Testimony of Michael G. Roman

Before the

Senate Committee on Health, Education,

Labor, and Pensions

"Protecting Patients from Defective Medical Devices"

August 4, 2009

Good Afternoon Mr. Chairman and Members of the Committee:

I have a simple story to share with this committee. A story of help, hope and heroes.

I am a one-legged race car driver with four land speed records to my name – you might think that makes me unique. In fact, most people who spend more than five minutes with me come away convinced that I am a “broke-the-mold” kind of guy.

But the chronic pain that I have lived with – and now successfully manage – isn’t just my story. According to the American Medical Association, 45 million Americans will seek care for persistent pain at some point in their lives.

But before I talk about those millions of people – your constituents – let me share my background.

In 1994, I was employed as an operating room technician. I underwent surgery to repair a torn knee ligament.

During that surgery a staph infection set in, and my nightmare began.

I endured 12 debridements, 28 weeks of intravenous antibiotics, 33 surgeries, and three progressive amputations of my right leg, which is now completely gone.

I immediately began to experience phantom limb pain. The pain was so severe that I could only make it through the day with increasingly large doses of pain medications – Vicodin, Percocet, OxyContin, Neurontin, Serzone, Valium and eventually Morphine – heavy drugs that left me with only hazy recollections of a decade of my life.

For that decade, I was a parent and a spouse in name only.

I cannot remember 10 years of my children's lives. I was depressed, and I even thought about ending my own life. I can only offer my sincerest thanks to my wife Susy for standing by me for those years. She helped give me hope – something I struggled not to lose.

During that time, I sought-out alternatives to manage my pain, including radiation, injections and even an implantable drug pump. In 2000 I tried a spinal cord stimulator, a device that electrically stimulates the spinal cord and disrupts the pain signals as they travel to the brain.

While different patients respond differently to therapies, for me, this spinal cord stimulator – which relied on old pacemaker technology – was worse than problem it was designed to treat. It replaced one type of pain with a new and different type of pain that was far worse for me.

So I went back on the meds, convinced that was where my family and I would remain.

And for a time we did. But as my tolerance for medication increased, I needed increasingly larger doses of medication to manage my pain, a cycle that had to change.

A Breakthrough

Finally, on yet another trip to a new physician in 2005, I agreed to try a new type of spinal cord stimulator. I was convinced it wouldn't work, but I agreed only because my doctor said that he wouldn't give me any more increases in medications until I tried this new device out.

Unlike the device that I tried in 2000, this device did something I didn't expect.

It managed my pain and provided me with some hope for recovery!

I am not pain free today, but I can manage my pain. I use a device called the Precision Plus ™ Spinal Cord Stimulator System, which is designed around the same technology used to bring back people's hearing – cochlear implant technology. It's programmable, easy to use, lightweight, and it has a long rechargeable battery life.

The system I use has an electrode lead implanted into my spine. I use a wireless remote control to "talk" with and control the impulses directed through these leads with a software program that lets me deliver a specific dose of electrical current precisely where I need it. That control lets me manage my pain based on my circumstances moment-to-moment. My pain management needs change based on whether I'm relatively quiet and watching TV, or more active and exercising even racing.

Once I got the device, the first thing we needed to do was to get me off the high doses of medication. I simply didn't need them anymore.

I slowly got my life back. And because I got my life back, I got my family back. My wife Susy is here with me today. It's safe to say that a decade ago, no one in our family would have believed that we might have the opportunity to share the story of our success with the United States Senate. It's an honor and a privilege to have received your invitation to be here today.

My Role in the Race Against Pain

Once I got my life and my family back, Susy calls it, “The Great Awakening”, I started doing one of the things I do best, complaining.

The first people I complained to were the people that built the device. I pity (a little bit) the day that Doug Lynch got his first call from me at Boston Scientific. He got a rant from me about what a poor job the company was doing telling patients and physicians about the benefits of this device.

Little did I know at the time how lucky I was that Doug answered my call. You see, Doug was deaf, and the same cochlear implant technology that had helped me manage my pain allowed him to hear again. He took my call with an open mind, and listened to what I had to say.

I knew I was not alone, that there were lots of people sitting in living rooms, or hiding in their bedrooms, all across the country who, like me, were prisoners of their pain and could benefit from the same technology that had helped me.

“What are you, as a company, doing to help them,” I said. “We gotta do more to spread the word about this amazing treatment!”

I had no idea what I was getting myself into.

Ultimately, I’m not sure whether I was drafted, or I enlisted. Today, in addition to our racing, Susy and I travel the country to talk about chronic pain and what can be done to treat it, to anyone who will listen.

Boston Scientific sponsors the Race Against Pain website, a place where pain patients can find support. They are also the primary sponsor of my race team.

After speaking with thousands of chronic pain sufferers all over this nation, I know how hard it is for patients to open up, to share what they’re feeling, and especially to seek out new treatments. It’s not every day that these patients meet a one-legged racecar driver, so we rarely need a conversation starter.

What I then try to do is get patients to see a different future by sharing the story of the path Susy and I have traveled. That’s an important first step for many chronic pain sufferers who have given up all hope for recovery.

In 2008, my wife Susy and I had the privilege of visiting some of the wounded soldiers who were rehabilitating over at Walter Reed here in Washington, something we encourage each of you to do. We planned to stop by for an hour. We ended up spending six hours visiting with men and women who have been seriously injured in the service of our nation. There I learned about the potential of medical technology. The cochlear implant technology that eventually morphed into the technology that helped me is just the beginning. We know so little about the human brain works, but we’re learning more every day about how medical technology can help not just these wounded veterans, but can lead to breakthroughs in fields like Alzheimer’s research, Parkinson’s treatment, and epilepsy.

Through my experience at Walter Reed, I also became familiar with the Wounded Warrior program that gets injured veterans back on track -- onto bicycles and into civilian careers. Susy and I were so moved by these men and women we placed the Wounded Warrior Project logo on our racecar to raise awareness and have participated in a number of these soldier rides to show veterans that with the right attitude and a little technology, it’s possible to get your life back. These men and women remain our personal heroes.

About the Medical Device Safety Act

I'm not an expert on the law, and I certainly do not have the awesome responsibility of shaping public policy. But I can assure you that in the space of just five short years, what may have seemed like small changes in spinal cord stimulator technology made a huge difference not just in my life, but also in the lives of my wife and children and grandchildren. They got their husband and father back, and the dad and grandfather who lost his leg once again found his purpose in life.

The technology that is implanted in me pushed the envelope when it was installed in 2005. Was it risky? Yes. Did I understand that this is technology might not work, because each patient responds differently? Yes. Did I talk with my doctor about the risks and benefits of this product? Absolutely. You could say I went under the knife, as I had done some 38 times previously, with my eyes wide open.

But what if Congress had enacted the Medical Device Safety Act in 2001? For me, I'm sure it would have been game over.

It scares us to think I would lose the life I have today because a researcher decided to throw in the towel in 2002 – deciding that the status quo was good enough – and that the $60 million in development and testing costs of my device weren't worth the risk of putting a cutting edge, FDA-approved product on the market, only to have that product's value systematically reduced by lawsuits. There are millions of people out there who might one day benefit from the breakthrough therapies still in development. We need to think about those people when we think about the consequences of this bill.

Do I want safe products? Absolutely. For me, the question is who decides.

Is it scientists at the FDA who carefully study every aspect of a device and can balance the benefits of a device to patients like me versus the risks? Or is it a jury made up of people like me? One-legged race car drivers, teachers, bus drivers, bikers, veterans, waiters and waitresses – who may not have the necessary expertise to make the best decision, especially since juries see only an injured person, not all the beneficiaries of medical technology.

To me, that choice is clear. We need safe products and we need innovation, and the best way to achieve both goals is not through litigation created by this bill, but through a strong, well-funded FDA.

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