Testimony of

M.D. Barry Maron

Director Hypertrophic Cardiomyopathy Center
Minneapolis Heart Institute Foundation
March 10, 2006

Testimony
United States Senate Committee on the Judiciary

Need for Reform in the Medical Device (Implantable Defibrillator) Industry

March 10, 2006

Testimony
Barry J. Maron, MD
Director, Hypertrophic Cardiomyopathy Center
Minneapolis Heart Institute
Minneapolis, MN

Chairman Specter, Senator Leahy and distinguished members of the Judiciary Committee. Thank you for the opportunity to share with you today my experiences and views on the recent medical device controversy (largely involving implantable defibrillators). My name is Dr. Barry Maron and I am a Minneapolis cardiologist and Director of the Hypertrophic Cardiomyopathy Center at the Minneapolis Heart Institute. Hypertrophic cardiomyopathy (also known by the acronym, HCM) is a common form of genetic heart disease and the most common cause of sudden cardiac death in young people, including competitive athletes. The Hypertrophic Cardiomyopathy Center at the Minneapolis Heart Institute is one of the few in the U.S. dedicated to the diagnosis and treatment of this important heart condition.

Since year 2000, I and my colleagues have promoted the implantable defibrillator as a preventive therapy for sudden death in hypertrophic cardiomyopathy---and with good reason---for we have been able to demonstrate in peer reviewed data analyses that the implanted defibrillator is frequently life-saving...by virtue of its power to recognize and automatically terminate potentially lethal disturbances of heart rhythm in patients with this and other profound cardiac diseases.

In this role, I and my colleague, Dr. Robert Hauser, came to diagnose and treat a young, 21-year-old, college student, Joshua Oukrop, in 1999. Mr. Oukrop was judged to have a severe form of hypertrophic cardiomyopathy and to be at high risk for sudden, unexpected and unpredictable...death.

Therefore, we recommended to Joshua and his father that a defibrillator be implanted as a prophylactic measure on October 4, 2001...and they readily agreed. The defibrillator model is known as Guidant Prizm 2DR 1861. Over the next 3 years, Joshua returned for 12 device maintenance checks every 3 months, as routinely advised, without any evidence of problems. Indeed, on March 14, 2005, 3 ½ years after receiving his defibrillator, Joshua Oukrop died suddenly and unexpectedly while on vacation in Utah. Detailed post-mortem analysis of the Oukrop defibrillator by representatives of Guidant found a short-circuiting defect that had caused the device to become electrically inoperative and to fail. In other words, when the defibrillator tried to issue a life-saving shock, the electrical energy short-circuited and was dissipated... and did not enter Joshua's heart as it should have. Due to this defect, he was unprotected...and died.

Shortly thereafter, in a meeting with 4 Guidant executives, I learned that this precise defect and problem had been known by the company for over 3 years...but only to Guidant...and not to any physicians or to any patients. During that meeting it was obvious from the Guidant executives that they believed it was correct and even prudent to conceal all information related to such defibrillator defects. I was asked directly for my opinion about that particular corporate strategy: I said...I think this is going to be the biggest mistake you could ever make. They said they didn't agree. Some would say that subsequent events have made my comment prophetic.

It then fell upon me to inform Joshua's father (who also has a defibrillator for hypertrophic cardiomyopathy) of developments. I have...as obviously any cardiologist has...often been the bearer of bad news. But I cannot forget Mr. Oukrop's reaction when told that Guidant had for several years known that his son's defibrillator was potentially defective and could not save him. Although he was controlled...it was as if his last breath had left his body. He said: "I told Joshua that the defibrillator was his shot...that it would allow him to survive and live his life... and you are saying that they knew all along."

In fact, at that time Guidant had already documented 25 other similar short-circuited defibrillators...and had already made manufacturing adjustments on two occasions in April and then again in November of 2002 to new defibrillators of the same model to correct the defects that were known and had been defined in detail. Still...Guidant had not informed physicians, patients or the government. Furthermore, and perhaps most disturbing, it has been documented that Guidant continued to sell defibrillators they knew to be defective. That is defibrillators that were manufactured before the changes in April and November of 2002.

Therefore, Joshua Oukrop's death was not due to an unforeseen "random" defibrillator failure, as suggested by Guidant to physicians...but in fact was a systematic, repetitive and to some extent predictable defect...and no one else knew. In effect, Guidant had by themselves taken over the medical management of thousands of high-risk defibrillator patients.

Probably only because the facts of this unfortunate scenario were documented in a series of New York Times articles by Barry Meier beginning in May of 2005, have these problems in this sector of the defibrillator industry---in what has come to be known as the Guidant Affair---now become evident to all. In fact, these circumstances have led to the largest recall/advisory of defibrillators and pacemakers in the 25 year history of this important industry, involving almost 200,000 devices, including combination defibrillator and pacemaker models implanted for coronary heart disease and heart failure---which have also been associated with several deaths.

It is important to focus on what this scenario and debate is really about. The Guidant Affair is about patients (and their physicians)...and the overwhelming importance of informed consent and full disclosure to patients through their physicians. Patients have a right to know...any information that could potentially impact their risks for injury or death. It is simply not ethical to withhold such information. Patients must have the opportunity to interact with and make such medically important decisions in conjunction with advice from their fully informed physician.

It is also important to establish what the Guidant Affair is not. It is not a statistical issue. It is not about percentages and likely probabilities. Patients are not numbers...they are individuals with the reasonable expectation that industry---in this case defibrillator manufacturers---will communicate openly and accurately with their physician...and in their best interest. Most observers agree that did not happen here. As one of our moms with 3 sons having both hypertrophic cardiomyopathy and defibrillators told a Guidant executive, "Shame on you. It just was not your call to make." I agree...and I believe that vast majority of the cardiovascular community does as well. It is about trust. It is time for change and greater oversight, transparency and communication between industry and the physician community to restore the trust of patients in sophisticated and powerful medical devices such as the implantable defibrillator.

To make it a crime to knowingly sell defective defibrillators to be implanted into high risk patients would I believe have the desired effect on the willingness of companies to make full disclosure. However, such a bill would have to be drawn narrowly so as to not have a potentially disastrous, chilling effect on law-abiding companies whose products may have occasional random defects. Thank you for the opportunity to tell this important story to the Committee.