

Statement of Bridget Robb

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**Before the Health Subcommittee of
the House Energy and Commerce Committee**

For a hearing on the Medical Device Safety Act of 2009

Tuesday, May 12, 2009

Chairman Pallone and Members of the Health Subcommittee:

Thank you for inviting me to speak to you about my personal experiences with a faulty medical device and my reasons for supporting the Medical Device Safety Act, H.R. 1346.

My name is Bridget Robb, and I am a thirty-five 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 am pleased that Chairman Pallone has reintroduced the Medical Device Safety Act, which would restore the rights of patients like me to hold device manufacturers accountable when their products cause injury and sometimes, even death.

Approximately five (5) 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 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 then 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 our 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.

My doctors have told me that I received a total of thirty-one (31) dangerous shocks to my heart in a matter of minutes that morning. Each time I was shocked, I saw my life flash before my eyes. It was excruciating pain. At one point, I began to pass out and thought that I would never see Emma again. Ever since that day, I have been unable to sleep in my own bed due to the trauma I experienced.

I later learned that the agonizing shocks and electricity coursing through 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 that 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. Despite receiving over a thousand complaints about the defective leads, it took Medtronic three years to issue this recall.

Since this terrifying experience, my health has declined significantly. I visit doctors almost weekly because of my ongoing health issues due to this event. After the inappropriate shocking from my lead, I underwent surgical replacement of my defibrillator and defective lead, and a second surgery to adjust the new lead. My second surgery resulted in an extended hospital stay where I had to undergo a blood transfusion.

Most recently, in September 2008, my incision ulcerated and became extremely painful. I was hospitalized a series of times, once for two weeks straight, in an effort to cure this problem. To prevent infection of the hardware in my chest, my doctors ultimately decided to remove my defibrillator altogether. Right now my doctors continue try to stabilize my decreased heart function, and I take various medications that carry serious health risks which I never took before. As you would expect, I risk serious harm each time another procedure is performed.

From the time between my diagnosis in 2004 and the horrifying shocking in December 2007, I was never hospitalized for my heart failure except to have my defibrillator implanted. My heart function had significantly increased due to my medications and I had a good outlook from my doctors. However, since my defective lead misfired, I have been hospitalized at least eight (8) times, mostly for one to two weeks at a time, and my heart function is much lower than it used to be. I am a single mother, so, as you can imagine, this has been trying for both my daughter Emma and myself. Each time I am hospitalized, it becomes more difficult on my daughter since she is afraid that one of these times I won't come home.

Even though Medtronic's defective device caused my injuries, my health insurance plan has been paying for the cost of my medical care. 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.

I would like to have the opportunity to hold Medtronic accountable for the injuries that I suffered that day and the physical and emotional after-effects that I continue to experience on a daily basis. I find it discouraging and demoralizing that I have no recourse for my injuries, and that a company that manufactured a defective product that has harmed me and thousands of other individuals has no accountability.

I encourage Congress to act quickly and pass the Medical Device Safety Act. It is extremely important that injured patients have a remedy for their injuries and that the costs of their medical expenses and other needs are not borne by Medicare, private insurance, employers and the patients themselves. The medical device industry should be accountable for its products just like drug companies or any other industry.

Thank you for your commitment to this critical issue. I am happy to answer any questions that you may have.