SJM failed and refused to change its policies and practices that obligated Relator to acquiesce in, or actively participate in, violations of Medicare and Medicaid compliance requirements and the Federal Anti-Kickback Law. That the actions of SJM of which Relator was complaining can constitute the basis for an FCA violation is confirmed by a press release issued December 23, 2009, by the United States Attorney's Office for the District of Massachusetts, in which DOJ announced that the Government had reached a $22 million civil settlement with Boston Scientific Corporation to resolve allegations that its subsidiary, Guidant Corporation, a competitor of SJM's, used post-market studies as vehicles to pay kickbacks to induce physicians to implant Guidant pacemakers and defibrillators. (This press release is a public record and can

be found on the U.S. Attorney's Office's website).

FALSE CLAIMS

118. In legitimate FDA registered, clinical trials, physicians do not bill the patients' insurance company (including Medicare or Medicaid) for the underlying physician services or products used. Similarly, products or pharmaceuticals used in legitimate FDA registered clinical trials are generally donated by the manufacturer; not billed to the patients' insurance company (including Medicare or Medicaid).

119. As a result of DEFENDANT SJM's kickbacks to Health Care Professionals, as alleged above, SJM caused such HCPs to submit false and fraudulent claims to Government Health Care Programs or to make or use false records or statements material to false or fraudulent claims paid or approved by the Government. Examples of patients for whom such false claims and/or false statements were made are described above and also are listed in Exhibits 3 and 5.

120. All claims for these specifically identified patients that were submitted to Medicare during and after the specifically identified kickbacks were paid by Defendant, are false claims. The Relator has further detailed information, including dates of service and patient information and forms, however, he does not believe it is appropriate to disclose such information in a to be public filing such as this Third Amended Complaint. He will file such information as deemed necessary by this Court and under such conditions as this Court believes to be appropriate. He will also produce such information in connection with his Fed. R. Civ. P. Rule 26 Initial Disclosures and pursuant to discovery subject to any necessary Protective Order.

LEGAL CLAIMS FOR RELIEF

Count I- Federal False Claims Act

121. Relator realleges and incorporates by reference each allegation in each of the preceding paragraphs as though fully set forth herein.

122. This is a claim by Relator, on behalf of the UNITED STATES OF AMERICA, for treble damages and penalties under the FCA, 31 U.S.C. §§ 3729-3733, against SJM for knowingly causing to be presented false or fraudulent claims to Government Healthcare Programs for payment or approval, and/or for making, using, or causing to be made or used, a false record or statement material to false or fraudulent claims paid or approved by the Government. DEFENDANT'S misconduct has been ongoing for at least the past six years preceding the filing of Relator's original Complaint, in the District of Massachusetts and elsewhere throughout the United States through the date of Relator's constructive discharge from his employment in April 2007. The false records or statements were: (a) HCP's false certifications and representations of full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the AKA; and (b) false information or material omissions in study paperwork.

123. DEFENDANT has made, used and/or caused to be made or used such false statements or records and has caused to be presented claims for payment or approval to the Government Healthcare Programs, knowing such statements or records were false and such claims were false or fraudulent.

124. DEFENDANT knew that its marketing strategy of: (1) offering kickbacks to physicians and healthcare providers in the form of free equipment and other items, and cash

payments for phony clinical trials and phony clinical registries; and (2) providing lavish entertainment and other inducements, was in violation of the AKA, 42 U.S.C. §1320a-7b(b)(2)(A), including because its own written compliance materials prohibited same.

125. As a result of SJM's kickbacks to induce HCP's to purchase, order, or recommend or arrange for the purchasing or ordering of SJM's products, in violation of the AKA, all of the claims SJM caused HCP's to present to Government Health Care programs for those products are false or fraudulent.

126. By virtue of the false or fraudulent claims, records or statements that SJM caused to be presented, the UNITED STATES OF AMERICA has suffered actual damages and is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false or fraudulent claim presented or caused to be presented and each false statement or record made, used or caused to be made or used.

WHEREFORE, Relator respectfully requests this Court to enter Judgment against DEFENDANT, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false or fraudulent claims and statements alleged within this Complaint, as the Federal Civil False Claims Act (FCA), 31 U.S.C. §§ 3729, *et seq.* provides;

(b) That civil penalties of $11,000 be imposed under the FCA for each and every false or fraudulent claim or statement that DEFENDANT caused to be presented to the Government Healthcare Programs;

(c) That pre- and post-judgment interest be awarded, along with reasonable attorney's fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant to the FCA;

Count II- Retaliation – 31 U.S.C. § 3730(h)

127. Relator realleges and incorporates by reference each allegation in each of the preceding paragraphs as though fully set forth herein.

128. DEFENDANT SJM has a duty under the False Claims Act, to refrain from taking retaliatory actions against employees in violation of 31 U.S.C. § 3730(h).

129. After reporting the common use of improper and illegal kickbacks by the SJM sales force as detailed above, SJM retaliated against Relator by failing to increase his compensation, failing to timely pay Relator's expense reimbursements, restricting Relator's sales territory, failing to consider Relator for an open sales representative position, providing him with a negative performance review, and tolerating threat of physical harm by co-workers at a Christmas party at Doug Helm's house in December 2006.

130. The policies and practices of SJM required that Relator disregard, acquiesce in, or actively participate in, violations of Medicare and Medicaid compliance requirements and the federal Anti-kickback law, as a condition of employment and advancement within the company.

131. Relator took lawful actions in furtherance of a False Claims Act action, including investigation for, testimony for, or assistance in an action filed under this section and, as such, engaged in protected activity under the False Claims Act and other laws

132. While employed by DEFENDANT SJM, Relator repeatedly questioned, investigated, and reported internally and subsequently to appropriate Government officials, SJM's illegal practices.

133. In retaliation for his efforts, while employed by SJM, DEFENDANT harassed, intimidated, and otherwise created a hostile work environment for Relator in retaliation for his objections to and reporting of SJM's wrongdoing and his investigation and other acts in furtherance of this action, without good cause.

134. On or about April 9, 2007, Relator learned that SJM would not remedy its retaliatory conduct toward Relator, and would not change its policies and practices that obligated Relator to acquiesce in, or actively participate in, violations of Medicare and Medicaid compliance requirements and the Federal Anti-kickback Law, as a condition of employment and advancement within the company.

135. Based on SJM's failure and refusal change its policies and practices that obligated Relator to acquiesce in, or actively participate in, violations of Medicare and Medicaid compliance requirements and the Federal Anti-Kickback Law as a condition of employment and advancement within the company, Relator correctly concluded that his future employment with the company would place him in legal jeopardy, and Relator further concluded that he could not reasonably be expected to subject himself to legal jeopardy as a condition of his employment.

136. SJM constructively discharged Relator by requiring that Relator acquiesce in, or actively participate in, violations of Medicare and Medicaid compliance requirements and the Anti-Kickback Law as a condition of employment and advancement within the company, and by placing

Relator in legal jeopardy; and accordingly Relator notified SJM that his employment would terminate effective April 17, 2007, because SJM refused to address or correct the ongoing violations of Medicare and Medicaid compliance requirements.

137. Immediately following Relator's resignation, SJM accelerated the termination of Relator's employment by removing him from his job duties effective April 9, 2007.

138. Relator provided SJM a reasonable opportunity to resolve the ongoing violations of Medicare and Medicaid laws and regulations and the Anti-Kickback law, prior to submitting his resignation.

139. The actions of DEFENDANT damaged and continue to damage Relator in violation of 31 U.S.C. § 3730(h), in an amount to be determined at trial.

140. As a direct and proximate result of SJM's actions, Relator has been damaged through the loss of past and future wages and benefits.

141. DEFENDANT'S conduct damaged Plaintiff by causing Plaintiff to suffer severe anxiety and depression that necessitated medical treatment and medication.

142. DEFENDANT SJM acted maliciously and with wanton disregard for Plaintiff/Relator and his legal rights.

143. Pursuant to 31 U.S.C. § 3730(h), Relator is entitled to damages, litigation costs and reasonable attorneys' fees incurred in the vindication of his reputation and the pursuit of his retaliation claims.

WHEREFORE, Relator respectfully requests this Court to enter Judgment against DEFENDANT, as follows:

(a) That the Court award all proper damages in favor of Relator as a result of DEFENDANT'S conduct in violation of 31 U.S.C. § 3730(h) including two times back pay, front pay and loss of future earnings, attorneys fees, costs and expenses, and damages for emotional distress.

(b) That this Court award such other and further relief as it deems proper, including without limitation pre and post judgment interest and punitive damages.

Count III--State Of Missouri Wrongful Discharge

144. Relator realleges and incorporates by reference each of the preceding paragraphs as though fully set forth herein.

145. Relator reported to management the common use of improper and illegal kickbacks by the SJM sales force including the improprieties concerning the AWARE trial.

146. After reporting the common use of improper and illegal kickbacks by the SJM sales force, SJM retaliated against Relator by failing to increase his compensation, failing to timely pay Relator's expense reimbursements, restricting Relator's sales territory, giving him a negative performance review, failing to consider Relator for an open sales representative position and tolerating threat of physical harm by co-workers at a Christmas party at Doug Helm's house in December 2006.

147. The policies and practices of SJM required that Relator disregard, acquiesce in, or actively participate in, violations of Medicare and Medicaid compliance requirements and the federal Anti-kickback law, as a condition of employment and advancement within the company.

148. Relator took lawful actions in furtherance of a False Claims Act action, including investigation for, testimony for, or assistance in an action filed under this section and, as such, engaged in protected activity under the False Claims Act and other laws

149. While employed by DEFENDANT SJM, Relator repeatedly questioned, investigated, and reported internally and subsequently to appropriate Government officials, SJM's illegal practices.

150. In retaliation for his efforts, while employed by SJM, DEFENDANT harassed, intimidated, and otherwise created a hostile work environment for Relator in retaliation for his objections to and reporting of SJM's wrongdoing and his investigation and other acts in furtherance of this action, without good cause.

151. On or about April 9, 2007, Relator learned that SJM would not remedy its retaliatory conduct toward Relator, and would not change its policies and practices that obligated Relator to acquiesce in, or actively participate in, violations of Medicare and Medicaid compliance requirements and the Federal Anti-kickback Law, as a condition of employment and advancement within the company.

152. Based on SJM's failure and refusal change its policies and practices that obligated Relator to acquiesce in, or actively participate in, violations of Medicare and Medicaid compliance requirements and the Federal Anti-Kickback Law as a condition of employment and advancement within the company, Relator correctly concluded that his future employment with the company would place him in legal jeopardy, and Relator further concluded that he could not reasonably be expected to subject himself to legal jeopardy as a condition of his employment.

153. SJM constructively discharged Relator by requiring that Relator acquiesce in, or actively participate in, violations of Medicare and Medicaid compliance requirements and the Anti-Kickback Law as a condition of employment and advancement within the company, and by placing Relator in legal jeopardy; and accordingly Relator notified SJM that his employment would terminate effective April 17, 2007, because SJM refused to address or correct the ongoing violations of Medicare and Medicaid compliance requirements.

154. Immediately following Relator's resignation, SJM accelerated the termination of Relator's employment by removing him from his job duties effective April 9, 2007.

155. Relator provided SJM with an opportunity to remedy DEFENDANT'S unlawful conduct and provided DEFENDANT with sufficient time to remedy its unlawful conduct, but DEFENDANT failed to take corrective action and failed to alleviate the unlawful obligations and expectations that DEFENDANT imposed on Plaintiff., prior to submitting his resignation.

156. The actions of DEFENDANT damaged and continue to damage, in an amount to be determined at trial.

157. SJM's actions violated the public policy of the State of Missouri because Relator objected to, and refused to participate in, acts by SJM that violate laws of the United States, and that violate R.S.Mo. § 570.150.1 which prohibits acts of commercial bribery, and which establishes that a person commits the crime of commercial bribery:

> (1) If he solicits, accepts or agrees to accept any benefit as consideration for knowingly violating or agreeing to violate a duty of fidelity to which he is subject as: (a) Agent or employee of another . . . (d) Officer, director, partner, manager or other participant in the direction of the affairs of an incorporated or unincorporated association;
> (2) If as a person who holds himself out to the public as being engaged in the business of making disinterested selection, appraisal or criticism of commodities or services, he solicits, accepts or agrees to accept any benefit to influence his selection, appraisal or criticism;

(3) If he confers or offers or agrees to confer any benefit the acceptance of which would be criminal under subdivisions (1) and (2) of this section.

157. As a direct and proximate result of SJM's actions, Relator has been damaged through the loss of past and future wages and benefits.

158. DEFENDANT'S conduct damaged Plaintiff by causing Plaintiff to suffer severe anxiety and depression that necessitated medical treatment and medication.

159. Relator is entitled to recover punitive damages from DEFENDANT because DEFENDANT SJM acted maliciously and with wanton disregard for Plaintiff/Relator and his legal rights, and punitive damages in an amount not less than $2,000,000.00 are necessary to deter DEFENDANT and others from similar conduct.

WHEREFORE, Relator respectfully requests this Court to enter Judgment against DEFENDANT, as follows:

(a) That the Court award all proper damages in favor of Relator as a result of DEFENDANT'S conduct in violation of § 570.150.1 including actual damages, exemplary damages, attorneys fees, costs and expenses.

(b) That this Court award such other and further relief as it deems proper, including without limitation pre and post judgment interest.

PRAYERS FOR RELIEF

Relator prays that the Court enter the relief requested above and such other relief as the Court deems appropriate and just.

PLAINTIFF DEMANDS A JURY TRIAL

Dated: January 19, 2010

Respectfully submitted,

Suzanne E. Durrell mm

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CERTIFICATE OF SERVICE

I hereby certify that I have caused a true and correct copy of the foregoing Third Amended Complaint to be delivered via first class mail to counsel for each government Plaintiff on January 21, 2010.

Suzanne E. Durrell mm

Suzanne E. Durrell

EXHIBIT 1

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Medicare Reimbursement Overview: ICD and CRT-D Implant and Replacement Procedures

ICD (implantable cardioverter defibrillator) and CRT-D (cardiac resynchronization therapy – defibrillator) procedures can be performed in inpatient or outpatient settings. The selection of site-of service is made by the physician based on a number of considerations including the patient's medical history and current medical needs. The admission decision must be supported in the medical record.

PHYSICIAN AND OUTPATIENT SURGICAL SERVICES

CRT-D system implant requires the insertion of the left ventricular (LV) lead (33225) which is reported separately in addition to insertion of the single or dual chamber ICD system (33249). For physician services, the LV lead procedure is exempt from the multiple procedure discount.[1] In the hospital outpatient and ambulatory surgical center (ASC) settings the discount applies.

Replacement of the ICD/CRT-D generator is reported with a code for the removal of the generator (33241) and another code for insertion of the generator (33240). Payment for the removal is subject to the multiple procedure discount.

Physician ***(Effective dates: January 1 – December 31, 2009)***

CPT Code	Short Descriptor	Base Payment
33249	Insertion of ICD system (pulse generator and leads)	$918.62
33240	Insertion of ICD pulse generator, single or dual	$472.47
33241	Removal of ICD pulse generator, single or dual	$230.83
+33225	Insertion of LV lead	$464.90

+ = Add-on code. Add-ons are always performed in addition to the primary procedure and are never reported as a stand-alone code.

Ambulatory Surgical Center ***(Effective dates: January 1 – December 31, 2009)***

CPT Code	Short Descriptor	SI	Base Payment
33249	Insertion of ICD system (pulse generator and leads)	T	$27,024.22
33240	Insertion of ICD pulse generator, single or dual	T	$20,249.29
33241	Removal of ICD pulse generator, single or dual	T	$893.10
+33225	Insertion of LV lead	T	$8,123.29

SI = Status Indicator. T= multiple procedure reduction applies.
+ = Add-on code. Add-ons are always performed in addition to the primary procedure and are never reported as a stand-alone code.

[1] Under the multiple procedure discount rule, surgical procedures furnished during the same operative session are discounted. The full amount is paid for the surgical procedure with the highest payment; fifty percent is paid for any other surgical procedure(s) performed at the same time.

Hospital Outpatient ***(Effective dates: January 1 – December 31, 2009)***

CPT Code	Short Descriptor	APC	SI	Base Payment
33249	Insertion of ICD system (generator and leads)	0108	T	$28,250.63
33240	Insertion of ICD generator, single or dual	0107	T	$21,139.88
33241	Removal of ICD generator, single or dual	0105	T	$1,461.70
+33225	Insertion of LV lead	0418	T	$9,144.16

SI = Status Indicator. T= multiple procedure reduction applies. S= not discounted when multiple procedures performed
+ = Add-on code. Add-ons are always performed in addition to the primary procedure and are never reported as a stand-alone code.

Product C-codes for Hospital Outpatient Setting

C-Code	Short Descriptor
C1721	ICD, dual-chamber
C1722	ICD, single-chamber
C1882	CRT-D
C1895	ICD lead, endocardial dual coil
C1777	ICD lead, endocardial single coil
C1896	ICD lead, other than endocardial single or dual coil
C1900	LV lead
C1898	Pacemaker lead

HOSPITAL INPATIENT SERVICES

ICD and CRT-D procedures are assigned to the same set of DRGs based on the presence or absence of cardiac catheterization; the presence or absence of AMI, heart failure or shock; and the presence or absence of major complications and comorbidities (MCC). Device type (ICD or CRT-D) does not influence DRG assignment.

Hospital Inpatient ***(Effective dates: October 1, 2008 – September 30, 2009)***

ICD-9-CM Procedure Code	Short Descriptor	MS-DRG	Descriptor	Base Payment
37.94 **00.51**	Implant of ICD system Implant of CRT-D system	222	ICD implant w cardiac cath w AMI/HF/Shock w MCC	$48,011
		223	ICD implant w cardiac cath w AMI/HF/Shock w/o MCC	$34,906
		224	ICD implant w cardiac cath w/o AMI/HF/Shock w MCC	$44,155
		225	ICD implant w cardiac cath w/o AMI/HF/Shock w/o MCC	$32,764
		226	ICD implant w/o cardiac cath w MCC	$37,267
		227	ICD implant w/o cardiac cath w/o MCC	$27,741
37.96 **37.98** **00.54**	Implantation of ICD pulse generator only Replacement of ICD pulse generator only Implantation/ Replacement of CRT-D pulse generator only	245	ICD generator procedures	$22,123

Disclaimer: *This information is provided to assist the recipient to understand the alternative codes and payment amounts that may be available when St. Jude Medical products are used. Note that codes, coverage, and payment can vary from setting to setting, and from insurer to insurer. This information does not guarantee that use of any particular codes will result in coverage or payment at any specific level. Insurers make reimbursement decisions according to the insurer's evaluation of the patient's medical needs. The hospital and physician should select the code or codes that most accurately describe the patient's conditions and the procedures performed and products used. The recipient should fully comply with the insurer requirements in submitting claims.*

EXHIBIT 2

SCIENTIFIC STUDY PLAN

This study uses FDA approved devices only.

ST. JUDE MEDICAL

AWARE: Analysis of a New AT/AF Detection Algorithm in Patients with Atrial Arrhythmias

January, 2005
CD0165, Rev. C

St. Jude Medical
Scientific Studies Organization
15900 Valley View Court
Sylmar, CA 91342

CRD #: 263
Study #: 03-06-001

STUDY SPONSOR

St. Jude Medical
Scientific Studies Organization (Dept. 751)
Telephone: 1-800-933-9956, ext. 2050, 2054, 2052, 2113, 2183, 2594 and 4278
Fax: 1-866-632-8191
15900 Valley View Court
Sylmar, CA 91342

TABLE OF CONTENTS

1.0 INTRODUCTION

1.1 Background

Although there have been considerable technologic advances in the management of atrial fibrillation (AF), providing effective treatment remains an on-going challenge. Prior to providing appropriate treatment for AF, accurate and comprehensive diagnostics are needed. Such diagnostics are imperative for detecting AF as it has been shown that asymptomatic episodes of AF occur with at least a 12 times higher incidence than symptomatic episodes in patients with implantable cardiac rhythm devices.[1,2] Moreover, atrial tachyarrhythmias (AT) also need appropriate detection as they often occur in patients with AF and may precede AF initation.[3,4]

Previously, Auto Mode Switch (AMS) algorithms have been used extensively to assess the frequency and pattern of AT or AF in dual-chamber pacemakers. Although these algorithms provide effective therapy in stabilizing ventricular rates during atrial arrhythmias [1,2], AMS has limited diagnostic capabilities. St. Jude Medical has introduced a new AT/AF detection algorithm, available in the new ADx family of pacemakers, which is designed to reliably and quickly detect the presence of AT/AF episodes, as well as provide the clinician with enhanced long-term patient diagnostics. Such diagnostics could help evaluate changes in patient condition and the efficacy of drug and device treatment. The AT/AF algorithm provides the clinician with a weekly AT/AF Burden Trend and AT/AF Frequency for up to 28 weeks. In addition, an AT/AF Episode Histogram is available, which provides detailed information on both episode rates and episode durations. Moreover, an AT/AF Log lists all recorded AT/AF episodes and provides the date, time, duration, and maximum rate achieved for each episode.

An AT/AF event is detected when the average atrial rate exceeds the programmed Atrial Tachycardia Detection Rate (ATDR). If the device measures five or more consecutive events with both an interval average and current interval rate above the programmed ATDR, the device classifies the event as AT/AF. When the device measures nine events with both an interval average and current interval rate below the programmed ATDR, the rhythm is classified as sinus, which marks the end of the AT/AF event. A corresponding AT/AF Detection stored electrogram (EGM) trigger is available to allow an EGM to be recorded when the AT/AF detection criteria are met. [5]

This study is designed to evaluate the accuracy of the AT/AF detection algorithm. The data will also be used for evaluating improvements in AT/AF detection performance in future devices.

The study is sponsored by St. Jude Medical (hereinafter referred to as SJM).

1.2 Purpose of Study

The purpose of this study is to evaluate the incidence of AT/AF and inappropriate detection of AT/AF events in patients with a history of AT or AF. The AT/AF detection algorithm data and AT/AF detection triggered stored EGMs will be compared with the physicians' clinical diagnoses.

2.0 STUDY OVERVIEW

2.1 Objectives/Hypothesis

The AT/AF detection algorithm has a high positive predictive accuracy (>90%) of appropriately detecting AT/AF events. The performance of the AT/AF detection algorithm is equivalent to conventional Auto Mode Switch (AMS) algorithms.

2.2 Primary Endpoint

The primary endpoint of this study is the positive predictive accuracy of identifying AT/AF by comparing device AT/AF detection algorithm data and AT/AF triggered stored EGMs with the physicians' clinical diagnoses.

2.3 Secondary Endpoint

The secondary endpoints include:

- Frequency of AT/AF (# of AT/AF events per week)
- AT/AF Burden (% time in AT/AF per week)
- Time to first AT/AF episode
- Asymptomatic AT/AF episodes
- Number and duration of total AT/AF episodes
- Number of mode switch episodes
- % time in mode switch
- % atrial pacing
- Incidence of inappropriate atrial sensing

3.0 STUDY DESIGN

3.1 Study Methods

This will be a prospective follow-up study. All patients will receive a St. Jude Medical Identity™ ADx DR Model 5380 or XL DR Model 5386 (or comparable FDA approved SJM dual chamber pacemaker with the AT/AF Detection Algorithm and stored EGMs). The physician may choose any compatible leads for use with the pacemaker. Chronically implanted leads may be used in this study.

Patients may be enrolled into the study within 2 weeks of device implant. Patients will be followed for 6 months after enrollment. The data will be collected at enrollment (including patient history), 1 month, 3 months, 6 months, and at any unscheduled follow-up visits. During the follow-up visits, device data (via printouts and floppy diskette) and stored electrograms will be collected. The AT/AF diagnostics and stored EGMs triggered by AT/AF detection, as well as surface ECGs at follow-up (if available), will be used to verify AT/AF episodes. The physician will provide a clinical diagnosis for all documented episodes on the case report form at each visit based on **any** of the following sources: stored electrograms, surface ECGs, and/or device diagnostics. To maximize accuracy, positive predictive value analysis will not begin until programming is confirmed to be correct after implant.

3.2 Sample Size

The AT/AF detection algorithm will be considered to be effective in detecting AT/AF events if one of the following 2 objectives is achieved:

Objective 1: Demonstrate a high positive predictive accuracy (>90%) of appropriately detecting AT/AF events.
Objective 2: Demonstrate equivalent performance when compared to a conventional AMS algorithm.

Objective 1 is based on the hypothesis that the AT/AF detection algorithm appropriately detects AT/AF events with a high level of accuracy. Previous studies using similar algorithms have demonstrated a positive predictive accuracy for AT/AF detection of $\geq 96\%$.[3,4,6] Assuming the positive predictive accuracy of identifying AT/AF using the new AT/AF detection algorithm is comparable with the results from other studies, 772 episodes with stored EGMs will be needed to achieve an 80% power to detect a 96% positive predictive accuracy at 0.05 significance level. Based on the ATTEST study, the frequency of AT/AF in patients with a history of symptomatic AF or AT is 1.3 episodes per month[6]. With a follow-up period of 5 months, it is estimated each patient will have 6 AT/AF episodes (implant to 1 month period will be used as a lead-in period to appropriately adjust device programming). Therefore, a sample size of 129 patients will be needed.

Objective 2 is based on the evaluation of the AMS algorithm in the ongoing St. Jude Medical "**RARE** - **R**eported **A**trial Fibrillation and Inapp**r**opriate Mod**e** Switch in Sick Sinus Syndrome Patients" study. The RARE study evaluates the incidence of AF and inappropriate mode switching in patients by comparing device AMS data with the AMS Entry triggered stored EGMs. Both RARE and AWARE utilize proprietary algorithms to indicate AF or AT in patients. While AWARE utilizes the AT/AF detection algorithm, the RARE study uses AMS. In order to compare the arrhythmia detection performance of the AMS algorithm in RARE to the AT/AF Detection algorithm in AWARE, the AWARE sample size has been increased to equal RARE, which is 1125 patients.

Therefore, to meet the sample size conditions of Objectives 1 and 2, a minimum of 1125 patients is required. It is expected that some patients will not be able to complete the study for various reasons. As a result, it is estimated that a total of **1200 patients** are needed to meet the sample size requirements.

3.3 Subject Selection

The investigator has the responsibility of screening all potential patients to determine if they meet **all** of the inclusion criteria. Patients with **any** of the indications outlined in the exclusion criteria must be excluded from participating in this study.

3.3.1 Inclusion Criteria

- Patient has a standard indication for a dual chamber pacemaker.
- Patient is in sinus rhythm or cardioverted into sinus rhythm at time of pacemaker implant.
- Patient has had an episode of symptomatic AT or AF within the last 6 months.
- Patient is geographically stable and willing to comply with the required follow-up schedule.
- Patient's antiarrhythmic medications are maintained stable during the study.

3.3.2 Exclusion Criteria

- Patient has an existing ICD or is being considered for an ICD implant.
- Patient is being considered for a bi-ventricular pacing pacemaker
- Patient's life expectancy is less than 6 months due to other medical conditions.

4.0 PROCEDURE

4.1 Enrollment

Patients will receive a St. Jude Medical Identity™ ADx DR Model 5380 or XL DR Model 5386 (or comparable FDA approved SJM dual chamber pacemaker with the AT/AF Detection Algorithm and stored EGMs) and compatible leads. Chronically implanted leads may be used in this study. Standard operating procedures for pacemaker and lead implant will be followed.

1. Program the Stored EGMs as described below:

Parameter	**Setting**
Sampling Option	Continuous
No. of stored EGMs	Maximum available
Channel	Atrial *
Atrial EGM Configuration	Atip – Aring *
Atrial Dynamic Range	± 3.0 mV * (Nominal)
AT/AF Detection	**ON (All other triggers: OFF)**

2. Evaluate the far field R-wave:
   - Set up to view both atrial and ventricular EGMs on the screen during a capture test.
   - Overdrive the ventricle to continuously pace.
   - Freeze the EGMs and view at a sweep speed of 50 mm/sec.
   - If a Far-R signal is being sensed by the atrial channel, measure from the beginning of the V pace to the Far R signal and document on the Case Report Form (CRF), then program the PVAB 40 msec longer.

3. Program device related parameters as recommended in the following table:

Parameter	Setting
Post Vent. Atrial Blanking (PVAB)	40 ms longer than measured Far R interval (V paced)
Atrial Refractory (PVARP)	As short as physiologically appropriate
Rate Responsive PVARP/VREF	Medium or High
Atrial Sensitivity	0.1 - 0.5 mV
Auto Mode Switch	DDI(R)
ATDR	200 ppm*

***Settings may be optimized at the physician's discretion to better view and detect AT/AF.**

4. Complete the Patient History/Enrollment CRF.
5. Print out and attach Measured Data, Stored EGM Parameters, and Final Programmed Parameters.

4.2 Follow-up (1, 3, 6 months ± 2 weeks and Unscheduled Visits)

1. Print out the following reports:
   - Initial Programmed Parameters
   - Measured Data
   - Event Histogram
   - Heart Rate Histogram
   - AT/AF Episode Histogram and Log
   - AT/AF Burden Trend and Log
   - AF Suppression Histogram (if available)
   - Stored EGMs
   - Stored EGM Parameters
2. **Number all stored EGMs and/or ECGs.**
3. **Clear all diagnostics** (including EGMs).
4. Evaluate the far field R-wave as indicated in *Section 4.1* and record the V pace to Far R interval on the case report form.
5. **Confirm Stored EGMs are programmed as recommended in the following table:**

Parameter	Setting
Sampling Option	Continuous
No. of stored EGMs	Maximum available
Channel	Atrial *
Atrial EGM Configuration	Atip – Aring *
Atrial Dynamic Range	± 3.0 mV * (Nominal)
AT/AF Detection	**ON (All other triggers: OFF)**

6. Confirm device parameters are programmed as recommended in the following table:

Parameter	Setting
Post Vent. Atrial Blanking (PVAB)	40 ms longer than measured Far R interval (V paced)
Atrial Refractory (PVARP)	As short as physiologically appropriate
Rate Responsive PVARP/VREF	Medium or High
Atrial Sensitivity	0.1 - 0.5 mV
Auto Mode Switch	DDI(R)
ATDR	200 ppm*

***Settings may be optimized at the physician's discretion to better view and detect AF.**

7. Clinical Diagnosis: Classify each atrial arrhythmia and/or AT/AF event based on the physician's best clinical judgment. **The episode number documented on the CRF should correspond to a numbered stored EGM or ECG.** Submit all EGM/ECGs and/or other necessary documentation which assisted in the clinical diagnosis with the case report form.
   - If any of the stored EGMs are diagnosed as Far-R/atrial oversensing, adjust the PVAB and/or atrial sensitivity as appropriate.
8. Print the Final Programmed Parameters and complete the follow-up CRF.
9. Collect electronic data as indicated in *Section 4.3*.

4.3 Electronic Data Collection (1, 3, 6 month and any Unscheduled Visits)

- Press Alt-A on the keyboard while on the start-up screen.
- Select the device model #, serial #, and session.
- Select appropriate session (should correspond to visit date).
- Press "Copy Selected Sessions."
- Insert **(High Density, IBM Compatible)** Floppy Disk.
- Select Continue button.
- Send disk to SJM Scientific Studies with CRF & all printouts.

5.0 ADVERSE EVENTS/PROTOCOL DEVIATIONS/TERMINATIONS

5.1 Adverse Events Reporting

All adverse events relating to this study protocol should be reported. For the purposes of this research study, adverse events are any unfavorable events that are deemed worthy of reporting by the investigator, the center, or by SJM, that are caused by or associated with following the procedures of this study and which impact, or could potentially impact, the health or safety of a Research Study participant. Death of a patient is considered an adverse event and must be reported to SJM as soon as possible [a complete interrogation and printing of the device data should be done in the case of a patient death]. Events are categorized into different subgroups, either as Complications or Observations and have the following definitions:

Complication: **For the purposes of this research study**, a complication is any adverse event that results in injury or invasive intervention that has occurred as a result of following the procedures of this study protocol.

Observation: **For the purposes of this research study**, an observation is any adverse event that is not associated with injury or invasive intervention and which has occurred as a result of following the procedures of this study protocol.

If an adverse event occurs due to the implanted device and/or system components, please follow the standard procedure for reporting events of FDA approved devices.

5.2 Protocol Deviations

Significant deviations from the protocol must be reported in writing to SJM within 60 days of the discovery of the deviation. All reported protocol deviations and justifications will be presented to SJM for a determination of the course of action to take.

5.2 Protocol Termination

If for any reason a patient is terminated from the study before completing the study follow-up duration (6 months), this should be reported to SJM. The patients will be terminated from the study data collection after their 6 month follow-up visit.

6.0 RISKS AND BENEFITS

6.1 Risks

The risks involved with this study are similar to those associated with any other commercially available pacemaker system. There is no additional risk to the patients participating in this research as this is a data collection only study.

6.2 Benefits

There are no direct benefits to the patient resulting from this study. The patient may be more closely monitored by his/her physician.

7.0 REQUIRED DOCUMENTATION

The following investigator signed documentation is required from each study center **prior** to patient enrollment:

- IRB/Ethics Committee approval letter **or** signed IRB/Consent Waiver Form
- IRB/Ethics Committee approved patient informed consent (A Suggested Informed Consent is attached; all modified consent forms must be approved by SJM's legal department before patient enrollment begins)
- Investigator Agreement
- Co-investigator Agreement (if applicable)
- Grant Agreement
- Investigator/Site Information Form
- Publication Agreement

8.0 REFERENCES

1. Lau CP, Leung SK, Tse HF, Barold SS. Automatic Mode Switching of Implantable Pacemakers: I. Principles of Instrumentation, Clinical, and Hemodynamic Considerations. PACE 2002;25:967-83.
2. Lau CP, Leung SK, Tse HF, Barold SS. Automatic Mode Switching of Implantable Pacemakers: II. Clinical Performance of Current Algorithms and Their Programming. PACE 2002;25:1094-1113.
3. Gillis AM, Unterberg-Buchwald C, Schmidinger H, Massimo S, Wolfe K, Kavaney DJ, Otterness MF, Hohnloser SH. Safety and Efficacy of Advanced Atrial Pacing Therapies for Atrial Tachyarrythmias in Patients With a New Implantable Dual Chamber Cardioverter-Defibrillator. J Am Coll Cardiol 2002; 40(9):1653-9.
4. Israel CW, Ehrlich JR, Gronefeld G, Klesius A, Lawo T, Lemke B, Hohnloser SH. Prevalence, Characteristics and Clinical Implications of Regular Atrial Tachyarrhythmias in Patients With Atrial Fibrillation: Insights From a Study Using a New Implantable Device. J Am Coll Cardiol 2001; 38(2):355-63.
5. St. Jude Medical, Cardiac Rhythm Management Division. St. Jude Medical Bradycardia Devices Reference Manual. California: March, 2003.
6. Lee MA, Weachter R, Pollak S. Kremers MS, Naik AM, Silverman R, Tuzi J, Wang W, Johnson LJ, Euler DE. The effect of atrial pacing therapies on atrial tachyarrhythmia burden and frequency. Results of a randomized trial in patients with bradycardia and atrial tachyarrhythmias. J Am Coll Cardiol 2003; 41: 1926-32.

APPENDIX A:

SUGGESTED CONSENT

STATEMENT OF INFORMED CONSENT

"AWARE"

Your doctor has determined that you are a suitable candidate to participate in the "AWARE: Analysis of a New AT/AF Detection Algorithm in Patients with Atrial Arrhythmias" study because you need a pacemaker and meet the requirements for this study. This study is being sponsored by St. Jude Medical (referred to as SJM in the rest of this document).

BACKGROUND

Your doctor has determined that you may benefit from a pacemaker to treat your abnormal heart rhythm. There are different types of abnormal heart rhythms, two of which are atrial tachyarrhythmia (AT) and atrial fibrillation (AF). AT is a fast heart rhythm starting in the upper chambers of your heart called the atria. AT can lead to AF, which is an even faster, irregular heart rhythm. During AF the atria do not pump blood as well, which can affect your health in many ways. You may have palpitations, feel tired much of the time, your stamina may be reduced and your risk of having a stroke may increase.

The pacemaker monitors your heart beat, and if it starts to beat too slowly, your pacemaker will deliver electrical impulses that will speed it up. Pacemakers are made up of two main parts: the pacemaker generator and thin insulated wires known as leads. The generator contains a battery and electronic circuitry, or "brain." This "brain" tells the battery to send electrical impulses to the heart (through the leads) to help it beat. The lead is connected to the pulse generator at one end and to your heart at the other which allows electrical signals to travel back and forth. The way the lead attaches to you heart is either through flexible whiskers called "tines" or a small coil; both attachment systems are commonly used in medical practices.

Your pacemaker has a feature that provides your doctor with detailed information regarding any AT or AF episodes you have. This information will help him/her provide you with the most appropriate treatment for your abnormal heart rhythms. This feature is called the AT/AF detection algorithm. Your pacemaker also has other features that will help manage any AT/AF episodes you have.

PURPOSE

The purpose of this study is to evaluate how well your pacemaker detects episodes of AT/AF with the AT/AF detection algorithm.

PROCEDURE

The implant procedure for this study will be similar to that used for any other pacemaker. Two wires, called leads, will be advanced through a vein and placed into the two chambers of your heart. One end of each lead will stay in your heart while the other is attached to the pacemaker. Your doctor will then do some tests to make sure that the leads and the pacemaker are working properly. After all of the testing is complete and the pacemaker is determined to be in good working order, your doctor will insert your pacemaker into a prepared area under the skin/muscle just above your right or left chest. Finally, the incision will be closed. Nothing additional is being done that would not normally be done at a pacemaker implant.

For patients receiving a replacement pacemaker, the original leads will most likely be left in their present location. The old pacemaker will be removed and replaced with a new one. Additional leads may be implanted if necessary.

This study will last for 6 months after your pacemaker implant. You will have a follow-up appointment at 1, 3 and 6 months. At each follow-up, your doctor or follow-up specialist will record data and check your pacemaker in the usual way. At the 6 month follow-up your doctor will program the pacemaker to the settings that are best for you. If you decide to participate in this study, you will be asked to sign this consent form.

BENEFITS

There are no direct benefits to you resulting from this study. However, participation in this study will help doctors gain valuable information on the pacemakers' performance of detecting AT and AF episodes with the AT/AF Detection Algorithm.

RISKS

The risks involved with this study are identical to those associated with the implant of any other commercially available pacemaker system. However, the risk should be minimized by using investigators experienced in the use and testing of pacemaker systems.

RISK MINIMIZATION

During the procedure your vital signs, such as blood pressure and heart rate, will be closely monitored. All non-essential testing will be stopped if it appears to jeopardize your health in any way.

ALTERNATIVES

If you choose not to participate in this study, your doctor will still implant the device in routine fashion but will not collect study data during the implant or at follow-up visits. Any other treatment options that are available to you should be discussed with your doctor.

REFUSAL TO PARTICIPATE AND WITHDRAWAL FROM THE STUDY

You may refuse to participate or withdraw from this study at any time without affecting your relationship with, or treatment at, this medical center. During the course of the study, if any new information becomes available that may relate to your willingness to continue to participate in this study, that information will be provided to you.

COST/COMPENSATION

You understand that you will receive no money or other form of compensation for your participation in this research study. Your insurance company will be billed for all procedures or tests that are standard medical treatment for your condition; this care would otherwise be performed whether or not you participated in this study. In the unlikely event that a physical illness or injury occurs as a direct result of this research, treatment of the illness or injury will be available to assist you in your recovery.

CONFIDENTIALITY

Every effort will be made to keep all information collected about you for this study private as far as the law will allow. While the results of the research study will probably be shared with other people and may be published in scientific reports, your name and the fact that you were in the study will be kept confidential. Only medical information that is necessary to the study will be given to the sponsor, St. Jude Medical (SJM). Regulatory agencies such as the United States Food and Drug Administration (FDA) and SJM reserve the right to review your medical records that apply to this study. By signing this consent form, you agree to permit these agencies to review and copy your records. If you receive medical care at another location while still being followed on this study, you agree to allow copies of your medical records from these locations to be made available for the collection of data related to this study.

PATIENT STATEMENT

I have talked with Dr._____ who has offered to answer any questions I have. I may reach him/her at _____ if I have any further questions or concerns.

I understand that I may refuse to participate or withdraw from this study at any time without affecting my relationship with or treatment at the _____.
Name of Institution

I have read this form and agree to participate in this study.

My signature below indicates that I have read and understand the attached information, and that I have discussed this study with the medical staff. I have decided by my own choice to participate in the study based on the information provided to me, not because of force or intimidation.

_____
Patient's Signature Date

_____
Physician Date

_____
Witness Date

APPENDIX B:

INVESTIGATOR GUIDELINES AND AGREEMENTS

Agreement to the following conditions by the investigator is required before the investigator may participate in the study:

1) The investigator at each center agrees to assume primary responsibility for compliance with the provisions of the "AWARE" protocol (hereinafter referred to as the study) and will return all information requested in the protocol (including Case Report Forms) to St. Jude Medical (hereinafter referred to as SJM), Scientific Studies Organization, 15900 Valley View Court, Sylmar, CA 91342.

2) This study is conducted using FDA approved devices, in the patient population indicated per the approved Premarket Approval (PMA), and within the approved labeling there is no need to obtain an Investigational Device Exemption (IDE) from the FDA before proceeding with the study.

3) The investigator agrees not to release any details of the study without the written consent of SJM.

4) The investigator agrees to comply with Institutional Review Board (IRB)/Ethics Committee (or equivalent) and/or Governmental regulations relating to the responsibilities of the investigators. The "Investigator Agreement" will be signed by the investigator and returned to SJM. A Curriculum Vitae is also required.

5) The investigator agrees to have the protocol for the above named study reviewed with the appropriate people from the institution's IRB committee to decide if an IRB approval or equivalent approval is or is not required by the institution. If an IRB/Ethics Committee is needed, a copy of the IRB approval letter must be submitted to SJM prior to beginning the study.

6) The investigator agrees to have reviewed the consent for the above named study with the appropriate people from the institution's IRB committee. If the patient consent is required, then patients taking part in the study must give informed consent prior to participation. Any changes made to the patient informed consent must be sent to SJM for approval prior to submitting the protocol to the IRB.

7) If an IRB/Ethics Committee (or equivalent) approval was required, special reports concerning withdrawal or approval of the study by the IRB/Ethics Committee (or equivalent) or modification of the protocol must be forwarded to SJM within 5 days.

INVESTIGATOR GUIDELINES AND AGREEMENT
(Page 2 of 2)

8) This is a trial being conducted in multiple study centers, and it is intended that the results of the study will be published and/or presented in an integrated manner reflecting the results observed across all participating centers. Publications and presentations proposed by participating centers should be furnished to SJM for review and comment 30 days (manuscripts) or 7 days (abstracts) prior to submission for publication. SJM reserves the right to deny submission of study results if based on data owned by SJM as expressed in the "Publication Agreement".

9) Investigator acknowledges that St. Jude Medical is a publicly-owned company and that information relating to this study and the results of this study could be considered to be material inside information under the securities laws of the United States. Accordingly, Investigator will not disclose any information about this study or its results to any third person or use information about the study or its results to trade in the securities of St. Jude Medical. This confidentiality obligation will cease once the study results are published or presented at a public meeting.

I hereby certify that I will conduct the "AWARE" study sponsored by SJM in accordance with the Investigator Agreement Guidelines.

My Curriculum Vitae is attached (if not sent previously), including the extent and type of my relevant experience with pertinent dates and locations.

Signature:_____ Date:_____

Name: _____

Address:_____

City: _____ State: _____ Zip:_____

Phone: _____ Fax: _____

APPENDIX C:

INVESTIGATOR APPROVAL OF CO-INVESTIGATORS

As investigator for the St. Jude Medical's "AWARE" study, I approve the following co-investigators to participate in the study under my direction. I understand that I remain responsible for the proper conduct of the study. I will also forward a copy of the approved co-investigators to my IRB/Ethics Committee (or equivalent) if a review was obtained.

CO-INVESTIGATORS	CENTER
_____	_____
_____	_____
_____	_____

In addition, as investigator for the "AWARE" study, I approve the following individual(s) (i.e., Research Nurse) to complete case-report forms.

INDIVIDUALS AUTHORIZED TO COMPLETE CASE REPORT FORMS:	TITLE
_____	_____
_____	_____
_____	_____

_____
Investigator's name

_____ _____
Signature of Investigator Date

APPENDIX D:

GRANT AGREEMENT

St. Jude Medical
"AWARE"

The purpose of this grant is to compensate you, the investigator, for performing procedures, tasks and follow-up care that is not otherwise reimbursed or paid for by the insurance or other federal or state health care programs. These additional procedures, tasks and obligations are for the purposes of collecting valuable patient and device data that assist in evaluating the performances of the device that is the subject of this study.

Therefore, St. Jude Medical (hereinafter referred to as SJM) will provide this research study grant for the thorough, accurate completion and timely submission of required research study data by the investigating centers. These funds are intended to defray the additional expenses associated with the research study investigation, which are incurred by the Investigator and his staff.

GRANT ALLOCATIONS

Each research center will receive a total of $1000 (direct and indirect costs) ($700 for Implant and $100 for each 1, 3 and 6 month Follow-up visit) per patient appropriately reported and studied in accordance with completing the study protocol; this reimbursement will be contingent upon data review and approval of SJM. Enrollment shall cease immediately upon written notification by SJM that the overall target population (140 patients) has been reached. Any patients enrolled subsequent to said notification shall not be subject to reimbursement unless previously agreed upon by SJM.

GRANT DISBURSEMENT INFORMATION/SCHEDULE

Research study grant money will be paid for on a quarterly basis based on data received, providing that all required consents and study Case Report Forms are accurately completed and submitted to SJM. Please note that reimbursements will be initially denied if paperwork is not submitted or submitted incorrectly.

Payments made by SJM pursuant to this investigation are for the legitimate reimbursement of time, effort and oversight by the Investigator and their professional staff, to accurately collect and submit valuable data relating to this research study protocol.

On a quarterly basis, reimbursement eligibility (on a per patient basis) will be established. An invoice detailing data received will be faxed to the Center, requesting verification of information. Two to three weeks after delivery of invoice, a check will be mailed to the Center (or addresses listed on signature page).

(To be signed and returned to St. Jude Medical)

"AWARE"

I understand and agree to the foregoing terms and conditions listed and accept them as the terms of the SJM, "AWARE" study Grant Allocation.

The Grant payments should be made out to the following:

Payable to: _____

(Please print or type)

Address: _____

_____

Note: If request from study site is to pay physician directly with a SS# – our accounting office needs the physician's home address

Home Address (if applic.) _____

Tax ID #: _____

Telephone # _____ Fax # _____

Mail to: _____

_____

_____
Investigator's Signature

_____
Investigator's Name (Please Print)

_____ _____
Investigating Center Date

ADDITIONAL INFORMATION REGARDING REIMBURSEMENT:

_____

_____

APPENDIX E:

SITE INFORMATION

"AWARE"

*Hospital: _____

Address: _____

City/State/Zip: _____

Phone Number: _____

Fax Number: _____

IRB/Ethics Chair: _____

Investigator: _____

Practice Name: _____

Address: _____

City/State/Zip: _____

Phone Number: _____

Pager Number: _____

Fax Number: _____

Email Address: _____

Coordinator: _____ Phone: _____

Investigator Signature: _____ Date: _____

* If implanting at multiple hospitals, please use separate sheet to list address/phone information for each hospital.

APPENDIX F:

PUBLICATION AGREEMENT

"AWARE"

The following guidelines have been established for publications and/or presentations of Scientific Studies:

- Investigator Agreement has been signed by the investigator who agrees that all the study data collected will be published and/or presented in an integrated manner reflecting the results observed across all participating centers.
- St. Jude Medical is the legal owner of the entire Scientific Studies database. Decisions on the timing and content of publications and presentations from the study will be coordinated by St. Jude Medical, in communication with participating centers contributing subjects to the study.
- Investigators have the right to request data analysis and summaries of study results (statistical tables, figures, and reports) developed from the St. Jude Medical Scientific Studies data pool for publications in journals, books and for abstracts. However, St. Jude Medical, reserves the right to deny any preliminary data analysis based on inadequate sample size, questionable results, or the priority of a study. To resolve any conflict of request, St. Jude Medical reserves the right to prioritize the requests based on:
  - Study Protocol Authorship
  - Date of request receipt
  - The amount of data contributed
  - Order of investigator entry into the study
- A proposal must be submitted to the Scientific Studies Organization (SSO) for review prior to preparation for publications and/or presentations with summarized information.
- Upon approval, the SSO will provide assistance in the release and analysis of the data for the proposed publication and/or presentation.
- SSO shall establish and maintain a position of cooperation and partnership with the investigators who wish to publish or present data obtained during the study.
- Any Investigator using the Scientific Studies data pool should provide a copy of any abstract, manuscript or presentation to SSO for final review and approval prior to submission.
- All abstracts, manuscripts, and presentations using information from the St. Jude Medical Scientific Studies data pool should include all primary investigators and centers in the acknowledgments.
- If an investigator(s) plans to publish or present study data collected at only his/her site, SSO will offer to review the abstract, manuscript, or presentation for technical accuracy. Furthermore, St. Jude Medical will request that a courtesy copy of the submitted abstract, manuscript, or presentation be forwarded to SSO.
- St. Jude Medical will follow the same publication policy as participating investigators but reserves the right to give presentations that do not require abstracts or manuscripts without approval.
- If an investigator(s) is to be named in any abstract, manuscript, or presentation proposed by St. Jude Medical, permission to use their name must be received prior to submission. Any investigator has the right to request that his/her name not appear on any abstract.

_____ / _____ _____

Investigator's Name / Signature Date

APPENDIX G:

CASE REPORT FORM(S)

Sample Only: DO NOT USE

ST. JUDE MEDICAL Office Use Only 263-

AWARE
Enrollment Form

1. General Information

Enrollment Date: ___ (Month) ___ (Day) 2 0 0 ___ (Year)

Patient ID: _____

Physician: _____ (Last) _____ (First) ___ (M.I.)

Center: _____ City: _____

Date of Birth: ___ (Month) ___ (Day) 1 9 ___ (Year)

Gender: ☐ Male ☐ Female

Ejection Fraction: ___ %

2. Primary Indication For Pacing System

☐ Sinus Node Dysfunction ☐ Heart Block (Type): _____

☐ Other (Specify): _____

3. Enrollment Criteria

- Patient is in sinus rhythm or cardioverted into sinus rhythm at time of pacemaker implant.
- Within the last 6 months, patient has had an episode of symptomatic AT/AF.

4. Previous Cardiovascular History (Check all that apply)

☐ None
☐ Coronary Artery Disease
  ☐ CABG
  ☐ PTCA
  ☐ Previous Myocardial Infarction
☐ Cardiomyopathy
  ☐ Dilated
  ☐ Hypertrophic
☐ Hypertension (Controlled)
☐ Valvular Heart Disease
☐ AF Cardioversion
☐ Catheter Ablation
  ☐ Type: _____
☐ Valve Replacement
☐ Other: _____
☐ CHF (If checked, indicate NYHA Class below)
  → NYHA Class:
  ☐ I ☐ II ☐ III ☐ IV ☐ Unknown

5. Non-Ventricular Arrhythmias (Check all that apply)

☐ Atrial Fibrillation
  ☐ Paroxysmal
  ☐ Persistent
☐ Atrial Flutter
☐ Atrial Tachycardia
☐ Premature Atrial Contractions
☐ Sinus Tachycardia
☐ Other: _____

6. Antiarrhythmic Drug Therapy ☐ None

Name of Drug	Total Daily Dosage (mg)	Discontinued Before Implant
1.		☐ Yes ☐ No
2.		☐ Yes ☐ No
3.		☐ Yes ☐ No
4.		☐ Yes ☐ No
5.		☐ Yes ☐ No

Sample Only: DO NOT USE

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AWARE
Enrollment Form

Patient ID: _____

7. Pacemaker/Lead Information

SJM Dual Chamber Pacemaker Model Number: _____ Serial Number: _____

Ventricular Lead Model Number: _____ Ventricular Lead Implant Date: ☐☐☐ Month ☐☐ Day ☐☐☐☐ Year

Atrial Lead Model Number: _____ Atrial Lead Implant Date: ☐☐☐ Month ☐☐ Day ☐☐☐☐ Year

Atrial Lead Position:

☐ Atrial Appendage ☐ Atrial Septum

☐ Other (Specify): _____

8. Lead Testing (Device Based)

	Atrial Lead	Ventricular Lead
Capture Threshold:	_____ V @ _____ msec	_____ V @ _____ msec
Sensing Threshold:	_____ mV	_____ mV
Lead Impedance:	_____ Ω	_____ Ω

9. Stored EGMs

- Channel: Atrial*
- Atrial EGM Configuration: Atip-Aring*
- Number of stored EGMs: Maximum # Allowed
- **Triggers: AT/AF Detection: ON (All other triggers: OFF)**

* optimize at physician discretion

- **All Counters Cleared**

10. Comments _____

11. Attached To This Form (Must include all of the following):

☐ Measured Data ☐ Final Programmed Parameters ☐ Stored EGM Parameters

12. Authorized Signature

I have reviewed and agree with the data reported on this CRF.

Do not send original case report forms
Photocopy programmer printouts

Investigator Signature: _____ Date: ☐☐☐ Month ☐☐ Day 2 0 0☐ Year

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60002075_Rev_003 01/05/05 (Rev 0)

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AWARE
Follow-up Data Form

1. General Information

Follow-up Date: ☐☐ (Month) ☐☐ (Day) 2 0 0 ☐ (Year)

Patient ID: _____ Device Serial Number: _____

Physician: _____ (Last) _____ (First) ____ (M.I.)

Center: _____ City: _____

Follow-up: ☐ 1 Month ☐ 3 Month ☐ 6 Month ☐ Other: _____

2. Lead Testing (Device Based)

	Atrial Lead	Ventricular Lead
Capture Threshold:	_____ V @ _____ msec	_____ V @ _____ msec
Sensing Threshold:	_____ mV	_____ mV
Lead Impedance:	_____ Ω	_____ Ω

3. Current Antiarrhythmic Drug Therapy ☐ None

Name of Drug	Total Daily Dosage (mg)	Change From Last Follow-up
1.		☐ Yes ☐ No
2.		☐ Yes ☐ No
3.		☐ Yes ☐ No
4.		☐ Yes ☐ No
5.		☐ Yes ☐ No

4. Clinical Diagnosis

*** Episode number(s) should correspond to a numbered stored EGM or ECG**

Were there any documented events? (verified by Stored EGM or ECG) ☐ No ☐ Yes

If yes, please classify each event as one of the following:

***Episode Number(s) (e.g.: 1-5, 7, 9, 11, 13-15)**

- ☐ Inappropriate detection of AT/AF event _____
- ☐ Atrial fibrillation _____
- ☐ Atrial flutter _____
- ☐ Sinus tachycardia _____
- ☐ Atrial tachycardia _____
- ☐ Unable to determine _____
- ☐ Other: _____ _____

Has the patient had a symptomatic AF episode since last visit?

☐ Yes ☐ No ☐ Unable to determine

→ Number of symptomatic AF episodes since last visit: _____

☐ Unable to determine

Page 1 of 2

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AWARE
Follow-up Data Form

Patient ID: _____

- Print out all the required data (see below "Attached To This Form")
- Evidence of inappropriate atrial sensing?
  - ☐ None
  - ☐ Oversensing
    - ☐ Far-R ☐ Other (Specify): _____
  - ☐ Undersensing
  - ☐ Noise
  - ☐ Other (Specify): _____
- Evaluate the far-field R-wave. V pace to Far-R interval _____ ms

Programming Recommendations

Parameter	Setting
PVAB (Post Ventricular Atrial Blanking)	40 ms longer than measured Far-R interval (V Paced)
PVARP (Atrial Refractory)	As short as physiologically appropriate
Rate Responsive PVARP/VREF	Medium or High
Atrial Sensitivity	0.1 - 0.5 mV
ATDR	200 ppm or at physician's discretion to better view and detect AT/AF

Stored EGMs

Date Counters Last Cleared: ☐☐☐ (Month) ☐☐ (Day) 2 0 0 ☐ (Year)

- Channel: Atrial*
- Atrial EGM Configuration: Atip-Aring*
- Number of stored EGMs: Maximum # Allowed
- Triggers: AT/AF Detection: ON (All other triggers: OFF)
  * optimize at physician discretion
- **All Counters Cleared**
- **Archive Data on Disk (Alt-A from start-up screen)**

5. Comments _____

6. Attached To This Form

- ☐ Initial/Final Programmed Parameters
- ☐ Event/Heart Rate Histogram
- ☐ Measured Data/Stored EGM Parameters
- ☐ AF Suppression Histogram (If applicable)
- ☐ Auto Mode Switch Diagnostics
- ☐ AT/AF Diagnostics
- ☐ Electronic Data on Disk
- ☐ Stored EGMs/Additional ECGs (if applicable)

7. Authorized Signature

I have reviewed and agree with the data reported on this CRF.

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Photocopy programmer printouts

Investigator Signature: _____ Date: ☐☐ (Month) ☐☐ (Day) 2 0 0 ☐ (Year)

Page 2 of 2

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Sample Only: DO NOT USE

ST. JUDE MEDICAL | Office Use Only 263- | *AWARE* Adverse Event Form

1. General Information Date Form Completed: ☐☐ Month ☐☐ Day 2 0 0 ☐ Year

Patient ID: _____ Device Serial Number: _____

Physician: _____ Last _____ First _____ MI

Center: _____ City: _____

2. Adverse Event Date: ☐☐ Month ☐☐ Day 2 0 0 ☐ Year

3. Event Description

☐ Ventricular ☐ Atrial Lead Dislodgment or Migration

☐ Ventricular ☐ Atrial Lead System Fracture diagnosed by: ☐ X-Ray ☐ Electrogram ☐ Impedance measurement

☐ Ventricular ☐ Atrial Lead System Insulation Damage diagnosed by: ☐ Electrogram ☐ Impedance measurement

☐ Ventricular ☐ Atrial Loss of Capture ☐ Complete ☐ Intermittent

☐ Ventricular ☐ Atrial Elevated Pacing Thresholds

☐ Ventricular ☐ Atrial Decreased R/P-Wave Amplitude/Loss of Sensing

☐ Ventricular ☐ Atrial Oversensing caused by: ☐ Noise ☐ EMI ☐ Crosstalk ☐ T wave sensing ☐ Double Sensing

☐ Far R-sensing resulting in: ☐ Inappropriate AMS ☐ No AMS

☐ Ventricular ☐ Atrial Undersensing

☐ Programming Difficulties (Specify): _____

☐ Ventricular Arrhythmias: ☐ VT ☐ VF ☐ Other: _____

☐ Pacing Rate Intolerable

☐ Cardioversion

☐ Other (specify): _____

☐ Patient Death (Please complete a Protocol Deviation/ Termination Form)

4. Description of Complication/Observation

1. Indicate the resolution for the adverse event that occurred:

☐ Device reprogramming
☐ Surgical Intervention (please provide surgical report)
☐ Lead Explant
☐ Other _____
☐ Lead Reposition
☐ System Revision
☐ Device Explant

2. Describe the adverse event and patient outcome:

_____

_____

_____

_____

5. Authorized Signature **Do not send original case report forms**

I have reviewed and agree with the data reported on this CRF.

Investigator Signature: _____ Date: ☐☐ Month ☐☐ Day 2 0 0 ☐ Year

Page 1 of 1

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60002078_Rev_002 (05/04/04Rev 02)

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AWARE

Protocol Deviation/Termination Form

1. General Information

Date Form Completed: ☐☐☐ Month ☐☐ Day 2 0 0 Year

Patient ID: _____ Device Serial Number: _____

Physician: _____ Last _____ First _____ M.I

Center: _____ City: _____

Visit: ☐ Implant ☐ 1 Month ☐ 3 Month ☐ 6 Month ☐ Other: _____

2. Deviation

Indication

☐ Inclusion criteria not met

Follow-up Visit

☐ Skipped

☐ Out of visit tolerance range

Study Procedure

☐ Non-protocol defined device implanted

☐ Device programming

☐ Data collection

☐ Documentation completion

☐ Other (specify): _____

Reason for Termination

☐ Patient's Death (specify in comments)

☐ Patient Lost to Follow-up

☐ Device Out of Service

☐ Other (specify): _____

3. Comments _____

4. Authorized Signature

Do not send original case report forms

I have reviewed and agree with the data reported on this CRF.

Investigator Signature: _____ Date: ☐☐☐ Month ☐☐ Day 2 0 0 Year

St. Jude Medical • Scientific Studies • 15900 Valley View Court • Sylmar, CA • 91342 • 800/423-5611 • Fax 866/632-8191

EXHIBIT 3

Dr. MK Patients

ST. JUDE	Lake Regional Health System			RARE		
NO.	Date Imp	Pt. Name	1 month	3 month	6 month	
1	5-May	[redacted]	22-Jun	30-Aug	**15-Nov**	
2	14-Jul		30-Aug	18-Oct	**jan**	
3	14-Jul		30-Aug	18-Oct	**21-Feb**	
4	21-Jul		30-Aug	**missed**	**17-Jan**	
5	2-Aug		missea	18-Oct	**21-Feb**	
6	19-Aug		missea	missed	missed	
7	13-Sep		29-Sep	missea	missed	
	15-Sep		18-Oct	missed	mar	
8	20-Sep		16-Nov	20-Dec	**21-Mar**	
9	24-Sep		**18-Oct**	20-Dec	mar	
10	29-Sep		missed	**20-Dec**	missed	6m0 done
11	3-Dec		**17-Jan**	**30-Mar**	jun	no meds
12	17-Dec		17-Jan	12-Mar	jun	
2005	paid	11500				
13	7-Jan		missed	21-Mar	jul	
14	13-Jan		2/21/2005	apr done	Jul	
15	14-Jan		21-Feb	apr done	Jul	
16	26-Jan		missed	exp.4/8	Jul	
17	2-Feb		21-Feb	apr done	Aug done	
18	11-Feb		21-Feb	apr	ug/missed	
19	21-Feb		apr	may	ug/missed	Done
20	7-May		June	Aug	Nov	
	21-May		June	Aug	Nov	
Kahn	25-Jul		Aug/Kahn			
	28-Jul		Sept			
	13-Aug		Oct	Dec		
	8-Aug		October			
	31-Aug		dr.kahn			
	03-Sept		October	dEc		
	03-Sept		October	dec		
	23-Sep					
	28-Sept		Oct	Dec		
	21-Sept					
	10-Oct		Nov			

ST. JUDE	Dr.McD	AWARE		AWARE		
NO.	Date Imp	Pt. Name	1 month	3 month	6 month	
1	7-Oct	[redacted]	18-Nov	17-Jan	apr	
2	20-Oct		16-Nov	20-Jan	apr	no meds
3	9-Nov		missea	**FEB**	may	no meds
4	9-Dec		20-Jan	mar	june	
5	15-Dec		20-Jan	17-Mar	june	
6						
7	14-Feb	[redacted]	Skip	June		
	22-Mar		apr			
8	26-Apr		June	Aug	Nov	NORx
9	30-May		June	Aug	Nov	No Rx
10	26-Jul		Aug	nov		
11						
12						
13						
14						
15						
16						
17						
18						

Dr. AH Patients

ST. JUDE	Moberly Reg. Med. Center			AWARE				
NO.	Date Imp	Pt. Name	1 month	3 month	6 month			
1	20-May	[redacted]	june	explanted d/t inf.				
2	20-May		june	aug	9-Nov			
3	8-Jun		july	missed	missed			
4	14-Sep		9-Nov	missed	mar			
5	14-Sep		missed	dec	12-Apr			
6	17-Sep		12-Oct	dec	mar	expired		
7	7-Oct		9-Nov	11-Jan	12-Apr	imdur60 Cozaar100 Procardia90		
8	14-Oct		nov	8-Feb	12-Apr	imdur30		
9	17-Dec		jan	mar	jun	toprol xl 12.5		
10	10-Feb	[redacted]	mar	May	august			
11	18-Feb		mar	june	Sept			
12	2-Mar		12-Apr	June	Sept	coreg 25		
14	8-Mar		Apr	june	Sept/Done, Aug			
15	10-Mar		12-Apr	june	Sept			
16	15-Mar		12-Apr	june	Sept			
17	15-Mar		12-Apr	june	Sept			
18	15-Mar		Apr	june	Sept			
	19-Apr	[redacted]	june	Aug		LISINOPRIL 5Mg		
	5-May		June	Aug				
	17-May		june	Aug				
	17-May		june	Aug				
	16-Jun		July	Sept		No Meds		
	23-Jul		Aug	Oct	January	Lisinopril 40mg, coreg 80mg, Dig		
	Aug		Sept	Nov				
	Aug		Sept	Nov				
	Sept-29		Oct	dec				
	Sept-29		Oct	dec				
	Sept-28		Nov					
	7-Oct		Nov			Sotalol 160 mg/day		

EXHIBIT 4

REGISTRY PLAN

This study uses FDA approved devices only.

ST. JUDE MEDICAL

Advancements in ICD Therapy (ACT) Registry

October, 2004
CD0180, Rev. A

St. Jude Medical
Scientific Studies Organization
15900 Valley View Court
Sylmar, CA 91342

CRD #: 286
Registry #: 04-06-003

REGISTRY PLAN

REGISTRY SPONSOR

St. Jude Medical
Scientific Studies Organization (Dept. 751)
Telephone: 1-800-933-9956
Fax: 1-866-632-8191
15900 Valley View Court
Sylmar, CA 91342

TABLE OF CONTENTS

REGISTRY PLAN

1.0 INTRODUCTION

1.1 Background

Approximately 460,000 people in the U.S. die from sudden cardiac death (SCD) each year[1]. In addition, SCD accounts for 63% of all cardiac mortality events[1]. SCD is also associated with heart failure (HF), which is a major cause of death in an estimated 5 million Americans. SCD usually arises from ventricular fibrillation (VF), which is often preceded by ventricular tachycardia (VT).

Pharmacological therapy for suppression of arrhythmias does not provide optimal results and may even be potentially harmful with drug-induced side effects in some patients[2]. Conversely, implantable cardioverter-defibrillators (ICD's) have shown to be effective in treating life threatening ventricular arrhythmias. Several randomized, controlled trials have demonstrated the superiority of ICD's over antiarrhythmic therapy in the primary and secondary prevention of SCD, while also expanding indications for ICD implantation[3-7]. However, the prevalent use and optimization of ICD therapy through appropriate programming have not been thoroughly identified.

Since the criteria for ICD implantation have continued to expand, it is important to gather data in order to understand the overall utility of ICD therapy on patient outcome. Therefore, St. Jude Medical has developed a registry for all modern St. Jude Medical ICD's, which also include cardiac resynchronization therapy defibrillators (CRT-D's). This registry will collect patient and device information for 2 years post enrollment on any St. Jude Medical ICD's. The registry's function of developing a comprehensive database may provide valuable insight on the utilization of advanced features and their impact on current ICD therapy in an ever-growing patient population.

The registry is sponsored by St. Jude Medical (hereinafter referred to as SJM).

1.2 Purpose of Registry

The purpose of this registry to produce a prospective, outcome-oriented registry of all patients implanted with an SJM ICD and to evaluate the utilization of advanced features in patients with current ICD indications.

2.0 REGISTRY OVERVIEW

2.1 Objectives

The primary aim of this registry is to produce a prospective, outcome-oriented registry of all patients implanted with an SJM ICD. The secondary aim of the registry is to evaluate the programming and application of advanced features on ICD therapy in patients with SJM ICD's.

2.2 Evaluation Aspects

- Indication for device implant
- Cardiac and arrhythmia history
- NYHA progression
- Cardiac drug utilization
- Cardiac measurements
  - Ejection fraction
  - QRS duration
- Programmed parameters
  - Advanced ICD features (AF Suppression, AutoIntrinsic Conduction Search, SVT discriminators, etc.)
- System Measurements
  - Defibrillation thresholds
  - Leads measurements (sensing/capture thresholds, high and low voltage impedance)
- Number of AT, AF, VT, and VF episodes
- Frequency of inappropriate ICD therapy during AT/AF
- Frequency of appropriate ICD therapy for VT/VF
- Percentage of atrial and ventricular pacing
- Cost-effectiveness

3.0 REGISTRY DESIGN

3.1 Methods

This is a prospective, follow-up data collection registry. Any patient that receives an FDA approved SJM ICD or CRT-D is eligible for enrollment into the registry. The physician may choose any compatible lead system for use with the ICD or CRT-D. Patients with chronically implanted leads and receiving device upgrades may be included in this registry.

Patients are followed for a period of 24 months after implant. Data are collected at enrollment (within 45 days of device implant), 6 months, 12 months, 18 months, 24 months and at any unscheduled follow-up visits. During the follow-up visits, arrhythmic episode diagnoses, device data and stored electrograms are collected. In case of device related hospitalizations, emergency room visits, and external cardioversions; the follow-up form includes a section for collection of cost-effectiveness data into this registry. **Device data and stored electrograms are downloaded onto a high density floppy diskette or equivalent.**

3.2 Patient Population

In order to build a database of significant information on ICD patient outcomes and the influence of advanced features on ICD therapy, the SJM ICD Registry will enroll 5,000 patients in a minimum of 300 centers.

3.3 Enrollment Criteria

The investigator and co-investigators have the responsibility of screening all potential patients to determine if the patient meets all of the enrollment criteria.

- Patient has a standard indication for an ICD or CRT-D device.
- Patient is implanted with a SJM ICD or CRT-D device.
- Patient is geographically stable and willing to comply with the required follow-up schedule.
- Patient's life expectancy is more than 24 months.
- Patient is NOT currently enrolled in another SJM clinical study.

4.0 PROCEDURE

4.1 Enrollment [within 45 days of device implant]

1) Patient receives an FDA approved SJM ICD or CRT-D system. Chronically implanted leads may be used in this registry.
2) ICD implantation should follow the manufacturer's standard procedures.
3) Print out the following reports:
   - Parameter Summary
   - Real-Time Measurement Trends
   - Tachycardia Diagnostics
   - Bradycardia Diagnostics
   - Stored EGM's
4) Perform standard ICD system evaluation, which may include capture and sensing thresholds, assessment of high and low voltage impedance, and any other testing deemed appropriate by the investigator.
5) Clear all diagnostics.
6) Print the final Parameter Summary report.
7) Download the device memory onto a high density floppy diskette or equivalent.
   a) Press "Main Menu" button.
   b) Press "Export Data" button.
   c) Press "Session Data to Diskette" button. The current session's Archived Data will be exported to the diskette.
   d) Enter the Patient ID as written on the case report form and the current date in the Comment area.
   a) Press the "Continue" button to begin copying data.
8) Complete the Patient Enrollment case report form.

4.2 Follow-up [6, 12, 18, and 24 Months (± 2 weeks) and Unscheduled Visits]

1) Print out the following reports:
   - Parameter Summary
   - Real-Time Measurement Trends
   - Tachycardia Diagnostics
   - Bradycardia Diagnostics
   - Stored EGM's
2) Perform standard ICD system evaluation, which may include capture and sensing thresholds, assessment of high and low voltage impedance, and any other testing deemed appropriate by the investigator.
3) Evaluate stored EGM's for appropriate or inappropriate therapies.
4) Reprogram, if necessary, any criteria that will optimize SVT/VT discrimination.
5) Clear all diagnostics.
6) Print the final Parameter Summary report.
7) Download the device memory onto a high density floppy diskette or equivalent.
   a) Press "Main Menu" button.
   b) Press "Export Data" button.
   c) Press "Session Data to Diskette" button. The current session's Archived Data will be exported to the diskette.
   d) Enter the Patient ID as written on the case report form and the current date in the Comment area.
   e) Press the "Continue" button to begin copying data.
8) Complete the Follow-Up case report form.

4.3 Pharmacological Therapy

The following pharmacological medications and their dosages should be documented at implant and all follow-up visits: antiarrhythmic drugs, β-blockers, calcium channel blockers, angiotensin II receptor blockers, ACE inhibitors, ARB's, diuretics, nitrates, digoxin, sprinolactone, amiodarone, sotalol, digitalis, or other cardiac medications.

5.0 RISKS AND BENEFITS

5.1 Risks

This is only a data collection registry. Consequently, there are no risks to the patients assigned to the registry.

5.2 Benefits

There are no direct benefits to the patient resulting from this registry, except from possibly being more closely monitored by his/her physician. However, it is possible that, with the information obtained from this registry, physicians may be able to better manage ICD patients.

6.0 REQUIRED DOCUMENTATION

The following investigator signed documentation is required from each registry center **prior** to patient enrollment:

- Investigator Agreement
- Co-investigator Agreement (if applicable)
- Grant Agreement
- Investigator/Site Information Form
- Publication Agreement

7.0 REFERENCES

1. Center for Disease control. State specific mortality from sudden cardiac death-United States, 1999. MMWR 2002;51;123-6.
2. Echt DS, et al. Mortality and morbidity in patients receiving encainide, flecainide, or placebo. The Cardiac Arrhythmia Suppression Trial. N Engl J Med 1991;324;781-8.
3. Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators. A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. N Engl J Med. 1997 Nov 27;337:1576-83.
4. Connolly, SJ, et al. Canadian Implantable Defibrillator Study (CIDS): A randomized trial of the implantable cardioverter-defibrillator against amiodarone. Circulation 2000; 101:1297.
5. Moss, AJ, et al. for the Multicenter Automatic Defibrillator Implantation Trial Investigators. Improved survival with an implanted defibrillator in patients with coronary disease at high risk from ventricular arrhythmia. N Engl J Med 1996; 335:1933.
6. Buxton, AE, et al. A randomized study of the prevention of sudden death in patients with coronary artery disease: Multicenter Unsustained Tachycardia Trial Investigators. N Engl J Med 1999; 341:1882-90.
7. Moss AJ, et al. Prophylactic Implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med 2002; 346:877.

APPENDIX A:
IRB/ETHICS COMMITTEE/CONSENT WAIVER FORM

Registry Title: Advancements in ICD Therapy (ACT) Registry
CRD # *286* ***Registry #:*** *04-06-003*

I have reviewed the protocol for the above named registry with the appropriate people from the hospital/center, we have determined:

Please indicate:
(choose one)
☐ IRB/Ethics Committee (or equivalent) approval is required by my institution.

☐ IRB/Ethics Committee (or equivalent) approval is ***not*** required by my institution.

(choose one)
☐ Patient Consent form is required by my institution.

☐ Patient Consent form is ***not*** required by my institution.

_____
Hospital/Center Name

_____
Hospital/Center Address

_____
Hospital/Center City, State, Zip

_____
Telephone Number Fax Number

_____
Investigator Name Investigator Signature Date Signed

Please mail or Fax to:
Scientific Studies Organization
St. Jude Medical, Dept. 751
15900 Valley View Court
Sylmar, CA 91342
Phone: (800) 933-9956 x. 2050, 2052, 2054, 2113, 2183, 2594, 4278
Fax: (866) 632-8191

APPENDIX B:

INVESTIGATOR GUIDELINES AND AGREEMENTS

Agreement to the following conditions by the investigator is required before the investigator may participate in the investigation:

1) The investigator at each center agrees to assume primary responsibility for compliance with the provisions of the "Advancements in ICD Therapy (ACT) Registry" protocol (hereinafter referred to as the investigation) and will return all information requested in the protocol (including Case Report Forms) to St. Jude Medical (hereinafter referred to as SJM), Scientific Studies Organization, 15900 Valley View Court, Sylmar, CA 91342.

2) This investigation is conducted using FDA approved devices, in the patient population indicated per the approved Premarket Approval (PMA), and within the approved labeling there is no need to obtain an Investigational Device Exemption (IDE) from the FDA before proceeding with the investigation.

3) The investigator agrees not to release any details of the investigation without the written consent of SJM.

4) The investigator agrees to comply with Institutional Review Board (IRB)/Ethics Committee (or equivalent) and/or Governmental regulations relating to the responsibilities of the investigators. The "Investigator Agreement" will be signed by the investigator and returned to SJM. A Curriculum Vitae is also required.

5) The investigator agrees to have the protocol for the above named investigation reviewed with the appropriate people from the institution's IRB committee to decide if an IRB approval or equivalent approval is or is not required by the institution. If an IRB/Ethics Committee is needed, a copy of the IRB approval letter must be submitted to SJM prior to beginning the investigation.

6) The investigator agrees to have reviewed the consent for the above named investigation with the appropriate people from the institution's IRB committee. If the patient consent is required, then patients taking part in the investigation must give informed consent prior to participation. Any changes made to the patient informed consent must be sent to SJM for approval prior to submitting the protocol to the IRB.

7) If an IRB/Ethics Committee (or equivalent) approval was required, special reports concerning withdrawal or approval of the investigation by the IRB/Ethics Committee (or equivalent) or modification of the protocol must be forwarded to SJM within 5 days.

8) This is a trial being conducted in multiple investigation centers, and it is intended that the results of the investigation will be published and/or presented in an integrated manner reflecting the results observed across all participating centers. Publications and presentations proposed by participating centers should be furnished to SJM for review and comment 30 days (manuscripts) or 7 days (abstracts) prior to submission for publication. SJM reserves the right to deny submission of investigation results if based on data owned by SJM as expressed in the "Publication Agreement".

INVESTIGATOR AGREEMENT
(Page 2 of 2)

9) Investigator acknowledges that St. Jude Medical is a publicly-owned company and that information relating to this investigation and the results of this investigation could be considered to be material inside information under the securities laws of the United States. Accordingly, Investigator will not disclose any information about this investigation or its results to any third person or use information about the investigation or its results to trade in the securities of St. Jude Medical. This confidentiality obligation will cease once the investigation results are published or presented at a public meeting.

* * * * * * * * * * * * *

I hereby certify that I will conduct the "Advancements in ICD Therapy (ACT) Registry" investigation sponsored by SJM in accordance with the Investigator Agreement Guidelines.

My Curriculum Vitae is attached (if not sent previously), including the extent and type of my relevant experience with pertinent dates and locations.

Signature:_____ Date:_____

Name: _____

Address:_____

City: _____ State: _____ Zip:_____

Phone:_____ Fax: _____

APPENDIX C:

INVESTIGATOR APPROVAL OF CO-INVESTIGATORS

As investigator for the St. Jude Medical's "Advancements in ICD Therapy (ACT) Registry" investigation, I approve the following co-investigators to participate in the investigation under my direction. I understand that I remain responsible for the proper conduct of the investigation. I will also forward a copy of the approved co-investigators to my IRB/Ethics Committee (or equivalent) if a review was obtained.

CO-INVESTIGATORS	CENTER
_____	_____
_____	_____
_____	_____

In addition, as investigator for the "Advancements in ICD Therapy (ACT) Registry" investigation, I approve the following individual(s) (i.e., Research Nurse) to sign off on case-report forms.

INDIVIDUALS AUTHORIZED TO COMPLETE CASE REPORT FORMS:	TITLE
_____	_____
_____	_____
_____	_____

_____
Investigator's name

_____ _____
Signature of Investigator Date

APPENDIX D:

GRANT AGREEMENT

St. Jude Medical
"Advancements in ICD Therapy (ACT) Registry"

The purpose of this grant is to compensate you, the investigator, for performing procedures, tasks and follow-up care that is not otherwise reimbursed or paid for by the insurance or other federal or state health care programs. These additional procedures, tasks and obligations are for the purposes of collecting valuable patient and device data that assist in evaluating the performances of the device that is the subject of this registry.

Therefore, St. Jude Medical (hereinafter referred to as SJM) will provide this research investigation grant for the thorough, accurate completion and timely submission of required research investigation data by the investigating centers. These funds are intended to defray the additional expenses associated with the research investigation, which are incurred by the Investigator and his staff.

GRANT ALLOCATIONS

Each research center will receive a total of $2,000 ($500 each for enrollment and $375 for all scheduled follow-up visits) per patient appropriately reported and studied in accordance with completing the registry protocol; this reimbursement will be contingent upon data review and approval of SJM. Enrollment shall cease immediately upon written notification by SJM that the overall target population (5,000 patients) has been reached. Any patients enrolled subsequent to said notification shall not be subject to reimbursement unless previously agreed upon by SJM.

GRANT DISBURSEMENT INFORMATION/SCHEDULE

Research investigation grant money will be paid for on a quarterly basis based on data received, providing that all required consents, Patient Information Forms and Patient Information Updates are accurately completed and submitted to SJM. Please note that reimbursements will be initially denied if paperwork is not submitted or submitted incorrectly.

Payments made by SJM pursuant to this investigation are for the legitimate reimbursement of time, effort and oversight by the Investigator and their professional staff, to accurately collect and submit valuable data relating to this research investigation protocol.

On a quarterly basis, reimbursement eligibility (on a per patient basis) will be established. An invoice detailing data received for the specified reimbursement period will be mailed to the Center (or address specified on signature page), along with a check for the corresponding amount. The invoice should be reviewed carefully to ensure there are no discrepancies. Any required corrections will be verified and updated in the following quarter's reimbursement invoice.

REGISTRY PLAN

(To be signed and returned to St. Jude Medical)

Advancements in ICD Therapy (ACT) Registry

I understand and agree to the foregoing terms and conditions listed and accept them as the terms of the SJM, "Advancements in ICD Therapy (ACT) Registry" Grant Allocation.

The Grant payments should be made out to the following:

Payable to: _____

(Please print or type)

Address: _____

Attention: _____

Note: If request from investigation site is to pay physician directly with a SS# – our accounting office needs the physician's home address

Home Address (if applic.) _____

Tax ID #: _____

Telephone # _____ Fax # _____

_____
Investigator's Signature

_____
Investigator's Name (Please Print)

_____ _____
Investigating Center Date

ADDITIONAL INFORMATION REGARDING REIMBURSEMENT:

_____

_____

APPENDIX E:

SITE INFORMATION

Advancements in ICD Therapy (ACT) Registry

Hospital*: _____

Address: _____

City/State/Zip: _____

Phone Number: _____

Fax Number: _____

IRB/Ethics Chair: _____

Investigator: _____

Practice Name: _____

Address: _____

City/State/Zip: _____

Phone Number: _____

Pager Number: _____

Fax Number: _____

Email Address: _____

Coordinator: _____ Phone: _____

Investigator's Signature: _____ Date_____

*If enrolling at multiple hospitals, please use separate sheet to list address/phone information for each hospital.

APPENDIX F:

PUBLICATION AGREEMENT

Advancements in ICD Therapy (ACT) Registry

The following guidelines have been established for publications and/or presentations of Scientific Studies:

- Investigator Agreement has been signed by the investigator who agrees that all the registry data collected will be published and/or presented in an integrated manner reflecting the results observed across all participating centers.
- St. Jude Medical is the legal owner of the entire Scientific Studies database. Decisions on the timing and content of publications and presentations from the registry will be coordinated by St. Jude Medical, in communication with participating centers contributing subjects to the registry.
- Investigators have the right to request data analysis and summaries of registry results (statistical tables, figures, and reports) developed from the St. Jude Medical Scientific Studies data pool for publications in journals, books and for abstracts. However, St. Jude Medical, reserves the right to deny any preliminary data analysis based on inadequate sample size, questionable results, or the priority of a study. To resolve any conflict of request, St. Jude Medical reserves the right to prioritize the requests based on:
    - Registry Protocol Authorship
    - Date of request receipt
    - The amount of data contributed
    - Order of investigator entry into the registry
- A proposal must be submitted to the Scientific Studies Organization (SSO) for review prior to preparation for publications and/or presentations with summarized information.
- Upon approval, the SSO will provide assistance in the release and analysis of the data for the proposed publication and/or presentation.
- SSO shall establish and maintain a position of cooperation and partnership with the investigators who wish to publish or present data obtained during the registry.
- Any Investigator using the Scientific Studies data pool should provide a copy of any abstract, manuscript or presentation to SSO for final review and approval prior to submission.
- All abstracts, manuscripts, and presentations using information from the St. Jude Medical Scientific Studies data pool should include all primary investigators and centers in the acknowledgments.
- If an investigator(s) plans to publish or present registry data collected at only his/her site, SSO will offer to review the abstract, manuscript, or presentation for technical accuracy. Furthermore, St. Jude Medical will request that a courtesy copy of the submitted abstract, manuscript, or presentation be forwarded to SSO.
- St. Jude Medical will follow the same publication policy as participating investigators but reserves the right to give presentations that do not require abstracts or manuscripts without approval.
- If an investigator(s) is to be named in any abstract, manuscript, or presentation proposed by St. Jude Medical, permission to use their name must be received prior to submission. Any investigator has the right to request that his/her name not appear on any abstract.

_____ / _____ _____

Investigator's Name / Signature Date

APPENDIX G:

CASE REPORT FORM(S)

REGISTRY PLAN

Sample Only: DO NOT USE

ST. JUDE MEDICAL | Office Use Only 286 -

ACT Registry
Patient Enrollment Form

1. General Information

Site Patient ID: _____ Enrollment Date: ☐☐☐ (Month) ☐☐ (Day) 2 0 ☐☐ (Year)

Physician: _____ (Last) _____ (First) ___ (M.I.)

Center: _____ City: _____

Date of Birth: ☐☐☐ (Month) ☐☐ (Day) 1 9 ☐☐ (Year)

Gender: ☐ Male ☐ Female

NYHA Class: ☐ I ☐ II ☐ III ☐ IV ☐ Unknown

Race:
☐ Asian/Pacific Islander ☐ American Indian or Alaskan Native
☐ African American ☐ Hispanic
☐ Caucasian ☐ Other: _____

Ejection Fraction: ☐☐ %
→ Collection Method: ☐ Echo ☐ MUGA ☐ Cath
→ Date Collected: ☐☐☐ (Month) ☐☐ (Day) 2 0 ☐☐ (Year)

Native QRS Duration: _____ ms

2. Primary Indication for ICD:

Indication		
VF	VF/VFL/PMVT	☐
VF and VT	VF/VFL/PMVT and MVT	☐
VT	MVT (sustained)	☐
MADIT II	Prior MI ≥ 1 Month, LVEF≤ 30%	☐
SCD - HeFT	NYHA Class II/III, LVEF≤ 35%	☐
Definite	Non - Ischemic CM, LVEF≤ 35%	☐
Familial Condition	Example: Long QT Syndrome	☐
Syncope	Meets AHA/ACC/NASPE classification I or IIb	☐
Other (Specify):	_____	☐

3. Device Information

Device Model Number: _____
Device Serial Number: _____
Device Implant Date: ☐☐☐ (Month) ☐☐ (Day) 2 0 ☐☐ (Year)

RA Lead Model Number: _____
→ Chronic: ☐ Yes ☐ No
RA Lead Implant Date: ☐☐☐ (Month) ☐☐ (Day) ☐☐☐☐ (Year)

RA Lead Position: ☐ RAA ☐ RA Septum

RV Lead Model Number: _____
→ Chronic: ☐ Yes ☐ No
RV Lead Implant Date: ☐☐☐ (Month) ☐☐ (Day) ☐☐☐☐ (Year)

RV Lead Position: ☐ RVA ☐ RVOT

LV Lead Model Number: _____
→ Chronic: ☐ Yes ☐ No
LV Lead Implant Date: ☐☐☐ (Month) ☐☐ (Day) ☐☐☐☐ (Year)

LV Lead Position: ☐ Anterior ☐ Lateral ☐ Posterior

60005125_REV_002 10/28/04 (Rev O1)

Sample Only: DO NOT USE

ST. JUDE MEDICAL | Office Use Only 286 - | *ACT Registry* **Patient Enrollment Form**

Site Patient ID: _____

4. Risk Stratification Parameters

TWA: ☐ Positive ☐ Negative ☐ Not Done

Holter: ☐ Positive ☐ Negative ☐ Not Done

EP Study: ☐ Positive ☐ Negative ☐ Not Done

→ Induced VT Cycle Length: _____

5. Previous Cardiovascular History (Check all that apply)

☐ None

☐ Coronary Artery Disease
- ☐ CABG
- ☐ PTCA
- ☐ Previous Myocardial Infarction
  - → Date: ☐☐☐ (Month) ☐☐ (Day) 2 0 ☐☐ (Year)

☐ Cardiomyopathy
- ☐ Dilated
- ☐ Hypertrophic
- ☐ Ischemic

☐ Hypertension (Controlled)

☐ Catheter Ablation

☐ Other: _____

6. Other Arrhythmias (Check all that apply)

☐ Paroxysmal Atrial Fibrillation ☐ Atrial Tachycardia ☐ Sinus Tachycardia

☐ Atrial Flutter ☐ Premature Atrial Contractions ☐ Sinus Node Dysfunction

☐ Heart Block:

☐ 1st degree ☐ 2nd degree - type 1 ☐ 2nd degree - type 2 ☐ 3rd degree

☐ Other (Specify): _____

_____

7. Current Cardiac Drug Therapy ☐ None

Name of Drug	Total Daily Dosage (mg)	Discontinued Before Enrollment
1.		☐ Yes ☐ No
2.		☐ Yes ☐ No
3.		☐ Yes ☐ No
4.		☐ Yes ☐ No
5.		☐ Yes ☐ No

Sample Only: DO NOT USE

ST. JUDE MEDICAL | Office Use Only 286 -

ACT Registry
Patient Enrollment Form

Site Patient ID: _____

8. Lead Testing (Device Based)

Lead	Capture Threshold (V)		Pulse Width	Sensing Threshold (mV)		No P or R Wave	Lead Impedance (Ohms)
RA Lead	☐ Unipolar ☐ Bipolar		0.5	☐ Unipolar ☐ Bipolar		☐	
RV Lead	☐ Unipolar ☐ Bipolar		0.5	☐ Unipolar ☐ Bipolar		☐	
LV Lead	☐ Unipolar ☐ Bipolar ☐ LVtip-RVring		0.5	☐ Unipolar ☐ Bipolar ☐ LVtip-RVring		☐	

Defibrillation Electrode Configuration: ☐ RV ☐ RV+SVC

Final DFT (if done): _____ V _____ J ☐ Not done

High Voltage Lead Impedance: _____ Ω

9. Comments _____

10. Attached To This Form

Do not send original case report forms
Photocopy programmer printouts

- Measured Data
- Final Programmed Parameters
- Floppy Diskette or Equivalent

11. Authorized Signature

I have reviewed and agree with the data reported on this form.

Date: ☐☐☐ ☐☐ 2 0 ☐☐
Month Day Year

Investigator Signature: _____

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60005125_REV_002 10/28/04 (Rev 0i)

Sample Only: DO NOT USE

ST. JUDE MEDICAL | Office Use Only 286 - | *ACT Registry* Follow-up Data Form

1. Visit ☐ 6 Months ☐ 12 Months ☐ 18 Months ☐ 24 Months
☐ Other: _____

2. General Information Follow-up Date: ☐☐ (Month) ☐☐ (Day) 2 0 0 ☐ (Year)

Site Patient ID: _____ Device Serial Number: _____

Physician: _____ (Last) _____ (First) ___ (M.I.)

Center: _____ City: _____

If new data is available, please complete the following:

NYHA Class:
☐I ☐II ☐III ☐IV
☐Unknown

Ejection Fraction: ☐☐ %
→ Collection Method:
☐Echo ☐MUGA ☐Cath
→ Date Collected: ☐☐ (Month) ☐☐ (Day) 2 0 0 ☐ (Year)

3. Current Cardiac Drug Therapy

Was the drug therapy adjusted? ☐ Yes ☐ No

Name of Drug	Total Daily Dosage (mg)	Change From Last Visit
1.		☐ Yes ☐ No
2.		☐ Yes ☐ No
3.		☐ Yes ☐ No
4.		☐ Yes ☐ No
5.		☐ Yes ☐ No

4. Lead Testing (Device Based)

Lead	Capture Threshold (V)		Pulse Width	Sensing Threshold (mV)		No P or R Wave	Lead Impedance (Ohms)
RA Lead	☐ Unipolar ☐ Bipolar		0.5	☐ Unipolar ☐ Bipolar		☐	
RV Lead	☐ Unipolar ☐ Bipolar		0.5	☐ Unipolar ☐ Bipolar		☐	
LV Lead	☐ Unipolar ☐ Bipolar ☐ LVtip-RVring		0.5	☐ Unipolar ☐ Bipolar ☐ LVtip-RVring		☐	

High Voltage Lead Impedance: _____ Ω

Sample Only: DO NOT USE

ST. JUDE MEDICAL | Office Use Only 286 - | *ACT Registry* Follow-up Data Form

Site Patient ID: _____

5. Clinical Diagnosis Total Episodes of Tachycardia Diagnosis _____ ☐ No Episodes

(Confirmed with stored EGMs)

Cause of Episode Detection:	Quantity	EGM # (s)
☐ VT		
☐ VF		
☐ Atrial Fibrillation		
☐ Atrial Tachycardia		
☐ Lead/Device Related Problem		
☐ Oversensing		
☐ Undersensing		
☐ Inappropriate Therapy		
☐ Other (specify): _____		
☐ Unknown		

6. Device Reprogramming

Was there any device reprogramming? ☐ Yes ☐ No

→ ☐ Bradycardia Parameters ☐ Tachycardia Parameters

If inappropriate therapy was delivered, what was the reason?

☐ SVT Detection ☐ T-wave Oversensing

☐ AF Detection ☐ QRS Double Sensing

☐ Antiarrhythmic Medication ☐ Other (specify): _____

How was the system reprogrammed to minimize this from occurring in the future?

☐ Nothing Done

☐ Adjust SVT Discriminators

☐ Adjust Atrial/Ventricular Sensitivity

☐ Adjust Decay Delay

☐ Adjust Threshold Start

☐ Adjust Antiarrhythmic Medication

Were there any programming changes done at the previous follow-up visit?

☐ Yes ☐ No

→ Were they effective in preventing inappropriate therapy? ☐ Yes ☐ No

Sample Only: DO NOT USE

ST. JUDE MEDICAL | Office Use Only 286 - | *ACT Registry* Follow-up Data Form

Site Patient ID: _____

7. Device Related Events

Hospitalizations ☐ Yes ☐ No
- → Number of hospitalizations: _____
- → Number of total hospital days: _____

ER Visit (Cardiac Related) ☐ Yes ☐ No
- → Number of emergency room visits: _____

External Cardioversion ☐ Yes ☐ No
- → Number of atrial external cardioversions: _____
- → Number of ventricular external cardioversions: _____

8. Comments _____

9. Attached To This Form

- Measured Data
- Final Programmed Parameters
- Floppy Diskette or Equivalent

Do not send original case report forms
Photocopy programmer printouts

10. Authorized Signature

I have reviewed and agree with the data reported on this form.

Investigator Signature: _____

Date: ☐☐☐ Month ☐☐ Day 2 0 ☐☐ Year

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IM005126_Rev_001
10/11/04 (Rev 0b)

REGISTRY PLAN

Sample Only: DO NOT USE

ST. JUDE MEDICAL | Office Use Only 286 -

ACT Registry
Adverse Event Form

1. General Information

Site Patient ID: _____ Device Serial Number: _____

Physician: _____ (Last) _____ (First) ____ (M.I.)

Center: _____ City: _____

2. Event Description

Adverse Event Date: ☐☐☐ (Month) ☐☐ (Day) 2 0 ☐☐ (Year)

☐ LV ☐ RV ☐ Atrial Lead Dislodgment or Migration

☐ LV ☐ RV ☐ Atrial Lead System Fracture diagnosed by: ☐ X-Ray ☐ Electrogram ☐ Impedance measurement

☐ LV ☐ RV ☐ Atrial Lead System Insulation Damage diagnosed by: ☐ Electrogram ☐ Impedance measurement

☐ LV ☐ RV ☐ Atrial Loss of Capture

☐ LV ☐ RV ☐ Atrial Elevated Pacing Thresholds

☐ LV ☐ RV ☐ Atrial Decreased R/P-Wave Amplitude/Loss of Sensing

☐ LV ☐ RV ☐ Atrial Oversensing caused by: ☐ Noise ☐ EMI ☐ AV sensing ☐ T wave sensing

☐ LV ☐ RV ☐ Atrial Undersensing

☐ Prolonged Detection/Redetection Time (attach a copy of the electrogram)

☐ Failure to Diagnose Ventricular Rhythm (attach a copy of the electrogram)

☐ Programming Difficulties caused by: ☐ Wand Problems ☐ EMI ☐ Unknown ☐ Device Flipped ☐ Implant depth

☐ Therapy/Aborted Therapy for Non-Ventricular Rhythm: ☐ AF/AFL ☐ ST ☐ SVT ☐ Other: _____

☐ Other (specify): _____

☐ Patient Death (Please complete Report of Patient Death Form and Patient Withdrawal Form)

3. Description of Complication/Observation

1. **Indicate the resolution for the complication/observation that occurred:**

☐ Surgical Intervention (please provide surgical report) ☐ Lead Reposition ☐ Device Explant
☐ Lead Explant ☐ System Revision ☐ Device reprogramming
☐ Other: _____

2. **Describe the complication/observation and patient outcome:**

_____

_____

_____

4. Authorized Signature

Do not send original case report forms

I have reviewed and agree with the data reported on this CRF.

Investigator Signature: _____ Date: ☐☐☐ (Month) ☐☐ (Day) 2 0 ☐☐ (Year)

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60006127_REV_001 10/01/04 (Rev 03)

Sample Only: DO NOT USE

ST. JUDE MEDICAL | Office Use Only 286 -

ACT Registry
Protocol Deviation Form

1. General Information

Site Patient ID: _____ Device Serial Number: _____

Physician: _____ (Last) _____ (First) _____ (M.I.)

Center: _____ City: _____

Visit: ☐ 6 Months ☐ 12 Months ☐ 18 Months ☐ 24 Months ☐ Other: _____

2. Deviation:

Deviation Date: ☐☐☐ (Month) ☐☐ (Day) 2 0 ☐☐ (Year)

Indication
- ☐ Inclusion/Exclusion criteria not met

Follow-up Visit/Remote Transmission
- ☐ Skipped
- ☐ Out of visit tolerance range

Study Procedure
- ☐ Non-protocol defined device implanted
- ☐ Non-protocol defined lead implanted
- ☐ Lead positioning
- ☐ Randomization
- ☐ Device programming
- ☐ Data collection
- ☐ Documentation completion
- ☐ Required testing
- ☐ Other (specify): _____

3. Reason for Deviation: (Explain in detail): _____

4. Authorized Signature

Do not send original case report forms

I have reviewed and agree with the data reported on this CRF.

Investigator Signature: _____ Date: ☐☐☐ (Month) ☐☐ (Day) 2 0 ☐☐ (Year)

Page 1 of 1

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60005128_REV_001 09/2004 (Rev OA)

Sample Only: DO NOT USE

ST. JUDE MEDICAL | Office Use Only 286 - | *ACT Registry* Report of Patient Death Form

1. General Information Date of Notification: ☐☐ Month ☐☐ Day 2 0 ☐☐ Year

Site Patient ID: _____ Device Serial Number: _____

Physician: _____ Last _____ First _____ MI

Center: _____ City: _____

2. Was the death witnessed? ☐ Yes ☐ No ☐ Unknown

Date and time of death or when patient found:

☐☐ : ☐☐ Hour Minute ☐ am ☐ pm ☐☐ Month ☐☐ Day 2 0 ☐☐ Year

OR

If death not witnessed, last date known alive: ☐☐ Month ☐☐ Day 2 0 ☐☐ Year

3. Was the device enabled at the time of death? ☐ Yes ☐ No ☐ Unknown

4. In the opinion of the investigator, was this death related to the implanted system? ☐ Yes ☐ No

5. Was an autopsy performed? ☐ Yes ☐ No ☐ Unknown

6. Time from onset of symptoms until death?

☐ < 5 minutes ☐ 5 - 60 minutes ☐ 61 minutes - 24 hours ☐ > 24 hours ☐ Unknown

7. Classify the patient death:

☐ **Sudden Cardiac Death:** A Sudden Cardiac Death is a death which is cardiac in origin that occurs unexpectedly within one hour of the onset of new symptoms or a death that was unwitnessed, unless the cause of death was confirmed to be non-cardiac.

☐ **Non-Sudden Cardiac Death:** A Non-Sudden Cardiac Death is a death which is cardiac in origin, but not a Sudden Cardiac Death.

☐ **Non-Cardiac Death:** A Non-Cardiac Death is a death which is not primarily cardiac in origin.

8. Comments: _____

9. Attached To This Form:

● Patient Withdrawal Form ● Adverse Event Form

10. Authorized Signature **Do not send original case report forms**

I have reviewed and agree with the data reported on this form.

Investigator Signature: _____ Date: ☐☐ Month ☐☐ Day 2 0 ☐☐ Year

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60005129_REV_001 10/01/04 (Rev 0A)

Sample Only: DO NOT USE

ST. JUDE MEDICAL

Office Use Only
286 -

ACT Registry
Patient Withdrawal Form

1. General Information

Site Patient ID: _____ Device Serial Number: _____

Physician: _____ (Last) _____ (First) ____ (M.I.)

Center: _____ City: _____

2. Reason for Withdrawal Withdrawal Date: ☐☐☐ (Month) ☐☐ (Day) 2 0 ☐☐ (Year)

☐ Patient Death (Complete Report of Patient Death Form)

☐ Patient Lost to Follow-up

☐ Device Out of Service

☐ Other (specify): _____

3. Comments _____

4. Authorized Signature **Do not send original case report forms**

I have reviewed and agree with the data reported on this CRF.

Investigator Signature: _____ Date: ☐☐☐ (Month) ☐☐ (Day) 2 0 ☐☐ (Year)

Page 1 of 1

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60005130_Rev_001

(10/2004 (Rev 0A)

EXHIBIT 5

ACT

Office	Last	First	Implant Date	Last Day to Enroll	Enroll Date	Device Model	Device Serial	Sent Date	6-Month Earliest	6 Month Actual	6 Month Latest	Sent Date
OBC	MET	GER	02/15/05	04/01/05	03/17/05	V193	123358	sent	07/31/05		08/28/05	
LRH	COL	LAW	03/02/05	04/16/05	03/21/05	V193	135000	04/15/05	08/15/05		09/12/05	
OBC	KEL	LEL	03/03/05	04/17/05	04/06/05	V193	137724	sent	08/16/05		09/13/05	
LRH	WEI	ALB	03/16/05	04/30/05	05/05/05	V193	153915	05/23/05	08/29/05		09/26/05	
LRH	KIR	MAR	03/16/05	04/30/05	04/18/05	V193	137742	04/27/05	08/29/05		09/26/05	
LRH	CRI	LEO	03/16/05	04/30/05	05/16/05	V193	144852	05/23/05	08/29/05		09/26/05	
LRH	REI	DOR	03/23/05	05/07/05	04/04/05	V193	152545	04/15/05	09/05/05		10/03/05	
MRMC	SMI	LIL	03/23/05	05/07/05	05/10/05	V242	131515	06/04/05	09/05/05		10/03/05	
LRH	LUT	WIL	03/23/05	05/07/05	04/18/05	V193	154383	04/27/05	09/05/05		10/03/05	
MRMC	GRO	DAL	04/05/05	05/20/05	05/10/05	V243	153670	06/04/05	09/18/05		10/16/05	
LRH	POW	WIL	04/06/05	05/21/05	04/18/05	V193	156495	04/27/05	09/19/05		10/17/05	
LRH	ELL	THO	04/06/05	05/21/05	04/18/05	V193	156519	04/27/05	09/19/05		10/17/05	
LRH	BRO	EUN	04/08/05	05/23/05	04/14/05	V242	142259	04/15/05	09/21/05		10/19/05	
LRH	WEB	PEG	04/11/05	05/26/05	04/14/05	V193	156510	04/15/05	09/24/05		10/22/05	
LRH	SEA	JOA	04/11/05	05/26/05	04/18/05	V193	156498	04/27/05	09/24/05		10/22/05	
MRMC	KLE	VIR	04/13/05	05/28/05	05/23/05	V239	123463	06/04/05	09/26/05		10/24/05	
LRH	GOF	PAU	04/13/05	05/28/05	05/10/05	V193	154651	06/04/05	09/26/05		10/24/05	
LRH	FRA	GER	04/13/05	05/28/05	05/05/05	V193	156558	05/23/05	09/26/05		10/24/05	
LRH	SHI	OSC	04/20/05	06/04/05	05/24/05	V193	151624	05/31/05	10/03/05		10/31/05	
MRMC	SHO	WEL	04/21/05	06/05/05	05/10/05	V242	131673	05/31/05	10/04/05		11/01/05	
OBC	SCH	FRE	05/03/05	06/17/05	05/19/05	V193	160275	05/23/05	10/16/05		11/13/05	
LRH	STE	HAN	05/09/05	06/23/05	05/24/05	V193	160547	05/31/05	10/22/05		11/19/05	
MRMC	CUM	SHE	05/24/05	07/08/05	05/24/05	V242	135943	06/04/05	11/06/05		12/04/05	
OBC	OSB	RUS	05/10/05	06/24/05	05/19/05	V193		05/23/05	10/23/05		11/20/05	
MRMC	JOH	DON	05/12/05	06/26/05	06/14/05	V242	143116	06/23/05	10/25/05	Exp 7/5	11/22/05	
LOH	JEN	JOH	05/16/05	06/30/05	06/20/05	V193	160080	06/21/05	10/29/05		11/26/05	
MRMC	LIL	JIM	05/17/05	07/01/05	06/28/05	V242	138636	sent	10/30/05		11/27/05	
LOH	RIL	DOR	05/18/05	07/02/05	06/20/05	V193	160254	06/21/05	10/31/05		11/28/05	

SSO TRACKING

12-Month Earliest	12 Month Actual	12 Month Latest	Sent Date	18-Month Earliest	18 Month Actual	18 Month Latest	Sent Date	24-Month Earliest	24 Month Actual	24 Month Latest	Sent Date	unscheduled fups	
01/27/06		02/24/06		07/26/06		08/23/06		01/22/07		02/19/07			
02/11/06		03/11/06		08/10/06		09/07/06		02/06/07		03/06/07			
02/12/06		03/12/06		08/11/06		09/08/06		02/07/07		03/07/07			
02/25/06		03/25/06		08/24/06		09/21/06		02/20/07		03/20/07			
02/25/06		03/25/06		08/24/06		09/21/06		02/20/07		03/20/07			
02/25/06		03/25/06		08/24/06		09/21/06		02/20/07		03/20/07			
03/04/06		04/01/06		08/31/06		09/28/06		02/27/07		03/27/07			
03/04/06		04/01/06		08/31/06		09/28/06		02/27/07		03/27/07			
03/04/06		04/01/06		08/31/06		09/28/06		02/27/07		03/27/07			
03/17/06		04/14/06		09/13/06		10/11/06		03/12/07		04/09/07			
03/18/06		04/15/06		09/14/06		10/12/06		03/13/07		04/10/07			
03/18/06		04/15/06		09/14/06		10/12/06		03/13/07		04/10/07			
03/20/06		04/17/06		09/16/06		10/14/06		03/15/07		04/12/07			
03/23/06		04/20/06		09/19/06		10/17/06		03/18/07		04/15/07			
03/23/06		04/20/06		09/19/06		10/17/06		03/18/07		04/15/07			
03/25/06		04/22/06		09/21/06		10/19/06		03/20/07		04/17/07			
03/25/06		04/22/06		09/21/06		10/19/06		03/20/07		04/17/07			
03/25/06		04/22/06		09/21/06		10/19/06		03/20/07		04/17/07			
04/01/06		04/29/06		09/28/06		10/26/06		03/27/07		04/24/07			
04/02/06		04/30/06		09/29/06		10/27/06		03/28/07		04/25/07			
04/14/06		05/12/06		10/11/06		11/08/06		04/09/07		05/07/07			
04/20/06		05/18/06		10/17/06		11/14/06		04/15/07		05/13/07			
05/05/06		06/02/06		11/01/06		11/29/06		04/30/07		05/28/07			
04/21/06		05/19/06		10/18/06		11/15/06		04/16/07		05/14/07			
04/23/06		05/21/06		10/20/06		11/17/06		04/18/07		05/16/07			
04/27/06		05/25/06		10/24/06		11/21/06		04/22/07		05/20/07			
04/28/06		05/26/06		10/25/06		11/22/06		04/23/07		05/21/07			
04/29/06		05/27/06		10/26/06		11/23/06		04/24/07		05/22/07			

SSO TRACKING

Office	Last	First	Implant Date	Last Day to Enroll	Enroll Date	Device Model	Device Serial	Sent Date	6-Month Earliest	6 Month Actual	6 Month Latest	Sent Date
LOH	MET	HAR	05/20/05	07/04/05	06/20/05	V193	160262	**06/21/05**	11/02/05		11/30/05	
LOH	DOU	TER	05/25/05	07/09/05	06/20/05	V193	160555	**06/21/05**	11/07/05		12/05/05	
MRMC	BED	ROB	05/26/05	07/10/05	06/14/05	V242	151122	**06/23/05**	11/08/05		12/06/05	
OBC	WEE	ROB	05/27/05	07/11/05	06/16/05	V242	151102	**06/23/05**	11/09/05		12/07/05	
LOH	JOH	KEN	05/27/05	07/11/05	06/20/05	V193	160556	**06/21/05**	11/09/05		12/07/05	
MRMC	BER	ERM	06/02/05	07/17/05	06/14/05	V239	135313	**06/23/05**	11/15/05		12/13/05	
LOH	WAR	JAM	06/06/05	07/21/05	06/20/05	V193	164790	**06/21/05**	11/19/05		12/17/05	
MRMC	BLO	BAR	06/21/05	08/05/05	07/12/05	V243	162532		12/04/05		01/01/06	
OBC	CAR	EMI	06/20/05	08/04/05	07/21/05	V193		**07/22/05**	12/03/05		12/31/05	
OBC	HUL	JEA	06/21/05	08/05/05	07/15/05	V242	157161		12/04/05	Expired	01/01/06	
OBC	BRA	JOH	06/21/05	08/05/05	07/21/05	V193	165418	**07/22/05**	12/04/05		01/01/06	
LRH	MAS	RIC	07/06/05	08/20/05	07/18/05	V193	165226	**07/19/05**	12/19/05		01/16/06	
LRH	SMI	JAM	06/27/05	08/11/05	07/18/05	V193	164795	**07/19/05**	12/10/05		01/07/06	
LRH	BRO	RIC	07/13/05	08/27/05		V193	165380		12/26/05		01/23/06	
LRH	GRE	MIC	07/18/05	09/01/05		V193	164776		12/31/05		01/28/06	
LRH	MCC	DON	07/18/05	09/01/05		V193	164794		12/31/05		01/28/06	
LRH	WON	JOS	07/20/05	09/03/05		V193	164785		01/02/06		01/30/06	
MRMC	DAU	WIL	07/21/05	09/04/05		V243	162538		01/03/06		01/31/06	
MRMC	RAY	PAT	07/26/05	09/09/05		V243	147502		01/08/06		02/05/06	
LRH	CON	PAT	07/27/05	09/10/05		V193	164812		01/09/06		02/06/06	
LRH	PAR	KAT	08/03/05	09/17/05		V193	234389		01/16/06		02/13/06	
LRH	DAV	DOR	08/03/05	09/17/05		V193	233640		01/16/06		02/13/06	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	

SSO TRACKING

12-Month Earliest	12 Month Actual	12 Month Latest	Sent Date	18-Month Earliest	18 Month Actual	18 Month Latest	Sent Date	24-Month Earliest	24 Month Actual	24 Month Latest	Sent Date	unscheduled fups	
05/01/06		05/29/06		10/28/06		11/25/06		04/26/07		05/24/07			
05/06/06		06/03/06		11/02/06		11/30/06		05/01/07		05/29/07			
05/07/06		06/04/06		11/03/06		12/01/06		05/02/07		05/30/07			
05/08/06		06/05/06		11/04/06		12/02/06		05/03/07		05/31/07			
05/08/06		06/05/06		11/04/06		12/02/06		05/03/07		05/31/07			
05/14/06		06/11/06		11/10/06		12/08/06		05/09/07		06/06/07			
05/18/06		06/15/06		11/14/06		12/12/06		05/13/07		06/10/07			
06/02/06		06/30/06		11/29/06		12/27/06		05/28/07		06/25/07			
06/01/06		06/29/06		11/28/06		12/26/06		05/27/07		06/24/07			
06/02/06		06/30/06		11/29/06		12/27/06		05/28/07		06/25/07			
06/02/06		06/30/06		11/29/06		12/27/06		05/28/07		06/25/07			
06/17/06		07/15/06		12/14/06		01/11/07		06/12/07		07/10/07			
06/08/06		07/06/06		12/05/06		01/02/07		06/03/07		07/01/07			
06/24/06		07/22/06		12/21/06		01/18/07		06/19/07		07/17/07			
06/29/06		07/27/06		12/26/06		01/23/07		06/24/07		07/22/07			
06/29/06		07/27/06		12/26/06		01/23/07		06/24/07		07/22/07			
07/01/06		07/29/06		12/28/06		01/25/07		06/26/07		07/24/07			
07/02/06		07/30/06		12/29/06		01/26/07		06/27/07		07/25/07			
07/07/06		08/04/06		01/03/07		01/31/07		07/02/07		07/30/07			
07/08/06		08/05/06		01/04/07		02/01/07		07/03/07		07/31/07			
07/15/06		08/12/06		01/11/07		02/08/07		07/10/07		08/07/07			
07/15/06		08/12/06		01/11/07		02/08/07		07/10/07		08/07/07			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			

SSO TRACKING

Office	Last	First	Implant Date	Last Day to Enroll	Enroll Date	Device Model	Device Serial	Sent Date	6-Month Earliest	6 Month Actual	6 Month Latest	Sent Date
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	
									06/14/00		07/12/00	

SSO TRACKING

12-Month Earliest	12 Month Actual	12 Month Latest	Sent Date	18-Month Earliest	18 Month Actual	18 Month Latest	Sent Date	24-Month Earliest	24 Month Actual	24 Month Latest	Sent Date	unscheduled fups	
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			
12/11/00		01/08/01		06/09/01		07/07/01		12/06/01		01/03/02			

SSO TRACKING