

October 18 2011

Senator Rachel Siewart
Chair
Community Affairs Reference Committee
Regulatory Standards for Approval of Medical Devices
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Senator

Re: Ms Karen Carey

- 1 I am writing in relation to the evidence given by Ms Karen Carey in the public hearings of the Committee that took place on 27 September 2011. The evidence given by Ms Carey is set out at pages 27 to 33 of the transcript and in part records her personal experience with an implanted St Jude Medical mechanical heart valve.
- 2 St Jude Medical places extraordinary value on its reputation in the Australian community. Our company was founded in 1976 on the pioneering invention of the bi-leaflet mechanical heart valve and we recently celebrated the implantation of two million St Jude Medical mechanical heart valves world-wide. As a company, we are keen to join the national health care debate and we invest a great deal of time and effort in participating in reviews and inquiries such as this. It is always our intention to support initiatives or reforms that are likely to improve health outcomes in Australians
- 3 It is disappointing, considering the above, that Ms Carey has chosen to make a number of inaccurate statements regarding St Jude Medical to the Committee in her evidence. While St Jude Medical has no wish to prevent Ms Carey expressing her opinions to the Committee, it is important for the proper operation of the Committee that it is able to safely rely on material that is presented to it as being factual.



- 4 Regrettably this is not the case with a number of aspects of Ms Carey’s evidence as to her personal experience and St Jude Medical considers that it has no choice other than to write to the Committee to correct the relevant inaccuracies.
- 5 Ms Carey in her evidence essentially makes four statements that St Jude Medical considers are incorrect. They are:
- (a) she asserts in the transcript on at least two occasions that she was an implanted with a ‘*failed medical device*’ – see pages 27 and 28;
 - (b) she asserts in a number of parts of her evidence that she was not told about the options that were available to her or that there was potential for complications if she received a mechanical heart valve. On page 29 of the transcript she is recorded as saying that ‘*had I had information about the options that were available to me I probably would have made a different choice*’, while she on page 31 states that ‘*I obviously had not been told about the fact that the complication was known and problems arose from that*’;
 - (c) she suggests in a number of places that St Jude Medical deliberately withheld information from and deliberately provided false information (P31) to the TGA as to complication rates and adverse reaction reports;
 - (d) she suggest that she was required to fight expensive litigation and that she has been bankrupted by St Jude Medical as a consequence of that litigation.
- 6 Each of these statements is incorrect. It is important that the Committee understands the claims made by Ms Carey have been the subject of Federal Court proceedings – which contrary to what she suggests, she initiated – in which each of the first three claims above were rejected. The proceedings were dismissed with costs on 6 July 2004, with the trial judge, Justice Susan Kiefel, making express findings that:
- (a) the St Jude Medical valve that Ms Carey received was not defective;
 - (b) the condition from which Ms Carey suffered, thromboemboli, was a well recognised risk from implanted mechanical valves; and



- (c) Ms Carey was advised by her doctors of the treatment options that she had and the risks that thromboemboli might develop from an implanted mechanical valve.
- 7 I enclose with this letter a copy of that judgment and a summary of its relevant findings.
- 8 What is particularly galling to St Jude Medical is the suggestion that it has bankrupted Ms Carey. This suggestion has no basis in truth. Although St Jude Medical received a costs order in the proceedings, that order has not been enforced and it has taken no steps to recover its significant legal costs from Ms Carey. Her answer to Senator Xenophon's question suggests in the clearest terms that St Jude Medical took active steps to bankrupt Ms Carey.
- 9 The final suggestion made by Ms Carey that St Jude Medical deliberately withheld information from the TGA is similarly entirely baseless. As the Court found the complication from which Ms Carey suffered was a recognised risk of the normal functioning of the device, which was warned against by St Jude Medical in its product literature and was extensively discussed and reported in the relevant medical literature. The suggestion that St Jude Medical was representing to the TGA that this was a one-off event is not based in fact.
- 10 The inaccuracies in Ms Carey's evidence before the Committee falsely impugn the reputation of St Jude Medical and the safety of its mechanical heart valve, which I note that has been implanted in over two million patients worldwide. As well as having the potential to wrongly influence the deliberations of the Committee, these inaccuracies if uncorrected have the potential to:
- (a) induce unnecessary stress and anxiety in patients who have implanted St Jude Medical mechanical heart valves; and
 - (b) cause St Jude Medical financial loss.
- 11 It is ultimately a matter for the Committee how it wishes to correct the inaccuracies that now exist in the transcript of Ms Carey's evidence. I note that the Procedures to be observed by Senate committees for the protection of witnesses propose two options:
- (a) paragraph 12 – expunging the incorrect evidence from the transcript; or



(b) paragraph 13 – providing an opportunity for a right of reply by written or oral means.

12 In this respect, St Jude Medical believes that the false statement concerning Ms Carey's bankruptcy should be expunged from the transcript. In relation to the other matters, St Jude Medical requests that a copy of this letter and attachments be included in the publicly available material of the Committee with a note within the transcript of Ms Carey's evidence recording that St Jude Medical disputes her assertions and referring to this material.

13 Please do not hesitate to contact me should you wish to discuss this further.

Yours faithfully

David Jolly

Managing Director, Australia and New Zealand