Testimony of Katherine Korgaokar
Senate Committee on Aging
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Chairman Kohl, Ranking Member Corker, and Members of the Committee, I thank you for giving me the opportunity to testify today. I am here to give a patient's perspective of what happens when a defective medical device is released to the public. Specifically, I was one of the 96,000 unlucky people who received the DePuy ASR prosthetic hip that was recently recalled in August 2010.

The reason I needed a new hip was because I was born with a congenital condition known as Perthes disease. This disease caused the premature deterioration of bones in my hip joint. Beginning in my early 30s I began experiencing extreme hip pain on a fairly regular basis and had trouble with mobility. Eventually, the pain in my hip became so unbearable that I consulted with an orthopedic surgeon to see if there was anything he could do to relieve my symptoms. The surgeon recommended total hip replacement surgery.

Prior to my operation, my surgeon and I discussed the type of hip that he would use. He told me that it was a new, state-of-the art metal on metal hip that was specifically designed for young active people such as myself. He told me that the metal on metal design was superior to other designs and that it should last at least 20 years or more. The new state-of-the-art hip that my surgeon used in my surgery was the DePuy ASR hip replacement system.

The initial hip replacement surgery was a huge success. Within three months of the surgery I was essentially pain free and was able to engage in activities that had previously been off limits. The surgery truly changed my life.

Three years later, I met my husband and we were married. Both my husband and I had always wanted to have children and immediately began trying to start a family. However, about eight months later, our plans changed.

At this time, I received a letter from my surgeon advising me that the hip he had put in my body four years prior had been recalled. He told me that I needed to come in for an appointment so that he could examine the hip. When I heard this news I really didn't understand the implications of what I was being told. In my mind, recalls were for dishwashers and cars; not body parts.

When I met with my surgeon he explained that there was some type of design problem with the DePuy ASR that was causing excessive wear and tear on the metal components of the hip. As a result, the hip could be releasing metal debris into my body. My doctor told me I needed to have a blood test performed to see if I had excessive levels of cobalt and chromium. I was told that these are two of the metals used to make the hip. If the levels of these metals were elevated, this meant there was excessive wear and tear occurring in my hip.

A few weeks later my doctor called to tell me that the blood tests showed that I did have elevated levels of cobalt and chromium in my system. In fact, my levels were about 1,000 % higher than they should be.

At that time, I became very concerned. I had no idea how these metals would effect my body, and more importantly, I didn't know if they would impact my ability to have children.

After speaking with my doctor about these concerns, I learned that research had shown that excessive levels of cobalt in the blood could potentially impact the development of a fetus. I also learned that excessive levels of cobalt and chromium had been linked to several serious health conditions such as cancer and cardiomyopathy. As a result, my doctor recommended that I have the hip replaced as soon as possible.

In January 2011, I underwent my second hip replacement surgery. This time, the surgeon installed a more traditional hip with a polyethylene liner in the cup.

The recovery from this second operation has been substantially more difficult than my first. The pain is much worse and it has been extremely difficult to get around. Only recently has my mobility improved to the point where I no longer need crutches. For the past three months I have essentially been confined to my home trying to get through this.

Going forward, I have serious concerns about how this incident will effect my life. I am told that undergoing a hip revision surgery so soon after my first surgery, will likely result in me experiencing more pain, dislocations, and other problems down the road. This is because each operation affects the muscles, tendons, and bones in the hip and makes the hip less stable. I am also told that as a result of this incident I may have to undergo one or more additional hip operations later in my life that could have possibly been avoided. Most importantly, however, I fear that given the small window I had to start a family, this operation may have forever prevented me from ever having children.

As I learned more about the ASR and the process by which it was approved by the FDA, I was shocked. Prior to this incident, I thought that any medical device that was actually being put into people's bodies had been extensively tested before it was released to the public. I had no idea that devices could be "fastracked" by the FDA with little or no testing. I also assumed that the FDA had systems in place to monitor drugs and medical devices for potential defects so that prompt action could be taken if problems arose. Apparently, this did not happen with the DePuy ASR.

Additionally, I am concerned that the doctors who are actually installing these medical devices may not be fully committed to the wellbeing of their patients. Specifically, I recently learned that the surgeon who recommended that I have the DePuy ASR installed in my body had actually received more than $600,000 from DePuy in "consulting income." (A Disclosure Statement from the DePuy website showing payments to my surgeon is attached hereto as Exhibit A.) This was never disclosed to me before my

surgery. Although I would like to think these payments had no influence on my doctor's decision to use the ASR, I will always have doubts.

Thank you Chairman Kohl and Ranking Member, Corker for holding this hearing and giving me the opportunity to tell my story. I truly hope that you and your colleagues take a serious look at how medical devices are approved in this country and take whatever steps are needed to make sure incidents like this do not happen again.