Sprint Fidelis Lead Wire Failure Rate Could Rise To 30 Percent By Four Years

About 260,000 Medtronic Sprint Fidelis Leads Were Implanted In US, With Approximately 143,000 Still Active

(Posted by Tom Lamb at www.DrugInjuryWatch.com on December 30, 2009; see http://bit.ly/5eRt5l)

The December 28, 2009 edition of "US Morning Meeting Highlights" from UBS Investment Research brought some relatively grim news for patients who have a defibrillator with a Sprint Fidelis lead wire.

As explained by Thomas Lee for *MedCity News* in his December 29, 2009 article, "Sprint Fidelis lead woes continue to haunt Medtronic, industry as FDA takes notice":

> 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. Leads are wires that doctor snake through veins that connect the battery of an implantable cardioverter defibrillator (ICD) to the heart. An ICD is a device that detects abnormal heart beats and shocks the heart back into rhythm....
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> Interestingly enough, one study, called Altitude, says healthy patients are more at risk because they live longer and thus more vulnerable to problems like lead failure, making the risk/reward scenario less appealing to patients who receive ICDs....
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> Earlier this year, Medtronic told doctors that lead failures may have factored into at least 13 deaths. About 260,000 Sprint Fidelis leads have been implanted in patients in the United States, with 143,000 still active.

Here are a couple of our earlier 2009 articles about the "consequences" associated with the October 2007 Sprint Fidelis recall:

March 2009 Update: Sprint Fidelis Heart Device Connected To At Least 13 Deaths

Sprint Fidelis Lead Wire Failures May Be On The Rise According To February 2009 Journal Article By Hauser And Hayes

To our knowledge, the last public communications from Medtronic about the Sprint Fidelis failure problem is their March 13, 2009 "Dear Doctor" letter and their March 13, 2009 "Open Letter to Sprint Fidelis Lead Patients".

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