UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

ROBERT FREEDMAN, on behalf of himself and all others similarly situated, Plaintiff, v. ST. JUDE MEDICAL, INC. and DANIEL J. STARKS, Defendants.	:	Civil Action No. _____ **Class Action Complaint for Violation of Federal Securities Laws** **Jury Trial Demanded**

Plaintiff, by his undersigned counsel, brings this action for violation of the federal securities laws on behalf of himself and all other similarly situated persons or entities (the "Class," as defined in ¶ 21 herein) who purchased or otherwise acquired the common stock of St. Jude Medical, Inc. ("St. Jude" or the "Company") during the period from October 17, 2012 through and including November 20, 2012 (the "Class Period"). The allegations in this complaint are based on plaintiff's personal knowledge as to himself, and on information and belief, including the investigation of counsel, as to all other matters. The investigation of counsel is predicated upon, among other things, review and analysis of St. Jude's public filings with the United States Securities and Exchange Commission ("SEC"), including, among other things, Forms 10-K, 10-Q, and 8-K; press releases; conference call transcripts and presentation materials; media reports about the Company; publicly available data relating to the prices and trading volumes of St. Jude securities; reports issued by securities analysts who followed St. Jude; and publicly-available information concerning the Company maintained by the United States Food and Drug Administration ("FDA"). Plaintiff believes that substantial, additional

evidentiary support for the allegations set forth herein will be obtained after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. St. Jude is a leading global medical device company, focusing on four areas: cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation. In 2011, the Company had net sales of over $5.6 billion.

2. St. Jude's cardiac rhythm management products include implantable cardiac defibrillators (ICDs) and the leads (or cables) that connect an ICD to the heart. Until 2010, one such lead manufactured and marketed by the Company was known as Riata. In December 2010, St. Jude notified physicians that the insulation on some of the Riata leads had experienced "abrasion failures," potentially impacting the ability of the ICD to function properly. As a result, St. Jude discontinued sales of the Riata lead, but not before more 227,000 had been distributed worldwide.

3. In November 2011, St. Jude updated physicians on the abrasion failures associated with the Riata leads, informing them that the failure rate was higher than previously reported by the Company. The FDA deemed this communication as a "Class 1" recall, the most serious type of recall involving situation in which there is a reasonable probability that the use of a recalled product will cause serious adverse health consequences or death. As of 2011, approximately 79,000 Riata leads remained implanted in patients in the United States. The FDA has recommended that such patients undergo imaging studies to assess whether there are insulation abnormalities.

4. Against this backdrop, St. Jude has manufactured and marketed a newer generation of ICD lead known as Durata. (The product was initially known as the "Riata ST,"

but St. Jude changed the name to Durata in 2008.) The Durata lead is coated with a proprietary material known as "Optim," a blend of silicone and polyurethane. St. Jude has represented that the Durata lead has performed reliably and that the Optim insulation is 50 times more resistant to abrasion than silicone, the standard coating. Nevertheless, concerns about possible problems with the Durata leads have recently been reported. In August 2012, *EP Eurospace*, a British cardiology journal, published a study of Durata conducted by Dr. Robert G. Hauser, a cardiologist affiliated with Abbott Northwestern Hospital in Minneapolis. Dr. Hauser's study reviewed data maintained by the FDA and found 52 instances of lead failures in the Durata or Riata ST, including one resulting in a patient's death. While Dr. Hauser acknowledged that further study was needed to assess the Durata's failure rate, he stated that the results of his study were a "red flag" and that "[t]here is no reason to use this lead until we have more confidence in its performance."

5. Indeed, just days earlier, on August 16, 2012, the FDA directed St. Jude to conduct post-market surveillance studies of Durata and Riata ST. In ordering these studies, the FDA's branch chief for pacing and defibrillator devices, Mitchell Shein, told the *Wall Street Journal* that the Durata lead "is sufficiently similar to the recalled Riata product to merit closer examination."

6. Given the failures already experienced with Riata, the performance of Durata was of intense interest to the investment community. After the FDA request for post-market studies of the Durata was disclosed, an August 17, 2012 *Bloomberg* report quoted an analyst at Jefferies & Co. as stating: "That the FDA is requiring an additional study of Durata, despite St. Jude's current and extensive registry data, again shows the FDA's level on unease with the situation.

Despite continued presentation by St. Jude of their internal data showing the Durata is safe, the FDA remains unconvinced."

7. On October 17, 2012, St. Jude issued its third quarter 2012 financial results and held an earnings conference call with securities analysts. On the conference call, St. Jude's CEO, Daniel J. Starks, noted that the Company's advisories concerning the Riata lead had drawn extensive attention from the FDA. In this context, Starks disclosed, for the first time, that a St. Jude production facility located in Sylmar, California was undergoing an FDA inspection. Although the inspection had not yet concluded, Starks stated that it was likely to result in the issuance of a "Form 483," a form used by FDA investigators to list observations of objectionable conditions found during the course of an inspection. Starks further stated that "[w]e would not be surprised if these observations are ultimately followed by issuance of a warning letter [from the FDA]." Notwithstanding these disclosures, Starks declined to specifically identify the problems being found at the Sylmar facility or the products that might be associated with any objectionable conditions being noted by the FDA investigators. Indeed, in response to a question from one analyst asking what was wrong with Sylmar, Starks responded, in part: "There's nothing. And what I mean by that is the reliability data, the level of transparency, what you see in the way our products perform on the market, … you'll see it across the board with the pacemaker line, with the ICD product line, with the Durata and Riata ST Optim product line that the reliability data and the evidence that that implies for the robustness of our quality systems is all very good."

8. On October 24, 2012, St. Jude filed a Form 8-K with the SEC, attaching a version of the Form 483 that had been issued by the FDA on October 17, 2012 in connection with the inspection of the Sylmar, CA facility. The version of the Form 483 released by St. Jude was

heavily redacted, so that a reader was unable to determine the products to which any of the FDA's observations related. The Form 8-K represented that the redactions were based on the Company's "good faith interpretation of Freedom of Information Act (FOIA) exemption (b)(4), which protects confidential and proprietary information from disclosure." The Form 8-K noted that St. Jude had sent its proposed redactions to the FDA for review, but that the FDA would make an independent assessment of the Form 483 before releasing it. The Form 8-K further represented that "[i]t is important to note that none of the observations [on the Form 483] identified a specific issue regarding clinical or field performance of any particular device."

9. On or about November 20, 2012, the FDA released its own version of the Form 483 for its inspection of the Sylmar facility. The version released by the FDA, while still redacted, nevertheless showed clearly that most of the observations of objectionable conditions listed on the Form 483 pertained to Durata. Indeed, no other product name appears on the version released by the FDA.

10. News media reports concerning the FDA's release of Sylmar inspection report did not surface until after the close of the market on November 20. As described in a November 20, 2012 report by the online version of the *New York Times*:

> A report on an inspection of a St. Jude Medical facility released Tuesday by federal officials found significant flaws in the company's testing and oversight of a controversial heart device component, a copy of the document shows. The report may also raise questions about how St. Jude executives recently depicted the inspection's contents to investors and others.
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> Although the agency blacked out many details of the inspection, which took place in September and October at the company's plant in Sylmar, Calif., the report appeared to focus on the methods St. Jude used to test the Durata, which was introduced in December of 2007. The agency inspectors found that the company failed to follow its own written protocols for testing the product, and did not properly evaluate some study results. The agency also concluded that St. Jude

did not adequately follow up on problems it identified in the manufacturing process, and also did not properly investigate some complaints about the lead.

11. On the Company's October 17, 2012, conference call with analysts, CEO Starks acknowledged that the then ongoing inspection of the Sylmar facility would be completed "very soon. It's near the end." Thus, by the time of the conference call, defendants were well aware that most of the observations of objectionable conditions were likely to pertain to Durata – observations that were deemed by the Company to be serious enough to possibly result in the FDA's issuance of a Warning Letter. That understanding was confirmed when St. Jude received the Form 483 later that day. Nevertheless, despite knowing that most of the inspection report concerned issues pertaining to Durata, defendants chose to conceal that information from the investment community and released a version of the Form 483 that redacted the name of the product.

12. When investors learned the truth, St. Jude's stock price spiraled downward. On November 21, 2012, the first trading day after the FDA's version of the Form 483 was disclosed publicly, St. Jude's stock suffered a one-day decline of $4.34 or 12 percent to close at $31.37, on enormous volume of over 26 million shares (in comparison with average daily volume of about 3.2 million shares in the preceding three months).

13. Moreover, while St. Jude's failure to disclose highly material information concerning the FDA inspection resulted in significant losses to investors, that same omission resulted in a handsome profit for CEO Starks. On October 31, 2012 and November 1, 2012, Starks sold a total of 200,000 St. Jude shares, realizing proceeds of more than $7.6 million.

PARTIES

14. Plaintiff, Robert Freedman, purchased shares of St. Jude stock during the Class Period as set forth in the attached certification and was injured thereby.

15. Defendant St. Jude Medical, Inc. ("St. Jude" or the "Company") is a Delaware corporation with its principal executive offices located at One St. Jude Medical Drive, St. Paul, MN. St. Jude trades on the New York Stock Exchange and, as of November 6, 2012, had 308,177,250 shares of common stock outstanding.

16. Defendant Daniel J. Starks ("Starks") served as the Chairman, President and Chief Executive Officer of St. Jude at all times relevant to the Class Period.

JURISDICTION AND VENUE

17. The claims asserted herein on behalf of the Class arise under Sections 10(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 (17 C.F.R. § 240.10b-5).

18. This court has jurisdiction pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. §§ 1331 and 1337.

19. Venue is proper in this district pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). Many of the acts and transactions giving rise to the violations of law complained of herein occurred in this district.

20. In connection with the acts, conduct and other wrong complained of herein, defendants, directly of indirectly, used the means and instrumentalities of interstate commerce, the United States mails, and the facilities of a national securities market.

CLASS ACTION ALLEGATIONS

21. Plaintiff brings this action on its own behalf and as a class action pursuant to Rule 23(a) and Rule 23(b)(3) of the Federal Rules of Civil Procedures on behalf of all persons or entities (the "Class") who purchased or acquired the common stock of St. Jude during the period from October 17, 2012 through and including November 20, 2012 (the "Class Period") and who suffered damages as a result.

22. Excluded from the Class are: (i) Defendants; (ii) members of the immediate family of each of the Defendants; (iii) any person who was an executive officer and/or director of St. Jude during the Class Period; (iv) any person, firm, trust, corporation, officer, director, or any other individual or entity in which a Defendant has a controlling interest or which is related to or affiliated with any of the Defendants; and (v) the legal representatives, agents, affiliates, heirs, successors-in-interest or assigns of any such excluded party.

23. The members of the Class, purchasers of St. Jude securities, are so numerous that joinder of all members is impracticable. While the exact number of Class members can only be determined by appropriate discovery, Plaintiff believes that Class members number in the thousands, if not higher. As of November 6, 2012, St. Jude reported that it had 308,177,250 shares of common stock outstanding issued and outstanding. Moreover, the average trading volume during the Class Period was approximately 4.1 million shares traded.

24. Plaintiff's claims are typical of the claims of members of the Class. Plaintiff and all members of the Class sustained damages as a result of the conduct complained of herein.

25. Plaintiff will fairly and adequately protect the interest of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests that are contrary to or in conflict with those of the members of the Class that Plaintiff seeks to represent.

26. A class action is superior to the other methods for the fair and efficient adjudication of this controversy. Because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it virtually impossible for the Class members individually to seek redress for the wrongful conduct alleged herein.

27. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to the Class are:

a. Whether the federal securities laws were violated by Defendants' acts as alleged herein;

b. Whether documents, including the Company's SEC filings, press releases and other public statements made by Defendants during the Class Period contained misstatements of material fact or omitted to state material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

c. Whether the market price of St. Jude stock during the Class Period was artificially inflated due to the material misrepresentations and/or non-disclosures complained of herein;

d. With respect to Plaintiff's claims under Section 10(b) of the Exchange Act, whether Defendants acted with the requisite state of mind in omitting and/or misrepresenting material facts in the documents filed with the SEC, press releases and public statements;

e. With respect to Plaintiff's claims pursuant to Section 20(a) of the Exchange Act, whether the Defendant named in that count is a controlling person of the Company; and

f. Whether the members of the Class have sustained damages as a result of the misconduct complained of herein and, if so, the appropriate measure thereof.

28. Plaintiff knows of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action.

29. The names and addresses of the record owners of St. Jude shares purchased during the Class Period are obtainable from information in the possession of the Company's transfer agent(s). Notice can be provided to such record owners via first class mail using techniques and a form of notice similar to those customarily used in class actions.

FACTUAL ALLEGATIONS

A. St. Jude and Its ICD Leads

30. The medical device business of St. Jude is focused on four areas: cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation. In 2011, sales of cardiac rhythm management products, including ICDs and ICD leads, contributed more than $3 billion to the Company's net sales of over $5.6 billion.

31. On August 30, 2012, St. Jude announced the realignment of its business units into two groups: the Implantable Electronic Systems Division (IESD) (comprised of the former cardiac rhythm management and neuromodulation divisions) and the Cardiovascular and Ablation Technologies Division (CATD) (comprised of the former atrial fibrillation and cardiovascular divisions).

32. St. Jude manufactures and markets cardiac rhythm management products, including ICDs and the leads that connect an ICD to the heart. ICDs monitor heart rhythms. When a potentially life threatening heart rhythm is detected, the ICD can deliver an electric shock to the heart to restore normal heart rhythms.

33. As described above, the Riata lead was sold by St. Jude until December 2010. The Company's decision to discontinue sales of the product were prompted by instances in which the insulation of the Riata leads were observed to have so-called "inside-out" abrasions. The insulation failure from this type of abrasion may cause some of the electrical conductors

inside the Riata leads to move within or move entirely outside the outer lead insulation. This could cause the lead to malfunction, resulting in inappropriate or no shock therapy and potentially life-threatening abnormal heart rhythms.

34. In November 2011, St. Jude updated physicians on the abrasion failures associated with the Riata leads. The FDA deemed this communication as a "Class 1" recall, the most serious type of recall involving situation in which there is a reasonable probability that the use of a recalled product will cause serious adverse health consequences or death. As of 2011, approximately 79,000 Riata leads remained implanted in patients in the United States. The FDA has recommended that such patients undergo imaging studies to assess whether there are insulation abnormalities.

35. According to an October 10, 2012 *Wall Street Journal* article, flaws in the Riata leads were evident well-before St. Jude discontinued sales of the product. For example, according to the article, St. Jude conducted an internal audit which "concluded in 2008 that Riata had potentially serious problems, including inside-out abrasion." The article further noted that St. Jude did not issue its December 2010 warning about the abrasion failures until after several doctors published case reports concerning the problem.

36. In 2006, the FDA approved a next generation ICD lead known as the Riata ST. St. Jude changed the name of the product to Durata in 2008. The Riata ST and the Durata are coated with a proprietary material known as "Optim," a blend of silicone and polyurethane. St. Jude has represented that the Optim insulation is 50 times more resistant to abrasion than silicone, the standard coating.

B. FDA Inspections and Warning Letters

37. Medical device manufacturers are required to comply with current Good Manufacturing Practices (cGMPs) of the FDA's Quality System regulation. The regulation requires that various specifications and controls be established for devices; that devices be designed and manufactured under a quality system to meet such specifications; that devices be correctly installed, checked and serviced; that quality data be analyzed to identify and correct quality problems; and that complaints be processed. The Quality Systems regulation is thus intended to help assure that medical devices are safe and effective for their intended use.

38. The FDA conducts inspections of FDA-regulated facilities to determine a firm's compliance with the Food, Drug & Cosmetic Act (FDCA) and relevant regulations, such as the Quality Systems regulation that is applicable to manufacturers of medical devices. A form, known as an FDA Form 483, is issued to firm management at the conclusion of an inspection when FDA investigators have observed conditions that they believe may constitute violations of the FDCA and related statutes and regulations. Observations listed on a Form 483 notify management of objectionable conditions and are typically noted when conditions or practices are observed indicating that a device (or other FDA-regulated product) has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health.

39. Failure to adequately respond to or correct issues raised in a Form 483 may result in the FDA's issuance of a Warning Letter. Warning Letters are intended for violations of the statute or regulations that are deemed to be of "regulatory significance." A matter is regulatory significance where the violation is such that it may lead to an enforcement action if not promptly and adequately corrected.

C. Concerns Emerge About the Performance of Durata

40. On June 12, 2012, reports in the news media asserted that a doctor had reported to the FDA a case of insulation failure associated with the Durata. St. Jude ultimately determined that the insulation failure in this instance was not the same type of "inside-out" abrasion experienced with the Riata. Instead, the abrasion resulted from contact with an external source (e.g., a calcified heart value) and is a known cause of failure across all cardiac leads in the industry. Nevertheless, St. Jude's stock declined by 6 percent on June 12, amid concerns expressed by analysts as to whether the Durata was truly immune from the same types of problems as had been experienced with the Riata.

41. On August 16, 2012, the FDA directed St. Jude to conduct post-market surveillance studies of Durata and Riata ST. This includes, for example, the routine X-ray of patients enrolled in the studies to detect any potential insulation problems. In ordering these studies, the FDA's branch chief for pacing and defibrillator devices, Mitchell Shein, told the *Wall Street Journal* that the Durata lead "is sufficiently similar to the recalled Riata product to merit closer examination." On this news, St. Jude's stock price decline by 4 percent.

42. On August 22, 2012, the news media reported on a study of the Durata published in *EP Eurospace*, a British cardiology journal, conducted by Dr. Robert G. Hauser, a cardiologist affiliated with Abbott Northwestern Hospital in Minneapolis. Dr. Hauser's study reviewed data maintained by the FDA and found 52 instances of lead failures in the Durata or Riata ST, including one resulting in a patient's death. Dr. Hauser noted that due to gaps in the FDA database, the number of lead failures reported in the study likely underestimates the actual number that occurred. The study identified three cases that appeared to show inside-out abrasion failure. While Dr. Hauser acknowledged that further study was needed to assess the Durata's

failure rate, he was quoted by the *New York Times* as stating: "I think it is a red flag. I think we need more data. But fundamentally, I'm afraid this material is not going to perform as advertised." He further stated that "[t]here is no reason to use this lead until we have more confidence in its performance."

D. St. Jude States That an FDA Warning Letter Is Possible, But Declines to Identify the Source of the Problem

43. On October 17, 2012, St. Jude issued its third quarter 2012 financial results and held an earnings conference call with securities analysts. On the conference call, St. Jude's CEO, defendant Starks, noted that the Company's advisories concerning the Riata lead had drawn extensive attention from the FDA. In this context, Starks disclosed, for the first time, that a St. Jude production facility located in Sylmar, California was undergoing an FDA inspection. Although the inspection was not yet concluded, Starks stated that it was likely to result in the issuance of a Form 483 and that "[w]e would not be surprised if these observations are ultimately followed by issuance of a warning letter." Notwithstanding these disclosures, Starks declined to specifically identify the problems being found at the Sylmar facility or the products that might be associated with any objectionable conditions being noted by the FDA investigators. Indeed, in response to a question from one analyst asking what was wrong with Sylmar, Starks responded, in part: "There's nothing. And what I mean by that is the reliability data, the level of transparency, what you see in the way our products perform on the market, … you'll see it across the board with the pacemaker line, with the ICD product line, with the Durata and Riata ST Optim product line that the reliability data and the evidence that that implies for the robustness of our quality systems is all very good."

44. Defendant Starks stated on the call that the FDA inspection of the Symar, CA facility would be completed "very soon" and that the inspection was "near its end." Indeed, the

inspection concluded on the same day as the conference call, October 17, 2012, and resulted in the issuance of a Form 483. Thus, by the time of the conference call, both he and the Company were aware, but failed to disclose, that the FDA inspection was focusing on issues relating to the Durata.

45. October 24, 2012, St. Jude filed a Form 8-K with the SEC, attaching a version of the Form 483 that had been issued by the FDA on October 17, 2012 in connection with the inspection of the Sylmar, CA facility. The version of the Form 483 released by St. Jude was heavily redacted, so that a reader was unable to determine the products to which any of the FDA's observations related. The Form 8-K represented that the redactions were based on the Company's "good faith interpretation of Freedom of Information Act (FOIA) exemption (b)(4), which protects confidential and proprietary information from disclosure." The Form 8-K noted that St. Jude had sent its proposed redactions to the FDA for review, but that the FDA would make an independent assessment of the Form 483 before releasing it. The Form 8-K further represented that "[i]t is important to note that none of the observations [on the Form 483] identified a specific issue regarding clinical or field performance of any particular device."

E. The Truth Is Revealed

46. On or about November 20, 2012, the FDA released its own version of the Form 483 for its inspection of the Sylmar facility. The version released by the FDA, while still redacted, showed clearly that most of the observations of objectionable conditions listed on the Form 483 pertained to Durata. Indeed, no other product name appears on the version released by the FDA.

47. News media reports concerning the FDA's release of Sylmar inspection report did not surface until after the close of the market on November 20. As described in a November 20, 2012 report by the online version of the *New York Times*:

> A report on an inspection of a St. Jude Medical facility released Tuesday by federal officials found significant flaws in the company's testing and oversight of a controversial heart device component, a copy of the document shows. The report may also raise questions about how St. Jude executives recently depicted the inspection's contents to investors and others.
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> Although the agency blacked out many details of the inspection, which took place in September and October at the company's plant in Sylmar, Calif., the report appeared to focus on the methods St. Jude used to test the Durata, which was introduced in December of 2007. The agency inspectors found that the company failed to follow its own written protocols for testing the product, and did not properly evaluate some study results. The agency also concluded that St. Jude did not adequately follow up on problems it identified in the manufacturing process, and also did not properly investigate some complaints about the lead.

48. On November 21, 2012, the first day of trading after the FDA's version of the Form 483 was publicly disclosed, St. Jude's stock suffered a one-day decline of $4.34 or 12 percent to close at $31.37, on enormous volume of over 26 million shares (in comparison with average daily volume of about 3.2 million shares in the preceding three months).

49. On November 26, 2012, the *New York Times* published an article regarding St. Jude's decision to redact product names from the version of the inspection report that it released to the public. A St. Jude spokesperson reiterated the Company's position that the redactions were based on a good faith interpretation of the FDA's rules. However, the article cited an FDA spokesperson as saying that the agency did not consider product names to be confidential. The article also quoted William Vodra, a former Associate Chief Counsel with the FDA, as stating that, "[i]n my experience, the FDA consistently rejects" arguments for redacting product names.

ADDITIONAL SCIENTER ALLEGATIONS

50. As alleged herein, the Defendants acted with scienter in that the Defendants knew that the public statements and documents issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Defendants, by virtue of their receipt of information reflecting the true facts regarding St. Jude and the FDA inspection of St. Jude's Sylmar, CA facility, their control over, and/or receipt and/or modification of St. Jude's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning St. Jude, participated in the fraudulent scheme alleged herein.

51. Additionally, defendant Starks, on October 31, 2012 sold 100,000 shares of St. Jude stock at a weighted average price of 38.14 per share. On November 1, 2012, Starks sold another 100,000 shares of St. Jude stock at a weighted average price of $38.77 per share. Starks realized total proceeds from these sales in the amount of $7,691,000.

52. These sales were unusual in their timing because Starks was then in possession of highly material, non-public information concerning the FDA inspection of St. Jude's Sylmar, CA facility and because Starks had not previously sold any St. Jude shares since February 29, 2012.

53. These sales not only constitute significant evidence of scienter, but also violate an insider's duty under the federal securities laws to "disclose or refrain from trading."

RELIANCE: APPLICABILITY OF FRAUD ON THE MARKET PRESUMPTION

54. At all relevant times, the market for St. Jude common stock was an efficient market that promptly digested current information with respect to the Company from all publicly-available sources and reflected such information in the prices of the Company's securities. Through the Class Period:

(a) St. Jude's stock met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient and automated market;

(b) St Jude met the requirements of a seasoned issuer to file registration statements under Form S-3; in addition, as a regulated issuer, St. Jude filed periodic public reports with the SEC and the NYSE;

(c) St. Jude regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services. Securities analysts and the business press followed and published research reports regarding St. Jude that were publicly available to investors;

(d) The market price of St. Jude securities reacted promptly to the dissemination of new, material information regarding the Company;

(e) The average daily trading volume for St. Jude stock during the Class Period was approximately 4.1 million shares traded; and

(f) The Company's market capitalization was approximately $12.8 billion on October 17, 2012 (when St. Jude announced its third quarter 2012 financial results), and $9.6

billion on November 21, 2012 (after the FDA released the inspection report for St. Jude's Sylmar, CA facility).

55. As a result of the misconduct alleged herein (including Defendants' misstatements and omissions), the market for St. Jude securities was artificially inflated. Under such circumstances, the presumption of reliance available under the "fraud-on-the-market" theory applies.

56. Plaintiff and the other Class members relied on the integrity of the market price for the Company's securities and were substantially damaged as a direct and proximate result of their purchases of St. Jude securities at artificially inflated prices and the subsequent decline in the price of those securities when the truth was disclosed.

57. Had Plaintiff and the other members of the Class known of the material adverse information not disclosed by Defendants, or been aware of the truth behind Defendants' material misstatements and omissions, they would not have purchased St. Jude securities at inflated prices.

58. Plaintiff is also entitled to the *Affiliate Ute* presumption of reliance to the extent that Defendants' statements concerning the FDA inspection of St. Jude's Sylmar, CA facility failed to disclose material facts.

NO SAFE HARBOR

59. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially

from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, the Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of St. Jude who knew that those statements were false when made.

COUNT I

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

60. Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein.

61. This Claim is brought pursuant to Section 10(b) of the Exchange Act and Rule 10-b(5) promulgated thereunder, on behalf of Plaintiff and all other members of the Class, against all Defendants.

62. Throughout the Class Period, Defendants, individually and in concert, directly and indirectly, by the use and means of instrumentalities of interstate commerce, the mails and the facilities of a national securities exchange, employed devices, schemes and artifices to defraud, made untrue statements of material fact and/or omitted to state material facts necessary to make statements made not misleading, and engaged in acts, practices and a course of business which operated a fraud and deceit upon Class members, in violation of Section 10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder.

63. Defendants' false and misleading statements and omissions were made with scienter and were intended to and did, as alleged herein, (i) deceive the investing public, including Plaintiff and the other members of the Class; (ii) artificially create, inflate and maintain

the market for and market price of the Company's securities; and (iii) cause Plaintiff and the other members of the Class to purchase St. Jude's securities at inflated prices.

64. By failing to inform the market of all material facts concerning the FDA inspection of St. Jude's Sylmar, CA facility, and by making other false statements and material omissions, Defendants presented a misleading impression of St. Jude's compliance with FDA regulations and prospects for its Durata product. This caused and maintained artificial inflation in the prices of St. Jude's publicly traded securities throughout the Class Period and until the truth was fully disclosed.

65. Defendants were individually and collectively responsible for making the statements and omissions alleged herein, by virtue of having prepared, approved, signed and/or disseminated documents which contained untrue statements of material fact and/or making direct statements to the investing public on the conference calls detailed herein.

66. During the Class Period, defendant Starks, as Chairman, President and CEO of St. Jude, was privy to non-public information concerning the Company. Both Starks and the Company knew or recklessly disregarded the adverse facts specified herein and omitted to disclose those facts.

67. As described herein, Defendants made the false statements and omissions knowingly and intentionally, or in such an extremely reckless manner as to constitute willful deceit and fraud upon Plaintiff and other members of the Class who purchased St. Jude securities during the Class Period. Throughout the Class Period, Defendants had a duty to disclose new, material information that came to their attention, which rendered their prior statements to the market materially false and misleading. There is a substantial likelihood that the disclosure of

these omitted facts would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information available about the prospects of the Company.

68. Defendants' false statements and omissions were made in connection with the purchase or sale of the Company's securities.

69. In ignorance of the false and misleading nature of Defendants' statements and/or upon the integrity of the market price for St. Jude securities, Plaintiff and the other members of the class purchased St. Jude securities at artificially inflated prices during the Class Period. But for the fraud, they would not have purchased the securities at artificially inflated prices.

70. The market price for St. Jude securities declined materially upon the public disclosure of the facts that had previously been misrepresented or omitted by the Defendants, as described above.

71. Plaintiff and the other members of the Class were substantially damaged as a direct and proximate result of their purchases of St. Jude securities at artificially inflated prices and the subsequent decline in the price of those securities when the truth was disclosed.

72. This claim was brought within two years after discovery of this fraud and within five years of the making of the statements alleged herein to be materially false and misleading.

73. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, and are liable to Plaintiff and the members of the Class, each of whom has been damaged as a result of such violation.

COUNT II

Violation of Section 20(a) of the Exchange Act
(Against Defendant Starks)

74. Plaintiff repeats and realleges each and every allegation above as if set forth fully herein. This Claim is brought pursuant to Section 20(a) of the Exchange Act against defendant

Starks on behalf of Plaintiff and all members of the Class who purchased St. Jude securities during the Class Period.

75. As alleged herein, St. Jude is liable to Plaintiff and the members of the Class who purchased St. Jude securities based on the materially false and misleading statements and omissions set forth above, pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

76. Throughout the Class Period, defendant Starks was a controlling person of St. Jude within the meaning of Section 20(a) of the Exchange Act, and a culpable participant in the St. Jude fraud, as detailed herein.

77. Defendant Starks exercised control over St. Jude during the Class Period by virtue of, among other things, his executive positions with the Company, the key role he played in the Company's management, and his direct involvement in its day to day operations, including its implantable cardiac medical device business.

78. Given his responsibilities for managing St. Jude throughout the Class Period, defendant Starks was regularly presented to the market as an individual who was responsible for St. Jude's implantable cardiac medical devices, its day-to-day business and operations, as well as the Company's strategic direction. Defendant Starks accepted responsibility for presenting quarterly and annual results, setting guidance for future periods, updating the investors about the status of the Company's implantable cardiac medical device business and assuring the market about the state of, and prospects for the Company.

79. As a result of the false and misleading statements and omissions alleged herein, the market price of St. Jude securities was artificially inflated during the Class Period. Under such circumstances, the presumption of reliance available under the "fraud on the market" theory

applies, as more particularly set forth above. Plaintiff and the members of the Class relied upon either the integrity of the market or upon the statements and reports of Defendant Starks in purchasing St. Jude securities at artificially inflated prices.

80. This claim was brought within two years after the discovery of this fraud and within five years of the making of the statements alleged herein to be materially false and misleading.

81. By virtue of the foregoing, Defendant Starks is liable under Section 20(a) to Plaintiff and the Class, each of whom has been damaged as a result of St. Jude's underlying violations.

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Declaring this action to be a proper class action pursuant to Rule 23(a) and Rule 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class defined herein;

B. Awarding Plaintiff and the members of the Class compensatory damages;

C. Awarding Plaintiff and the Class pre-judgment and post-judgment interest, as well as reasonable attorneys' fees, expert witness fees and other costs; and

D. Awarding such other relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Plaintiff hereby demands a trial by jury in this action for all issues so triable.

Dated: December 7, 2012

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