Testimony of

Bridget Robb

June 11, 2008

Statement of Bridget Robb

Gwynedd, PA

Before the

Senate Judiciary Committee

For a hearing entitled

"Short-change for Consumers and Short-shrift for Congress? The Supreme Court's Treatment of Laws that Protect Americans' Health, Safety, Jobs and Retirement"

Wednesday, June 11, 2008

Chairman Leahy and Members of the Senate Judiciary Committee:

Thank you for the invitation to speak on the topic of laws that protect Americans' health and safety. In a time when big business and corporate profits seem to take precedence over individuals' rights, we tend to forget the reasons why certain laws were in fact enacted, and why it remains important for people who have been injured by defective products, to be able to hold companies accountable and to have their day in court. I am here today not only because of my own tragedy but also to protect the rights of those who have or may suffer similar events such as mine.

My name is Bridget Robb. I am a thirty-four year old mother and resident of Gwynedd, Pennsylvania. On December 31, 2007, I suffered greatly and thought I was going to die because of a defective heart device implanted in my body. I am thankful to be here today and to be able to share my experience with you.

Approximately four (4) years ago, I was diagnosed with non-ischemic, viral cardiomyopathy and congestive heart failure. In May 2005, to prevent me from dying from a fatal arrhythmia, I had a

Medtronic cardiac defibrillator with pacemaker implanted in my chest. This heart device is a small metal case that contains electronics and a battery. Its components work much like a pacemaker, but unlike a pacemaker, an ICD delivers an electrical shock to the heart when the heart rate becomes dangerously fast. My particular device combined a pacemaker and ICD in one unit.

On December 31, 2007, I was awoken from my sleep by a series of shocks to my heart which felt as if a cannon was being repeatedly shot at my chest at close range. Along with these recurrent shocks was a strong, electrical current racing through my body. After feeling the first shock, I immediately phoned 9-1-1 for help. My six-year old daughter, Emma, had snuck into bed with me that night and was present during this horrific experience. I remember Emma being scared and confused. She crouched down in front of me hugging her cat, saying "Mommy's dying." She was present during the entire seven minutes that I was on the telephone with the 911 operator until the EMS arrived. I cannot imagine how terrified she must have been to see her mother in such pain.

The doctors have told me that I received a total of thirty-one (31) inappropriate shocks to my heart in a matter of minutes that morning. Each time I was shocked, I saw my life flash before my eyes. At one point, I began to pass out and thought that I would never see Emma again.

I later learned that the inappropriate shocking and electrical feeling throughout my body was caused by a defective cardiac lead implanted in my heart, the Sprint Fidelis lead manufactured by Medtronic. A lead is a thin wire which connects the ICD to the heart and delivers the actual shock to the heart when it is beating too fast. Medtronic's Sprint Fidelis lead was recalled on October 15, 2007, because of its potential to fracture. Unfortunately, Medtronic never notified me that my lead was recalled and I did not learn of the recall until after this "life-saving" medical device seriously hurt me.

Since this terrifying experience, my health had declined significantly. I have been visiting doctors almost weekly for follow-up appointments and testing, and have suffered from severe anxiety. I have since undergone surgical replacement of my defibrillator and the defective lead, and a second surgery to revise the lead. My second surgery resulted in an extended hospital stay where I had to undergo a blood transfusion. As you would expect, I risk serious harm each time another procedure is performed. Even though Medtronic's defective device caused my injuries, my health insurance plan has been paying for the cost of my medical care.

I would like to have the opportunity to hold Medtronic accountable for the injuries that I suffered that day and the emotional after-effects that I continue to experience on a daily basis. Medtronic knew that its Sprint Fidelis lead was faulty, yet the company never took reasonable steps to notify me that this lead needed to be replaced. Instead, I suffered indescribable pain that day and continue to suffer from the emotional toll of my near-death experience.

However, my attorneys tell me that a jury may never hear my case due to a legal doctrine known as "preemption," which the Supreme Court recently discussed in another Medtronic medical device case,

Riegel v. Medtronic

. In that case, the Supreme Court found that any claims brought by people injured by another Medtronic device were "preempted" and that the company would have complete immunity from any claims brought against it given that the FDA had approved the device. My attorneys are

concerned that the

Riegel

decision also may apply to my case and, as a result, I would have no recourse for my injuries. I find this discouraging and demoralizing.

In addition, the considerable costs for my healthcare have been shifted from Medtronic, the company that knew about this problem but failed to take action, to my health insurance provider. This may result in an increase in the cost of my insurance. It is wrong to shift the cost of medical care from the responsible party to private insurers, patients, and in some cases to taxpayer sponsored programs like Medicare and Medicaid.

Therefore, I am asking Congress to pass legislation to ensure that victims of faulty medical devices, like me, will continue to have the ability to hold a medical device manufacturer accountable for their injuries. I find it hard to believe that Congress ever intended to prohibit me from even having the opportunity to go to court to obtain justice. Thank you for your attention to this critical issue. I am happy to answer any questions that you may have.