There Is Disagreement Over The Three-Year Failure Rate For Sprint Fidelis Lead Wires

Medtronic Says 4.6 Percent Of Leads Failed, While Reports From Some Hospitals Indicate 9.2 Percent Of Sprint Fidelis Wires Failed

(Posted by Tom Lamb at www.DrugInjuryWatch.com on February 4, 2010; see http://bit.ly/cyssuI)

In our December 30, 2009 article, "Sprint Fidelis Lead Wire Failure Rate Could Rise To 30 Percent By Four Years", we provided the little bit of information we could find, then, about the future failure rates for the Medtronic Sprint Fidelis lead wires that were removed from the market back in 2007:

> A report by UBS Investment Research Monday said lead failures could accelerate over time, citing independent studies that predict failure rates could hit 30 percent by four years. Medtronic's own data suggests a 3 percent failure rate at three years.

Now we have some additional data regarding the three-year failure rate, or survival rate, of these Sprint Fidelis leads thanks to a February 4, 2010 article, "Hospitals Dispute Medtronic Data on Wires", by *Wall Street Journal* (*WSJ*) reporter Thomas M. Burton.

From this February 2010 *WSJ* article we get the following numbers:

> Medtronic says its own research shows the Sprint Fidelis leads survive for three years at least 95.4% of the time, for a failure rate of 4.6%. Reports from hospitals including the University of Rochester in New York state, the Minneapolis Heart Institute, the Mayo Clinic and the University of Ottawa, say the overall failure rate for Sprint Fidelis leads is as much as two times as great as the company's own data indicate. Some of the hospitals also report that the rate of fracture accelerates as the leads age.
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> "The hazard of [Sprint] Fidelis lead fracture is increasing exponentially with time and, based on our data, occurring at a higher rate than the latest manufacturer's performance update," doctors at the University of Rochester concluded in findings published in January's American Journal of Cardiology. The report said the three-year survival rate of 426 Medtronic leads inserted in the hospital's patients was 90.8%, meaning 9.2% failed.

Mr. Burton also looked back at a number of other studies that have been performed since the 2007 Sprint Fidelis recall, and he reports:

> Last February, a joint report from the Minneapolis Heart Institute and the Mayo Clinic, published in the journal HeartRhythm, said the estimated rate of failure among 848 leads at three years of use was 12.1%. An October 2008 study by the University of Ottawa Heart Institute, also published in HeartRhythm, found that the fracture rate of Sprint Fidelis leads "increased significantly with time."
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> In November, a separate Mayo Clinic study showed the failure rate for Sprint Fidelis leads after two years was higher in patients younger than 50, at 20.4%, than in older patients, with a rate of 3.5%. There were 89 patients under 50 who received the leads, and 362 patients who were 50 or above.

Our law firm continues to review possible Sprint Fidelis lawsuits involving incidents of harmful unnecessary shocks in anticipation that the Medical Device Safety Act (MDSA; HR 1346 / S 540) will become law in 2010 and, thereafter, lawsuits can be filed against Medtronic on behalf of those injured patients.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
http://www.DrugInjuryWatch.com