UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

ROBERT L. SATOW, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. ST. JUDE MEDICAL, INC. AND DANIEL J. STARKS, Defendants.	Civil No. _____ **CLASS ACTION** **COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

INTRODUCTION AND OVERVIEW

1. This is a putative class action for violations of the federal securities laws on behalf of all purchasers of the publicly traded securities of St. Jude Medical, Inc. ("St. Jude" or the "Company") between December 15, 2010 and April 4, 2012 (the "Class Period"), who were damaged thereby (the "Class"). St. Jude develops, manufactures and distributes cardiovascular medical devices.

2. During the Class Period, defendants told investors that two of the leads[1] sold by St. Jude, the Riata and Riata ST electrical wire, had been observed to wear through the silicone casing meant to contain them and protrude into the body. St. Jude thereafter discontinued sales of the Riata and Riata ST.

3. Defendants, however, failed to disclose the full extent of the problems with its products. First, defendants failed to disclose that the Riata and Riata ST were also associated with short circuits unrelated to the protruding wires. Although less frequent than the protrusions, the short circuits were much more dangerous. Second, defendants failed to disclose that two other leads sold by the company, the QuickSite and QuickFlex Left-Ventricular leads, suffered from the same protruding wires that plagued the Riata and Riata ST.

4. Subsequently, on March 27, 2012, *The New York Times* disclosed the results of an analysis performed by an independent researcher, Dr. Robert Hauser, which indicated that the Riata and Riata ST caused short circuits. Defendants vehemently challenged these findings, thus maintaining the artificial inflation in St. Jude's stock.

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[1] A "lead" is a wire that connects a defibrillator to the heart.

5. On April 4, 2012, defendants finally disclosed that the QuickSite and QuickFlex Left-Ventricular leads also suffered from the same protruding wire defect as the Riata and Riata ST. Sales of the QuickSite and QuickFlex Left-Ventricular leads were discontinued.

6. As a result of these disclosures, the closing price of St. Jude's stock dropped from $43.80 to $38.91 over three trading days, a decline of over 11%. This decrease was a result of the artificial inflation caused by defendants' misleading statements coming out of the price.

7. Defendants were aware of the undisclosed defects in their products throughout the Class Period. Indeed, during the Class Period, defendant Daniel J. Starks ("Starks" or "Individual Defendant"), St. Jude's Chairman, President and Chief Executive Officer ("CEO"), told investors that "we have the most robust post-market surveillance of lead reliability of anybody in the industry....So we have a lot of confidence that we have a good handle on St. Jude Medical device reliability."

8. The wire protrusions from the QuickSite and QuickFlex left-ventricular leads were apparent to Starks since they utilized the same silicone coating that malfunctioned in the Riata leads. Regarding the short-circuiting of the Riata leads, *The New York Times* reported that defendants knew about but chose not to disclose them: Dr. Mark Carlson, chief medical officer at St. Jude, said "St. Jude had not called more attention to the electrical malfunctions – in contrast to its warnings about the protruding wires – because the electrical failures were far more common."

9. Since the disclosure of the defects in St. Jude's leads, several prominent experts have criticized the Company's conduct. Dr. Ernest W. Lau of Belfast, Northern Ireland took his concerns about St. Jude's leads to Company officials in 2010. "There should have been more warning," said Dr. Lau, who is a heart device expert at Royal Victoria Hospital.

10. Dr. Kenneth Ellenbogen, a device expert in Richmond who has consulted for St. Jude and its competitors, stated, "***They have at multiple steps underplayed the gravity of the situation.***" Indeed, *The New York Times* reported that, "It is the wide difference between the data reported by outside researchers and the early reports put out by St. Jude that has led some experts, like Dr. Ellenbogen in Richmond, to question why St. Jude did not root out the problem's scope."

11. Dr. Robert J. Myerburg, who led an independent investigation into the decision by one of St. Jude's competitors about short-circuiting defibrillators, stated, "Someone in the company should have been watching this."

12. Dr. Edward J. Schloss of Cincinnati stated, "I would hope that anybody looking at that data would say, hey, something is not right here...I think if you saw 20 high-voltage fatalities with a pretty clear pattern of insulation abrasion, that should get your attention."

JURISDICTION AND VENUE

13. The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated there under. Jurisdiction and venue are conferred by §27 of the Exchange Act. St. Jude's headquarters

are located in St. Paul, Minnesota and acts giving rise to the violations complained of occurred in this District.

THE PARTIES

14. Plaintiff Robert L. Satow purchased St. Jude securities during the Class Period as set forth in the attached certification and was damaged thereby.

15. Defendant St. Jude develops, manufactures and distributes cardiovascular medical devices. St. Jude's common stock is traded under the symbol STJ on the New York Stock Exchange, which is an efficient market.

16. Defendant Daniel J. Starks was, at all relevant times, Chairman, President, and CEO of the Company.

17. During the Class Period, defendants had both the motive and opportunity to conduct fraud. They also had actual knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time. In so doing, defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchasers of St. Jude securities during the Class Period.

MISLEADING CLASS PERIOD STATEMENTS AND OMISSIONS

18. On December 15, 2010, defendants published an open letter to physicians announcing the protrusion problem with the Riata leads and ending all further sales of those leads. The letter stated in relevant part:

> This letter provides important product information regarding the St. Jude Medical Riata and Riata ST family of defibrillation leads which use

silicone as the outer insulation material. As part of St. Jude Medical's commitment to transparency on device performance, we are bringing to your attention performance information regarding lead abrasion failures identified in the Riata silicone insulated defibrillation leads as compared to our newer lead models utilizing the Optim® insulation material (Riata ST Optim and Durata® family of defibrillation leads).

The Riata and Riata ST family of silicone defibrillation leads have exhibited an insulation abrasion rate of 0.47% over 9 years of use. Silicone rubber, while representing the industry's most commonly used defibrillation lead insulation material over the past 20 years, has been observed to be vulnerable to abrasion. Abrasion of silicone defibrillation leads is acknowledged within the clinical community as a well known clinical risk and is well documented in the literature as the number one cause of lead failure across the industry with reported failure rates ranging from 3 to 10 %. Lead insulation damage and its possible effects are also described as a potential adverse event in all silicone defibrillation lead user's manuals, including Riata User's manuals.

In contrast, St. Jude Medical's newer generations of defibrillation leads utilizing the Optim insulation material have demonstrated a reduction in lead abrasion-related observations by greater than 80% ($p < 0.0001$) at 44 months of follow-up as compared to our silicone leads. In addition, the difference in the overall survival rate at 44 months for St. Jude Medical defibrillation leads using Optim insulation (98.8%) vs. the Riata and Riata ST silicone leads (98.4%) is attributable to the lower rate of abrasion reported for Optim leads. The November 2010 issue of the St. Jude Medical Product Performance Report that provides a section on Optim lead performance (pages 213-214) can be found at http://www.sjm.com/professional.

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Recommendations and Mitigations
Based on the above data and demonstrated superior abrasion resistance of defibrillation leads utilizing Optim insulation, St. Jude Medical is completing the planned phase-out of all models of Riata and Riata ST silicone leads by December 31, 2010.

19. On March 2, 2011, St. Jude filed an Annual Report on Form 10-K with the Securities and Exchange Commission ("SEC") setting forth the financial results for the year ended January 1, 2011. The Form 10-K stated in relevant part:

Our ICDs are used with the single- and dual-shock electrode transvenous defibrillation leads. Our latest ICD lead offerings include the Durata™ SJ4 (FDA approval in April 2009) and Durata™ high voltage lead (FDA approval in January 2008), which features a soft silicone tip and curved right-ventricular (RV) coil designed to further improve implant performance. The Durata™ leads, along with the Riata® ST Optim leads (FDA approval in July 2006), are small-diameter ICD leads and feature our exclusive Optim™ insulation material that combines the durability of polyurethane and the softness of silicone. Optim™ insulation has demonstrated a statistically significant reduction in the incidence of insulation abrasion when compared to our previous silicone insulated leads. Optim™ insulation material was designed specifically for high- and low-voltage cardiac pacing leads. We now have Optim™ insulation available in all of our lead segments and have phased out our older silicone insulated leads in favor of the improved reliability of Optim™ based leads.

In December 2007, we released the QuickFlex™ family of LV leads in the United States and Europe. We also received approval for our smaller diameter lead QuickFlex (micro) LV lead (FDA approval in May 2010 and European CE Mark approval in September 2008).

20. The Form 10-K was accompanied by a certification signed by defendant Starks stating in relevant part:

1. I have reviewed this annual report on Form 10-K of St. Jude Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting....

21. On October 19, 2011, defendants held a conference call with investors during which defendant Starks engaged in the following colloquy:

Rick Wise - Leerink Swann, LLC - Analyst

You did. I'll just follow up on two things. I'm just focusing on some of the controversies this morning. If you could address – just a few of your thoughts on Riata and quadpole. Riata – how concerned are you if at all that this could develop to a more significant issue for St. Jude?

And quadpole, you clearly are stating that it's murky at the FDA these days. I assume the fourth quarter, since nothing from quadpole, if I understood you. When are you hoping – or is it right to think about first half, first quarter '12? How should we think about it?

Dan Starks - St. Jude Medical, Inc. - Chairman, President & CEO

* * *

...we have the most robust post-market surveillance of lead reliability of anybody in the industry.

A lot of times people will talk about the limitations of passive reporting. And we always point out that we have the most robust active reporting, active follow-up of our device reliability including our ICD lead reliability. We have a robust score registry, we have a robust optimum registry both of which are active registries. We conduct additional studies as needed on an active basis.

If you look at all of the fine print in the product performance reports that come out in the CRM space, you'll see that we break out more data and that the inputs into our data are far more comprehensive and robust than is the case from other organizations. So we have a lot of confidence that we have a good handle on St. Jude Medical device reliability.

22. On November 28, 2011, defendants published another open letter to doctors providing updated data regarding the wire protrusion in Riata leads. That letter stated in relevant part:

The purpose of this letter is to provide updated estimates of failures associated with all cause insulation failure on our Riata® (8Fr) and Riata ST (7Fr) silicone endocardial defibrillation leads, with a specific emphasis on externalized conductors. The information provided is based on updates to worldwide complaints and returns analysis as well as new peer reviewed publications. Out of over 227,000 Riata and Riata ST silicone leads sold worldwide over the past 9 years, the incidence rate based on returns and complaints (reports from the field with no product returned) is now estimated to be 0.63% for all cause abrasion versus the prior rate of 0.47% communicated in December 2010 (attached for your reference), with approximately 15% of those exhibiting externalized conductors.

Issuance of this letter is in conjunction with our recently released November 2011 Product Performance Report (available online at http://sjmprofessional.com). For your convenience the relevant sections of the November 2011 Product Performance Report (PPR), which provide details on the performance of our defibrillation leads and specific failure

mechanisms, are also attached. Although returned product analysis is recognized to underestimate failure rates, the relative rates of failure from one model to another should be representative of the overall clinical experience.

Lead Performance Summary

Kaplan-Meier analysis, which takes into account differences in follow-up duration between the lead models, shows that the Riata ST (7Fr) silicone leads, which included conductor configuration design changes, exhibit significantly lower externalized conductor incidence rates than the Riata (8Fr) silicone leads ($p=0.006$). As documented in our PPR, the large majority of implanted Riata and Riata ST silicone leads are expected to function normally. Also, Kaplan-Meier analysis shows at a highly statistically significant level that the Durata® and Riata ST Optim® leads that have the Optim insulation material are not prone to externalized conductors and have lower incidence rates for all cause abrasion compared to the Riata and Riata ST silicone leads (both $p<0.0001$).

New peer reviewed literature from one single center site in Belfast, Northern Ireland, has indicated a 15% incidence rate of externalized conductors in Riata silicone leads (25 out of 165 patients) during fluoroscopic screening, including 5 leads (3%) that were associated with an electrical abnormality. One significant finding out of the Belfast experience is that a large percentage (35%) of the patients with Riata leads at the site had Riata (8Fr) single shock coil models. Analysis of worldwide complaint and returns information has identified that Riata (8Fr) single shock coil models exhibit a significantly higher incidence rate of externalized conductors than all other Riata (8Fr) and Riata ST (7Fr) models, which helps explain why the Belfast experience has shown such a high incidence rate.

Root Cause

Externalized conductors occur when an abrasion results in an outer insulation breach within the vascular or cardiac systems allowing the normally contained conductors to become visible outside the lead body. Externalized conductors can be a result of relative motion of the conductor cables within the lead insulation lumen, referred to as "inside-out" abrasion, or from external sources of abrasion, e.g. lead-to-lead abrasion, where the outer insulation is breached and as a result the conductor cables are observed to be outside the lead body. Approximately 85% of the leads confirmed through laboratory analysis to exhibit externalized conductors occurring in Riata silicone leads are due to the inside-out variety while approximately 15% are attributed to external sources of abrasion (i.e.,

> outside-in). Also, the most common (approximately 75% of the confirmed cases) location of the externalization along the lead body is within 8 centimeters proximal to the RV shock coil , as the stress on that area of the lead may be higher than other areas of the lead due to lead movement associated with a patient's heart beat.

23. On December 15, 2011, defendants issued a press release announcing that the FDA had categorized the Riata and Riata ST letters to doctors a Class I Recall. That release stated in relevant part:

> St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced that the U.S. Food and Drug Administration (FDA) has classified its voluntary medical device advisory letter to physicians from Nov. 28, 2011, regarding the performance of Riata® and Riata® ST Silicone Defibrillation Leads, as a Class I Recall.
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> The classification of this recall is part of the process that follows any medical device advisory issued by a device manufacturer to physicians. The FDA's classification updates the recommendations provided in the Nov. 28, 2011 Physician Advisory Letter....The FDA has classified this recall as a Class I recall because of the potential risk of serious injury or patient death if affected devices malfunction.

24. On February 3, 2012, defendants held a conference call with investors during which defendant Starks stated in relevant part:

> I'd like to just spend a little bit of time talking about our post-market studies that support the performance and reliability of our Optim and our Durata leads. St. Jude Medical has by far and away the industry leading, prospective, actively monitored lead registries. And I want to make sure and just take a minute to talk about what we mean when we say prospective, actively monitored lead registries.
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> Patients who enrolled in these studies around the time of their implant, whenever they have a follow-up visit, whether it's scheduled or unscheduled or if they have an adverse event, the center will fill out a case report for them and send that back to the Company. We also have a dedicated group of field employees who are tasked with just going to these centers to make sure and monitor them and make sure that not only is the data that's coming back to us accurate, but also that there's no missing data.

So this is very different than the passive sort of reporting that gets done with just complaints and returned devices, which really forms the basis for all of the companies' product performance reports.

So in terms of the specific registries for our Optim and Durata leads, we have three large registries. The first one is our OPTIMUM Registry that was begun in August of 2006 with the introduction of our Optim lead insulation. In the OPTIMUM Registry we have almost 6,000 Durata and Riata ST Optim leads that were implanted in over 200 sites, and that registry has now been ongoing for more than five years.

Our SCORE Registry was started in September of 2007. We have over 3,100 Durata and Riata ST leads that were implanted at 58 sites, and that registry has now been ongoing for more than four years.

And then finally we have our SJ4 Post Approval Study that was begun in June of 2009 with the introduction of our DF4 version of our Durata leads. We have almost 1,700 DF4 Durata leads that were implanted also at 58 sites with greater than 2.5 years of follow-up in that registry.

So if you look at the combined experience for the prospective, actively monitored registries, we really have an extremely large patient cohort that represents the true commercial experience. And I can say the true commercial experience because those combined registries have over 10,800 defibrillation leads that were implanted at 292 clinical sites by 571 implanting physicians.

So really a very, very broad-based experience is included in these registries. The registries collectively have been running now for more than five years, and we have over 24,000 patient years of follow-up.

25. On February 29, 2012, St. Jude filed an Annual Report on Form 10-K with the SEC setting forth the financial results of the Company for the year ended December 31, 2011. The Form 10-K stated in relevant part:

Our latest ICD lead offerings include the Durata® SJ4 (FDA approval in April 2009) and Durata™ high voltage lead (FDA approval in January 2008), which feature a soft silicone tip and curved right-ventricular (RV) coil designed to further improve implant performance. The Durata® leads, along with the Riata® ST Optim® leads (FDA approval in July 2006), are small-diameter ICD leads and feature our exclusive Optim® insulation material that combines the durability of polyurethane and the softness of

silicone. Optim® insulation has demonstrated a statistically significant reduction in the incidence of insulation abrasion when compared to our previous silicone insulated leads. Optim® insulation material was designed specifically for high- and low-voltage cardiac pacing leads. We now have Optim® insulation available in all of our lead segments and have phased out our older silicone insulated leads in favor of the improved reliability of Optim® based leads.

In December 2007, we released the QuickFlex® family of LV leads in the United States and Europe. Additionally, our LV lead platform includes the smaller diameter lead QuickFlex® μ (micro) LV lead (FDA approval in May 2010 and European CE Mark approval in September 2008).

26. The Form 10-K was accompanied by a certification signed by defendant Starks stating in relevant part:

1. I have reviewed this Annual Report on Form 10-K of St. Jude Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting....

DEFENDANTS' STATEMENTS WERE MISLEADING

27. Defendants' statements set forth above in ¶¶18-26 were materially false and misleading because they failed to disclose that (i) the Riata and Riata ST were associated with short circuits as well as protruding wires; and that (ii) the QuickSite and QuickFlex Left-Ventricular leads also suffered from the same problem of protruding wires that plagued the Riata and Riata ST.

THE TRUTH BEGINS TO COME TO LIGHT

28. On March 27, 2012, *The New York Times* published an article entitled "Bad Wire in Heart Device Led to 22 Deaths, Study Says," which stated:

> A defect in wires that connect hearts to defibrillators caused at least 22 deaths, possibly as a result of a short circuit that is difficult to detect during routine monitoring, according to a study in the journal Heart Rhythm.

The manufacturer of the wires, St. Jude Medical, estimated that about 79,000 patients in the United States and about 49,000 patients elsewhere have had the wires implanted. Removing the wires is considered dangerous.

The study looked at deaths reported to the Food and Drug Administration that were associated with two models of the wires, also known as leads, under the brand names Riata and Riata ST. St. Jude stopped making the leads in 2010, and in 2011 warned physicians about problems involving wires that were found to be protruding from the protective casing on the leads.

St. Jude introduced the Riata in 2002 and the Riata ST in 2005.

The most recent study found that the problem with the protruding wires did not contribute to any deaths, while the electrical malfunction was more serious, said Dr. Robert Hauser, the author of the study and an advocate for improved safety of medical devices.

'When I went in, I thought I would find more deaths related to externalized cables,' he said, referring to the problem of wires poking through the casing. 'But as it turned out, the externalized cables really didn't factor in.'

Defibrillators, small battery-powered canisters implanted into muscle under the collarbone, apply electrical shocks to the heart when its beating becomes dangerously rapid or chaotic. The shocks can restore normal heart rhythms before the heart stops and prevent sudden death. The leads are used to sense when the heart is experiencing a rhythm that requires a shock and then helps deliver the shock.

Dr. Hauser said he found that the silicone insulation on the Riata cables was breaking down and resulting in an electrical short. Such shorts are dangerous, he said, because they can prevent the device from delivering the shock that restores a normal heartbeat. They can also occur without any warning that the device is defective.

In his study, released on Monday, Dr. Hauser found that eight patients had died during procedures to remove the wires.

He said that the number of deaths was small compared with the number of patients who had these models of wires. However, 'because it may be catastrophic, we need to be paying more attention to what are the electrical signs that might help us identify patients who are at risk,' he said.

Dr. Mark Carlson, chief medical officer at St. Jude, questioned some of Dr. Hauser's conclusions. He said the reports the F.D.A. collects are often

> incomplete. He said the company's data showed the number of deaths to be 20, not 22, and he said seven of the deaths resulted from a far more common type of failure caused by the wire rubbing against the defibrillator. ***He said St. Jude had not called more attention to the electrical malfunctions – in contrast to its warnings about the protruding wires – because the electrical failures were far more common.***
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> Dr. Lawrence M. Epstein, chief of the arrhythmia service at Brigham and Women's Hospital in Boston and an associate professor of Medicine at Harvard Medical School, said two of his patients had suffered electrical failures of Riata leads but survived because they were in the hospital at the time. Dr. Epstein has worked as a consultant for St. Jude and other device makers. Since removing the wires is dangerous, 'it creates a real clinical dilemma for patients and the doctors taking care of them,' he said.

29. As a result of defendants' denials, the price of St. Jude's stock remained artificially inflated.

30. On April 4, 2012, defendants issued a press release that finally disclosed the protruding wires observed in the Company's QuickSite and QuickFlex Left-Ventricular leads as well as halting all further sales of those leads. The release stated in relevant part:

> St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced it is proactively informing physicians about visual observations of ***externalized conductors*** on the silicone end of QuickSite® and QuickFlex® Left-Ventricular (LV) Leads, used to connect Cardiac Resynchronization Therapy (CRT) devices to the heart.
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> There have been no reports of patient injury or loss of therapy due to externalized conductors in these leads, but as a conservative measure, St. Jude Medical is communicating with physicians about the incidence rate so they have the most updated lead performance information with which to make important patient care decisions. The company will no longer sell these lead models. It is important to note, however, that the overall safety and reliability of QuickSite and QuickFlex leads continues to be comparable to currently available CRT leads from other manufacturers.
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> * * *

An LV lead (a thin, coated wire) is placed on the lower left chamber of the heart (the left ventricle) to stimulate the two sides of the heart to beat in synchronization with each other, which helps the heart to beat more efficiently. These left-ventricular leads are intended to improve the efficiency of the heart in patients with heart failure, but are not responsible for delivering immediate life-sustaining pacing or life-saving defibrillation therapy. If an LV lead were to fail, the other leads attached to the patient's device would continue to deliver life-saving therapy.

St. Jude Medical has confirmed 39 cases of externalized conductors, out of 171,000 QuickSite and QuickFlex leads sold worldwide, resulting in a current reported incidence rate of 0.023 percent, or 2.3 in 10,000. Because these leads continue to function normally, the company expects that this rate is under-reported. Based on an analysis of leads returned to the company and recent fluoroscopic images of implanted leads still in clinical use, St. Jude Medical estimates that 3 to 4 percent of QuickSite and QuickFlex leads may exhibit externalized conductors. As a result of this estimated rate, the company felt it was prudent to communicate with physicians about the externalized conductors at this time.

31. On April 4, 2012, the *Dow Jones Newswire* issued a wire stating in relevant part:

St. Jude Medical Inc. (STJ) said Wednesday that it would stop selling another type of heart-device cable following reports of wires wearing through their silicone covering, a problem seen with some of the company's other products with similar coating.

St. Jude said it will cease selling its QuickSite and QuickFlex left-ventricular leads used to connect cardiac resynchronization therapy devices to the heart. Cardiac resynchronization therapy devices are used to help the heart beat more efficiently, while defibrillators are designed to deliver life-saving shocks when needed.

Roughly 171,000 of the leads in question have been sold world-wide. St. Jude said in a letter to physicians that it has confirmed 39 cases of the metal wires wearing through their silicone covering, leading to an incidence rate of 2.3 in every 10,000 leads. The company said the rate is likely under-reported and estimates it to be 3% to 4%.

No incidents of death, serious injury or loss of therapy have been reported as a result of the problem.

St. Jude shares slumped 4.9% to $41.65 in recent trading. The stock is down more than 20% over the past year.

The announcement marks another heart-device wire problem for St. Jude. In a medical journal last month, prominent cardiologist Robert G. Hauser wrote that separate Riata leads, used in the company's implantable defibrillators, are responsible for at least 20 deaths.

The Riata leads are no longer on the market but are still implanted in about 128,000 patients world-wide. The U.S. Food and Drug Administration has termed the defibrillator issues a Class I recall, which applies to grave dangers like chance of death.

St. Jude, like with Riata, is recommending the QuickSite and QuickFlex patients be monitored, but the leads stay intact. A St. Jude spokeswoman said the QuickSite and QuickFlex leads represent less than 10% of cardiac resychronization therapy leads sold today.

The leads are placed on the lower left chamber of the heart to stimulate it to beat more efficiently. If the leads were to fail, other leads attached to the device would continue to deliver therapy, the company said.

'It's a real stretch to think that this is going to compromise therapy in any way,' said Dr. Bruce Wilkoff, president of the Heart Rhythm Society, a group for doctors, nurses and scientists treating rhythm disorders. ***He said that the reported incidents aren't surprising, given the similarities in construction between the leads in question and Riata leads. Both have silicone coating.***

Still, perception is likely to affect the company's other products.

'***Do I think it's going to have a negative impact? It has to,***' said Dr. Laurence Epstein, chief of the arrhythmia service at Brigham and Women's Hospital in Boston. 'What size of an impact? Hard to say.'

He added that physicians at the hospital had stopped using St. Jude's newer generation Durata leads following news of the Riata issues. Epstein receives consulting fees from St. Jude as well as competitors Medtronic Inc. (MDT) and Boston Scientific Corp. (BSX).

The company says the wiring problems are restricted to QuickSite, QuickFlex and Riata products. "We do not anticipate that this is likely to be a problem in other leads," St. Jude's chief medical officer Mark Carlson said in an interview.

It isn't clear, though, how the latest announcement will affect St. Jude's sales. Medtronic and Boston Scientific stand to gain share in the heart rhythm market.

32. As a result of these disclosures, the closing price of St. Jude's stock dropped from $43.80 to $38.91 in three trading days, a decline of over 11%. This decrease was a result of the artificial inflation caused by defendants' misleading statements coming out of the price.

POST CLASS PERIOD EVENTS

33. On April 6, 2012, defendants issued a press release that stated in relevant part:

> St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced it is seeking a retraction of the manuscript accepted for publication in the *Heart Rhythm Journal* by Dr. Robert Hauser, et al., titled, 'Deaths Caused by the Failure of Riata and Riata ST Implantable Cardioverter-Defibrillator Leads.'
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> The manuscript presented results from an analysis that assessed the number of death reports associated with St. Jude Medical Riata® and Riata ST defibrillation leads compared with Medtronic Quattro Secure leads. This assessment was based on a search of the U.S. Food and Drug Administration (FDA) Manufacturers and User Facility Device Experience (MAUDE) database. In the analysis, the authors classified the deaths in one of three categories (lead related, indeterminate or not lead related) and drew conclusions about how Riata and Riata ST leads compare with Medtronic's Quattro Secure leads. Using the same search criteria outlined in the manuscript, the company has identified that Dr. Hauser's research substantially undercounted total deaths in the MAUDE database for Quattro Secure, which therefore resulted in substantial errors related to how Riata and Riata ST leads compared to the Quattro Secure lead.
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> **Inaccurate Facts and Biased Analysis**
> St. Jude Medical's independent search of the MAUDE database found 377 reports of deaths involving Quattro Secure leads, not 62 as stated by Dr. Hauser in a manuscript posted online and accepted for publication in the *Heart Rhythm Journal*. St. Jude Medical's analysis of Riata and Riata ST lead events found in the MAUDE database also indicate that Dr. Hauser did

not report an additional three deaths, which would change the number from 71 in Dr. Hauser's manuscript to 74.

Dr. Hauser's manuscript is mistaken or misleading in a number of other respects as well. It is important to note that Dr. Hauser has selectively chosen to include only one Quattro Secure lead model in his analysis versus all of the Riata and Riata ST models for St. Jude Medical. Although we did not include those lead models in our analysis, there are also deaths associated with those additional model numbers.

There is a range of detail available in MAUDE reports, with Medtronic generally reporting the least amount of detail compared with other companies in the industry. In addition, the detail and rate of reporting has increased since Medtronic's Cardiac Rhythm Management business received a warning letter from the Food and Drug Administration in 2009, meaning events prior to this date in the analysis may have been under-detected. An analysis of 'lead-related' deaths is biased against manufacturers that more transparently report on device malfunctions. A less biased manner of comparison would combine 'lead-related' and 'indeterminate' deaths, because the resulting number only excludes the reports that are clearly not lead-related.

Finally, the entire premise of the comparison of a recalled silicone-only insulated lead versus Quattro Secure, which is a product insulated with a polyurethane outer insulation, is flawed. It is acknowledged in the industry that silicone-insulated leads are more susceptible to abrasion than leads with newer insulation materials. A more appropriate comparison would have been to compare the Riata and Riata ST leads to other recalled leads. For example, there are approximately 1,200 MAUDE death reports associated with the recalled Medtronic Sprint Fidelis lead, out of approximately 268,000 leads sold worldwide, or a rate of 447.8 per 100,000. For Sprint Fidelis leads, note that many cases indicate 'under litigation' in the MAUDE report and no detail on the cause of failure is provided. Alternatively, Dr. Hauser could have compared Quattro Secure to St. Jude Medical's currently available Durata® lead, which the company is confident would have resulted in a favorable comparison as well.

St. Jude Medical was not consulted prior to the publication, nor asked to validate any of the data against its returns analyses. Since the manuscript was published, the company has spent more than 300 hours attempting to reach the same conclusions as Dr. Hauser, but can find no way of analyzing the MAUDE database that reproduces the same numbers reported in the manuscript. The company has identified duplicate reports, inconsistent categorizations and failures to include all available reports.

> The method of the study itself, using MAUDE reports to compare devices, is not appropriate. The home page of the Food and Drug Administration's MAUDE database even states, 'MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices.'
>
> **Conclusion**
> Given these factual errors and biased analysis, we are requesting that the manuscript immediately be retracted by the authors and removed from online publication by the official journal of the Heart Rhythm Society.

34. On April 6, 2012, *The New York Times* published an article entitled "Troubling Flaws in a Heart Device Shake Implant Makers," which stated in relevant part:

> For the heart device industry, the problem with the St. Jude leads is the third highly visible safety episode in the last seven years. As such, it is raising questions about whether the industry is adequately scrutinizing the safety of heart devices or whether the Food and Drug Administration needs to take a more aggressive role. A defibrillator is a device that sends out an electrical jolt to interrupt a potentially fatal heart rhythm and restore the heart to normal beating.
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> Since 2005, St. Jude's two major competitors – Guidant, which sold its heart unit in 2006 to Boston Scientific, and Medtronic – have both faced instances in which patients were killed or injured by flawed products. Device producers have since adopted safeguards to alert them to problems before too many patients are injured.
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> Officials at St. Jude Medical, one of the nation's biggest producers of heart devices, insist they acted appropriately in warning doctors about the problem.
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> Daniel J. Starks, St. Jude's chief executive, said in a telephone interview that the company had hidden nothing. 'We've been more transparent than others,' he said.
>
> But several experts say they believe the company was slow to warn of the problem with the lead, which is estimated to be implanted in 128,000 patients worldwide.

One of the first investigators to examine the problem, Dr. Ernest W. Lau of Belfast, Northern Ireland, said that he took his concerns about the issue to St. Jude in 2010 and did not think that company officials responded appropriately.

'***There should have been more warning***,' said Dr. Lau, who is a heart device expert at Royal Victoria Hospital.

Several heart device experts said that the St. Jude incident represented a troubling repeat performance. As with Guidant and Medtronic, the crucial data highlighting the problems with St. Jude's leads did not come from its own monitoring systems, but from outside researchers. Several experts also said St. Jude appeared to play down the issue's seriousness.

'***They have at multiple steps underplayed the gravity of the situation***,' said Dr. Kenneth Ellenbogen, a device expert in Richmond who has consulted for St. Jude and its competitors.

The St. Jude leads at issue involve two models, the Riata and the Riata ST. The company stopped selling both models in late 2010. For the last several years it has been selling a defibrillator lead called the Durata, which it says has an extra coating of insulation that prevents the types of problems affecting the Riata models.

On Friday, St. Jude responded aggressively to its critics. It called for a medical journal, Heart Rhythm, to retract an article published last week about deaths associated with the Riata lead. The company contended that a researcher, Dr. Robert G. Hauser of Minneapolis, made several errors that made it appear that the Riata had produced more deaths than another widely used lead made by a competitor, Medtronic.

Mr. Starks and other St. Jude executives have also accused Medtronic of carrying out a whispering campaign suggesting that St. Jude's new Durata lead is prone to the same types of failures as the Riata.

St. Jude officials also maintained that their reports about product-related problems to a publicly available database run by the F.D.A made their devices look more troubled because St. Jude's reports were more detailed and complete than those filed by Medtronic.

The company's stock has fallen sharply over the last week. On Thursday, it fell 1.7 percent to close at $40.97 a share. This week, the company also said it would stop selling two other models of older heart device wires with similar insulation problems.

A spokesman for Medtronic, Christopher Garland, said that St. Jude claims were 'false' and that the company filings were extremely thorough. Dr. Hauser, the researcher, said that he was not surprised that St. Jude was disputing his report.

'They have been very contentious' about this, he said.

According to St. Jude officials and experts outside the company, the issues surrounding the Riata involve two separate problems.

Dr. Hauser's report involved cases where the silicone coating of the defibrillator lead wore away, setting up the potential for a short circuit when the device fires a life-saving jolt.

St. Jude officials have acknowledged that reports show that at least 20 patients have died in such episodes, but say that such incidents are not unique to the Riata and that the rate of the fatal episodes is comparable to that of other devices.

The problem specific to the Riata involves those cases in which the internal wires work their way out of their casing. No deaths have been attributed to that problem and in most cases, those wires continue to function.

But when the wires fail to work they can lead to a variety of electrical malfunctions.

In late 2010, St. Jude sent a letter to doctors alerting them about data showing that the silicone coating of the Riata lead could wear away. However, the letter estimated that the overall rate of abrasion was tiny, just 0.47 percent, and that the exposed wire issue represented just a small fraction of that figure.

But the issue took off nearly a year later with the report of Dr. Lau's group in Belfast. Rather than simply looking at reports of failures, he and his colleagues began to run diagnostic imaging tests on patients and saw the protruding wires.

Since that report appeared, other researchers have done additional tests and found incidences of wire protrusions running as high as 30 percent. The insulation-related problem appears to develop only after several years of implant and so its scope may accelerate as the devices age.

35. On April 10, 2012, *The New York Times* published a story entitled "St. Jude Is Rebuffed Over Report on Device," which stated:

In a setback for St. Jude Medical, a medical journal late Monday rejected the company's request that it retract a published report that found that 20 deaths were linked to failures of a heart device component made by the company.

St. Jude's stock fell 53 cents a share, or 1.4 percent, to $38.38 Tuesday afternoon after a 5 percent decline on Monday. The stock has tumbled in the last week amid reports involving other failures of the same component, a lead, or cable, connecting a defibrillator to a patient's heart.

St. Jude, which is one of the country's biggest medical device producers, did not dispute that the deaths had occurred. But on Friday, the company accused the author of the report, Dr. Robert Hauser of Minneapolis, of making critical errors in the research and showing a bias against St. Jude by failing to properly account for deaths involving a similar component made by a competitor, Medtronic.

The company also asked the medical journal that had published the report, HeartRhythm, to retract it. However, the journal's editor, Dr. Douglas P. Zipes, said in an interview late Monday that the publication had looked at St. Jude's complaint and did not plan to pull back the article, which had undergone review by experts associated with the journal before its online publication two weeks ago.

Dr. Zipes said that the data St. Jude released Friday to rebut Dr. Hauser's report had not been independently reviewed to determine its accuracy. He said he had offered the company an opportunity to submit its data to the journal for review, but planned to publish Dr. Hauser's article in the next print edition of HeartRhythm.

'I understand industry's pain, but I will not abrogate the rules and regulations that have served us so well,' Dr. Zipes said, referring to the peer review process.

He said that Dr. Hauser had agreed to make some changes to his article before its print publication involving what he called 'inflection' but added that 'the bulk of the manuscript stays as is.'

St. Jude, based in St. Paul, had no immediate response on Tuesday to the rejection of its request. Dr. Zipes said he informed the company of his decision on Monday.

The controversy involves a lead that St. Jude once widely sold. Wires within the cables are working their way through the insulation surrounding

them and are causing, in some cases, electrical problems, including shocks at inappropriate times. The company says its newer leads are not affected by the same problem.

Dr. Hauser's research involved the same older leads but a different issue with potentially fatal consequences. He reported that the insulation surrounding the leads could wear away, causing a short-circuit when a defibrillator fired an electrical jolt needed to restore a failing heart to normal beating.

Dr. Hauser's report was based on his review of a publicly available device safety database run by the Food and Drug Administration. His analysis showed that the number of reported deaths involving the St. Jude lead were significantly higher than similar reports involving a lead made by Medtronic.

Medtronic has disputed St. Jude's claims about the number of deaths attributable to its device.

St. Jude issued a news release Tuesday that did not directly address the journal's decision to reject its request for a retraction.

Instead, the company announced that it had publicly posted 377 reports of deaths of patients who had used the Medtronic Quattro defibrillator lead.

Dr. Hauser said he had reviewed only 62 reports of the patient deaths involving the Quattro because some other filings by Medtronic did not have sufficient information for analysis.

A spot check of the 377 reports also showed that some of them did not contain an allegation that a patient's death was associated with the failure of a Quattro lead. Under federal rules, medical device companies must submit a death report whether or not they contain an allegation of device involvement.

36. On April 13, 2012, *The Wall Street Journal* published an article entitled "St. Jude Wrestles with Image Woes," that stated:

St. Jude Medical Inc. is struggling to protect its heart-rhythm division from a growing image problem.

The problems involve the Riata lead, a wire that connects defibrillators to heart tissue and that St. Jude stopped selling in 2010. A recent medical study tied a malfunction in Riata to at least 20 deaths, and now some

doctors are scrutinizing the company's newer product, the Durata lead. The Durata has some design similarities to the older Riata, though it hasn't been linked to patient problems to date.

'I decided to stay away from it until the dust settles and we know more about how the Riata problem happens,' said Samir Saba, director of electrophysiology at the University of Pittsburgh Medical Center, who has financial relationships with both St. Jude and its competitor Medtronic Inc.

Doubts about Durata could weigh on St. Jude's foothold in the nearly $7 billion global market for implantable defibrillators–matchbox-size devices that zap a misfiring heart beat into normal rhythm.

Shares in the company, with a market capitalization of $12.4 billion, have fallen 10% over the last month.

St. Jude reports first-quarter earnings next week. It is expected to see a modest gain in its 28% share of the cardiac-rhythm management market, which includes defibrillators, on the strength of a new product unveiled in November.

But investors will be closely watching for signs that concerns over the leads will have an impact down the road. The Durata device has been implanted in 145,000 Americans.

St. Jude said concerns about Durata are unfounded and that design changes will prevent a repeat of the Riata episode, in which wires broke through their silicone coating in some patients.

The leads have been prone to sometimes-lethal short circuiting, which some doctors believe may be related to protruding wires. St. Jude said it has no evidence of any connection.

Adding to the company's challenges is that St. Jude said last week it will stop selling two other models of leads because of safety problems. St. Jude said that no incidents of death or serious injuries have been reported as a result of the problems, and the problems are perceived as more minor. But 'it's still egg on their face,' said Michael Matson, an analyst at Mizuho Securities USA.

St. Jude has retained the services of the Population Health Research Institute at McMaster University in Ontario, Canada, to examine Durata's durability and performance data, and expects the group to submit its findings to peer-reviewed journals following a May meeting of the Heart Rhythm Society, a medical specialty group.

Doctors will 'understand there is a lot of history to give them confidence,' said Eric Fain, the president of the company's rhythm-management group.

Some doctors remain confident in Durata, and said they're awaiting evidence of problems before giving up on the leads, which have a slim profile and may fit more easily in smaller heart vessels. 'We can't extrapolate that because there's a problem with the Riata that there will definitely be a problem with Durata,' said Joshua Cooper, attending clinical electrophysiologist at the Hospital of the University of Pennsylvania who has received lecture fees from St. Jude and its competitors, and continues to use Durata.

Other physicians are limiting use or have stopped using Durata altogether, saying more data are needed on the leads, which were introduced in 2008. Hartford Hospital in Hartford, Conn., stopped implanting them in December after the U.S. Food and Drug Administration announced a Class I recall of Riata, meaning it believed the device could kill or seriously harm patients.

'In my mind, if you look at the construction of Durata versus Riata leads, the inner part is very similar,' said Steven Zweibel, director of electrophysiology at the hospital. Dr. Zweibel has in the past received fees from St. Jude and its competitors.

In containing the fallout from the Riata leads, St. Jude has pursued an unusually aggressive public-relations strategy that has included pushing for a retraction of the Riata study, authored by Robert G. Hauser, a Minnesota cardiologist, and published online in the Heart Rhythm Journal last month, and calling out competitors for using its problems to their advantage. St. Jude said the study misstated the differences between Riata's safety record and competitors. Dr. Hauser has said he stands by the findings.

Competing device makers have sought to leverage Riata's problems by comparing the discontinued product to Durata, according to documents reviewed by The Wall Street Journal. The documents, including purported emails between sales managers and senior executives at Medtronic and Boston Scientific Corp., were gathered by members of St. Jude's sales force and provided to an outside attorney working on behalf of St. Jude.

One purported Boston Scientific email instructs sales representatives to tell customers that 'Durata=Riata=Durata=Riata,' and that Durata may face the same problems as the earlier leads.

'While we provide our sales force with relevant information about competitor's products, we do not provide guidance to physicians about how to manage competitor issues,' said Denise Kaigler, a Boston Scientific spokeswoman, in an emailed statement. Christopher Garland, a Medtronic spokesman, said the company would not enter a public dispute with St. Jude.

Many doctors also said they still don't know how to handle patients implanted with the older Riata leads. So far, St. Jude has advised doctors to monitor patients and suggested they screen problems with X-rays if electrical abnormalities are found, but the company doesn't advise removing the lead.

Edward J. Schloss, director of electrophysiology at the Christ Hospital in Cincinnati, said he urged St. Jude to offer doctors more specific guidance about what to do with Riata patients.

Dr. Schloss said doctors can do 'a high-voltage, lead-integrity test' that he calls 'somewhat painful' to patients. He said he hopes St. Jude can advise doctors whether they should be bringing patients in to do that test.

Meanwhile, patients with Riata leads continue to face unexpected problems. Two such patients were lucky enough to be at Brigham & Women's Hospital in Boston one weekend late last year when their Riata leads short-circuited, according to Laurence M. Epstein, chief of the arrhythmia service there.

'They survived because they had their life-threatening arrhythmias in the hospital,' said Dr. Epstein. 'With a high-voltage short, there may be no warning.'

37. On April 18, 2012, *The New York Times* published an article entitled "Device Malfunction Casts Doubt on Industry Pledge," which stated in relevant part:

Last month, an outside researcher, Dr. Robert Hauser of Minneapolis, released a study indicating that short-circuits and other failures of the St. Jude lead might have played a role in some 20 patient deaths.

His report followed several studies showing that the lead, called the Riata, was also prone to another malfunction, a tendency for internal wires to break through the protective outer coating and cause electrical problems like unintended shocks in some patients. An estimated 128,000 patients

worldwide still use the Riata lead, which the company stopped selling in late 2010.

St. Jude executives, including the chief executive, Daniel J. Starks, quickly reacted to Dr. Hauser's report by unleashing a public relations campaign aimed at discrediting the study's accuracy and Dr. Hauser. But left unanswered amid the noise was the question: how closely had St. Jude been examining those deaths for signs pointing to a broader problem involving the Riata lead?

"***Someone in the company should have been watching this***," said Dr. Robert J. Myerburg, who led an independent investigation into Guidant's decision not to warn doctors that some of its defibrillators could short-circuit. A defibrillator emits an electrical jolt to interrupt a potentially fatal heart rhythm and restore the normal heartbeat.

In a statement issued in response to questions from The New York Times, Amy Jo Meyer, a St. Jude spokeswoman, said ***the company regularly updates a panel of outside safety specialists about patient deaths potentially tied to lead failure***. But the company declined to disclose how many deaths involving short-circuits and other electrical failures involving the Riata had been presented to that panel.

One member of St. Jude's lead safety panel, Dr. Bruce Wilkoff of the Cleveland Clinic, said in an e-mail that he did not 'have specific recollections of how many patient scenarios' had been presented but added that he was aware of the conditions that could result in a patient's death. Four other specialists on that board either did not respond to repeated requests for comment or declined to comment on the number of patient deaths St. Jude officials had presented to the panel.

In a telephone interview last week, the company's chief medical officer, Dr. Mark D. Carlson, said that some patient deaths were inevitable because defibrillators occasionally fail; he added that the types of insulation problems with the Riata were common.

However, other heart device specialists said they were disturbed by St. Jude's explanations, adding that the number of Riata-related deaths appeared unusually high compared with other leads and pointed to a troubling pattern.

"***I would hope that anybody looking at that data would say, hey, something is not right here,***" ***said Dr. Edward J. Schloss of Cincinnati,*** "***I***

think if you saw 20 high-voltage fatalities with a pretty clear pattern of insulation abrasion, that should get your attention."

It was not supposed to be this way. The safeguards that the major defibrillator makers–Medtronic, St. Jude and Boston Scientific, which acquired Guidant's heart unit in 2006–adopted in recent years were supposed to arm doctors with facts rather than opinions.

St. Jude is not the first producer to have encountered product problems since then. In 2007, Medtronic recalled a widely used lead called the Sprint Fidelis after reports emerged that it was cracking and failing in patients.

However some specialists questioned why St. Jude reacted as it did to Dr. Hauser's recent report, since that study was based on reports of possible Riata-related deaths that St. Jude had filed with the Food and Drug Administration.

'I would have expected that they would have done his study in advance,' said Dr. Jeffrey N. Rottman, a heart device specialist at Vanderbilt University.

The Riata, specialists say, has had what appears to be a unique failure. Wires in the cable can work through its insulation and become exposed. The wires have continued to function properly in most patients. But in others, electrical problems have occurred.

Since 2010, the company had been receiving reports about the problem, and in a letter to doctors late that year it made a passing reference to the issue. Then, ***in 2011, a cardiologist at Royal Victoria Hospital in Belfast, Northern Ireland, alerted St. Jude that growing numbers of exposed Riata wires were occurring among patients there. That cardiologist, Dr. Ernest W. Lau, also urged St. Jude executives to immediately alert cardiologists about the seriousness of the problem.***

'I am sorry to say this,' Dr. Lau wrote in an e-mail to company officials that he provided to The Times. 'I believe there should and will be a much more serious advisory.'

Last April, Dr. Carlson, the company's top doctor, discussed the problem of protruding wires with the lead safety panel. By then, German researchers had also reported that the Riata lead failed in 8 percent of the patients they had examined. Dr. Wilkoff of the Cleveland Clinic said that the St. Jude lead safety board decided at that time that it was premature to

specifically alert doctors about the exposed wire problem, as Dr. Lau had urged. Instead, the panel recommended that St. Jude gather more data.

* * *

In November, the company finally sent an alert to doctors about the exposed wires and said it would start a study of the problem. The F.D.A. reviewed that letter and categorized it as a 'Class I recall,' the most serious designation. But as doctors tried to figure out how to manage affected patients, Dr. Hauser's report appeared, pointing to a separate and potentially more serious problem, the likelihood that the Riata's insulation could wear away, short-circuiting the device.

Today, specialists say they are still groping for answers, not knowing all of the risks that the Riata lead poses to patients and whether it was limited to the external wires or if there was also a short-circuiting risk.

In a recent study at Vanderbilt, researchers found that about a third of Riata leads in patients they examined showed signs of protruding wires. Nearly a third of those showed electrical failures.

'Every patient you are seeing you have in the back of your mind whether the device is causing them harm,' said Dr. Christopher R. Ellis, one of the Vanderbilt researchers.

38. On June 12, 2012, it was disclosed that St. Jude's Durata – which the Company earlier defended (¶36) – was also linked to a case of an externalized wire. In response to this news, the Company's stock price slumped nearly 6% on heavy trading volume.

LOSS CAUSATION/ECONOMIC LOSS

39. During the Class Period, as detailed herein, defendants made false and misleading statements and engaged in a scheme to deceive the market. This artificially inflated the price of St. Jude's securities and operated as a fraud or deceit on the Class. Later, when defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of St. Jude's securities fell precipitously, as the prior

artificial inflation came out of the price over time. As a result of their purchases of St. Jude securities during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

NO SAFE HARBOR

40. St. Jude's "Safe Harbor" warnings accompanying its forward-looking statements issued during the Class Period were ineffective to shield those statements from liability.

41. The defendants are also liable for any false or misleading forward-looking statements pleaded because, at the time each forward-looking statements was made, the speaker knew the forward-looking statements were false or misleading and the forward-looking statements were authorized and/or approved by an executive officer of St. Jude who knew that the forward-looking statements were false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

42. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) The Company's securities traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

(e) Plaintiff and other members of the Class purchased St. Jude securities between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

43. At all relevant times, the market for St. Jude securities was efficient for the following reasons, among others:

(a) As a regulated issuer, St. Jude filed periodic public reports with the SEC; and

(b) St. Jude regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

CLASS ACTION ALLEGATIONS

44. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased the publicly

traded securities of St. Jude during the Class Period. Excluded from the Class are defendants, directors and officers of St. Jude and their families and affiliates.

45. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. St. Jude had more than 313 million shares outstanding, owned by thousands of persons.

46. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

(a) Whether the Exchange Act was violated by defendants;

(b) Whether defendants omitted and/or misrepresented material facts;

(c) Whether defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether defendants knew or recklessly disregarded that their statements were false and misleading;

(e) Whether the prices of St. Jude securities were artificially inflated; and

(f) The extent of damage sustained by Class members and the appropriate measure of damages.

47. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

48. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

49. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

COUNT I

For Violation of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

50. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

51. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of St. Jude securities during the Class Period.

52. Plaintiff and the Class have suffered damages in reliance on the integrity of the market in paying artificially inflated prices for St. Jude securities. Plaintiff and the Class would not have purchased St. Jude securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

53. As a direct and proximate result of defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of St. Jude securities during the Class Period.

COUNT II

For Violation of §20(a) of the Exchange Act Against All Defendants

54. Starks acted as controlling person of St. Jude within the meaning of §20 of the Exchange Act. By virtue of his position and his power to control public statements about St. Jude, he had the power and ability to control the actions of St. Jude and its employees. St. Jude controlled the Individual Defendant and its other officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

A. Declaring this action to be a proper class action pursuant to Federal Rule of Civil Procedure 23;

B. Awarding plaintiff and the members of the Class damages and interest;

C. Awarding plaintiff's reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: June 14, 2012

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