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Sprint Fidelis Recall Showed That FDA's Medical Device Safety System Is Flawed

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FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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Dr. Hauser: "Just because a device is FDA-approved does not necessarily mean it is safe."

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

In his March 5, 2008 article -- "[Medical device safety in spotlight; M.D. uses Medtronic recall in critique of FDA, manufacturers](#)" -- reporter Christopher Snowbeck explores how the Sprint Fidelis lead wire recall in October 2007 by Medtronic Inc. showed the medical device safety system as it currently operates here in the U.S. is fundamentally flawed.

For this article about the Medtronic recall last year, Mr. Snowbeck uses as his starting point a "Perspective" piece by William H. Maisel, M.D., M.P.H., which was published in the March 6, 2008 edition of *The New England Journal of Medicine (NEJM)*, "[Semper Fidelis — Consumer Protection for Patients with Implanted Medical Devices](#)", which he describes as follows:

Dr. William Maisel, an expert on medical device safety at Boston's Beth Israel Deaconess Medical Center, writes in today's edition of the New England Journal of Medicine that the Medtronic recall is the latest example of how manufacturers and the U.S. Food and Drug Administration have failed to provide the public with timely, critical information about device malfunctions....

Maisel said that five months before Medtronic recalled the Sprint Fidelis lead wire, the company submitted an application to the FDA to change the product's design and manufacturing.

That request was not publicized to physicians or patients, Maisel wrote, even though doctors had received letters from Medtronic in February 2007 stating that there could be a problem with the lead. He noted that after FDA approved the design changes, old versions of the Sprint Fidelis lead remained on hospital shelves for use in patients.

"Often, a flawed product continues to be marketed while the manufacturer submits a revised marketing application to the FDA and

awaits approval of the amended product design and manufacturing plan," Maisel wrote. "Manufacturers have repeatedly and knowingly sold potentially defective devices without public disclosure."

Mr. Snowbeck then permits Medtronic an opportunity to respond to these contentions by Dr. Maisel:

Rob Clark, a Medtronic spokesman,... maintained Maisel's editorial omits key details in describing how the company handled the Sprint Fidelis matter.

"The narrative is incomplete and omits facts that are essential to any full accounting or analysis of the events and their ramifications," Clark said.

.. Clark said the Sprint Fidelis design change sought by the company in May had nothing to do with the problems that ultimately led to the recall. Manufacturers regularly make such design changes as they improve products, Clark said, and those changes don't indicate earlier versions are flawed.

Finally, Mr. Snowbeck goes beyond the *NEJM* article dispute to get the insight and opinion of [a man who helped bring the Sprint Fidelis problem to light](#). In July 2007 Dr. [Robert Hauser](#), of the Minneapolis Heart Institute, published a medical journal article that suggested patients with implantable defibrillators which had Sprint Fidelis lead wires were being needlessly and repeatedly shocked because those lead wires were fracturing at an unusually high rate. Here's what Dr. Hauser told Mr. Snowbeck as he prepared his March 2008 story:

"When you stand back and look at this, what's so disturbing is that physicians started implanting this lead because it was FDA-approved — they thought, 'Well, it's a nice, small lead, and it's FDA-approved so it must be OK,'" said Hauser. "Just because a device is FDA-approved does not necessarily mean it is safe."

Unfortunately for us, however, Medtronic and other makers of medical devices like implantable defibrillators are now immune from legal liability any injury or death their product might cause as long as it was FDA-approved. This situation is the result of an opinion issued by the U.S. Supreme Court on February 20, 2008, in the case *Riegel v. Medtronic Inc.* (No. 06-179).

As explained by *New York Times* reporter in her February 21, 2008 article, "[Justices Shield Medical Devices From Lawsuits](#)":

The 8-to-1 decision [in the *Riegel v. Medtronic* case] was a victory for the Bush administration, which for years has sought broad authority to pre-empt tougher state regulation.

In 2004, the administration reversed longstanding federal policy and began arguing that "premarket approval" of a new medical device by the F.D.A. overrides most claims for damages under state law. Because federal law makes no provision for damage suits against device makers, injured patients have turned to state law and have won substantial awards.

The Bush administration will continue its push for pre-emption in another F.D.A. case that the court has accepted for its next term, on whether the agency's approval of a drug, as opposed to a device, pre-empts personal injury suits. Drugs and medical devices are regulated

under separate laws.

The prescription drug injury case referred to in that last paragraph is *Wyeth v. Levine* and in that case [the Supreme Court will decide whether a patient should be able to sue a pharmaceutical company](#) when there is a serious side effect that the company did not fully disclose, amongst other scenarios where currently the patient does have access to the court system here in the U.S.

The short of it is, as seen by this March 5 article about the defective Sprint Fidelis lead wire, just because a medical device was approved by the FDA does not mean it is a safe product.

P.S. A well-written Opinion article from attorney Thomas R. Kline, "[Immunity is a bad medicine for Americans' well-being](#)", was published by *The Philadelphia Inquirer* on March 7, 2008. It begins with this paragraph:

On Feb. 20, the U.S. Supreme Court granted legal immunity to manufacturers of medical devices that secure "pre-market approval" from the Food and Drug Administration for their products. The 8-1 decision in *Riegel v. Medtronic* guarantees medical-device manufacturers will have no financial accountability for their mistakes when their products are simply made according to FDA minimum specifications. Those standards are, in the words of noted Harvard pharmaco-epidemiologist Jerry Avorn, so minimal they "would be unacceptable anywhere else in research."...

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