

Minneapolis Heart Institute
920 East 28th Street, Suite 300
Minneapolis, Minnesota 55407

April 12, 2010

The Honorable Donovan W. Frank
Judge of the United States District Court of Minnesota
United States District Court ☐
724 Federal Building ☐
316 No Robert Street ☐
St. Paul, MN 55101

Sir:

We are physicians who cared for Joshua Okrup, a 21 year-old college student, who died when his Guidant Prizm 2 implantable cardioverter-defibrillator (ICD) short-circuited and failed to deliver a life-saving shock. His unnecessary death was caused by a product defect that Guidant Inc. had known about for years and failed to inform patients, physicians, and the U.S. Food and Drug Administration. Accordingly, we are extremely dismayed by the U.S. Attorney General's decision to enter into a plea agreement with Guidant LLC, rather than prosecute the company and the individuals responsible for this egregious act. On behalf of the patients who died or suffered pain and mental anguish as the direct result of Guidant's illegal and unethical behavior, we urge you not to accept the plea agreement.

Also at issue in this case is the safety of future generations of patients who receive medical devices. Manufacturers control the quality of their products. Manufacturers are the first to know when a medical device is dangerous or underperforming. Thus, it is in the best interest of patients, and society in general, for manufacturers to be liable for the safety and effectiveness of their products. To allow a repeat offender, like Guidant, to escape with a fine (that is entirely borne by the shareholders of Boston Scientific) does not hold the guilty parties fully accountable and inevitably undermines patient safety.

We are available to meet with you or respond to your questions.

Respectfully,

Robert G. Hauser MD

Barry J. Maron MD