

Press Release

US Court Certifies Nationwide Consumer Fraud Case Against St. Jude Medical, Inc. for Recalled Silzone Prosthetic Heart Valves.

For immediate release

(MINNEAPOLIS, MN, Oct. 14 2006) District Court Judge John R. Tunheim has granted class certification to more than 11,000 people nationwide who received one of St. Jude Medical's Silzone heart valves, enabling them to pursue their consumer fraud claims for recovery for the cost of the recalled valve, expenses associated with these allegedly defective devices, medical surveillance. The class action consists of all persons in the United States who were implanted with the flawed device prior to St. Jude Medical (NYSE:STJ) disclosing the life threatening risks associated with the device.

Steven E. Angstreich, a member of the Philadelphia, Pennsylvania law firm of Levy, Angstreich, Finney, Baldante, Rubenstein & Coren, P.C., and one of the co-lead counsel appointed by the court to represent the implant recipients in the suit, responded to the Court's October 13 ruling: "Our clients and the attorneys in the plaintiffs steering committee prosecuting the suit are very pleased with the Court's ruling. It is the culmination of a long, very thorough, and pain staking review and analysis process conducted by the Court on consumer protection law and the facts surrounding St. Jude's alleged misconduct in marketing its ill-fated, premium priced silver-coated cuffed version of its widely used mechanical heart valve. The patients in the class action were implanted with a device that was never part of a wide-scale clinical trial before it was put on the market. Many safety tests normally required by both FDA guidelines and international medical device standards were not done as St. Jude rushed to get this purported enhanced version of this product on the market. The Court's ruling on Friday is an important step in assuring that these individuals have a vehicle to pursue their claims as a group. As a class action, we are able to move forward to protect the interests of all affected individuals; they can now enjoy representation through this case. We are eager to continue this fight."

St. Jude Medical produced the Silzone cuffed prosthetic heart valves from 1997 until January 21, 2000, at which time St. Jude stopped their world-wide marketing and recalled any that had not yet been implanted. In the United States these valves were sold from April, 1998 to January, 21, 2000. Similar class actions are pending in Canada on behalf of Canadian residents.

St. Jude's recall was in response to mounting and overwhelming evidence the Silzone coating was causing patients to experience serious and at times life threatening medical problems. While the Food & Drug Administration was studying information on the problem it was gathering, other governments had already responded by issuing special advisory warnings or taking the devices off the market. Long prior to that, a number of hospitals in Canada and Europe, including ones performing clinical research for St. Jude, had stopped implanting Silzone valves after discovering and reporting to St. Jude large number of serious problems in patients implanted with them. The U.S. recall came only

after an international post regulatory approval clinical trial sponsored by St. Jude was stopped by its safety oversight committee following a specially called review of both the data and surgical findings collected in the study. The safety committee's review found a higher rate of paravalvular leaks in patients who were implanted with the Silzone cuff, many with reports of unusual and alarming pathological findings by the explanting surgeons.

Heart valves are typically surrounded on the outside by a polyester cuff called a sewing ring. Surgeons sew through this ring to stitch the artificial valve to the heart muscle. St. Jude's Silzone heart valves contained one significant variation from previous models: a sewing ring with a silver coating. Although the silver coating was designed to ward off infection, St. Jude's clinical findings obtained after it had already put the valve on the market revealed that not only did the coating not work to reduce infection, it also greatly increased the likelihood of leaks and blood clots.

Over 11,000 were implanted in the United States before the recall. A great many of these patients are still alive with the valve still implanted. According to an extensive medical review and report filed with the court as part of the class certification proceedings that was prepared by an internationally renown heart expert who St. Jude had, prior to the recall, retained to study the Silzone valve, those still alive and implanted with a Silzone valve require special medical surveillance that is not normally required by prosthetic valve patients because of the ongoing danger the silver coating poses.

The patients' case has been difficult. In 2004, the case was certified to proceed as a class action. Upon news of the certification, St. Jude Medical appealed the decision to the 8th Circuit Court of Appeals. Last year, the 8th Circuit decertified the case and then sent the case back to the District Court to rule again on the issue of whether the case could proceed as a consumer class action under Minnesota's consumer protection laws. After many months of extensive briefing by the parties, Judge Tunheim issued an order on Friday, October 13, 2006, certifying a class and finding that individuals throughout the U.S. can assert claims under Minnesota's consumer fraud statute to obtain compensation and other relief, such a medical surveillance and unbiased epidemiological study. According to Angstreich, "the order is based on existing law in Minnesota; nothing has been broadened by this decision. What the Order makes clear is that if deceptive activities emanate from within Minnesota, then a Defendant like St. Jude Medical can be held accountable to individuals throughout the country under Minnesota statutes."

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The Class Action Complaint and Judge Tunheim order and opinion are available upon request.

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