

**Testimony of James Shull**  
**U.S House Committee on Energy and Commerce/Subcommittee on Health**  
**February 15, 2012**

My name is Jim Shull and I am from Browns Mills, New Jersey. I would like to thank you for allowing me the opportunity to speak here today.

My story goes back to 2005 when I was told I had a hernia. I was told that I was young and would recover quickly. I was told I would be walking up stairs in 3 days and back to work in 2 weeks.

I awoke in the recovery room from the surgery in excruciating pain, the nurses gave me some pain medication and told me I would be fine and sent me home. Two days later I was in such pain that I couldn't stand up straight or barely walk. I called my surgeon's office and he told me to meet him at the hospital Emergency Room. He took me in to an examination room, looked at the surgical site and told me that it was very infected. He prescribed an anti-biotic and Morphine for the pain but, nothing seemed to help. The infection was so bad that I had streaks running down my groin; I was still very swollen, bruised and in severe pain.

I continued to call the surgeon over the next 2 weeks only for him to tell me that I am just a slow healer. Quite a difference from walking up stairs in 3 days, like he told me before the surgery. As time went on I was still in unbearable pain. At my 6 week follow up I explained again to my surgeon that the pain was unbearable, so, he decided to inject my groin with Novocain, right thru the incision and sent me back to work.

The pain I was feeling, was as if there was a sharp object left inside of me. My boss told me that I couldn't be at work if I couldn't stand up straight and walk, so, he sent me home. After continuously going back to the surgeon he decided to send me to Pain Management, where over the course of 6 weeks the pain doctor injected my groin upwards of 70 times with steroids and Novocain.

Nothing would help the pain so I decided to investigate myself. The internet is a wonderful tool to launch an investigation. I googled complications from hernia surgery and was amazed at what I found.

It was only then that I figured out that a Hernia Mesh kit must have been put inside of me. I went back to the surgeon and explained what I found. Only then did he tell me that he had put a Synthetic Mesh inside of me and told me that, it was not the mesh,

because the mesh is inert and my problem has to do with the nerves in my groin. I tried to go back to work because I couldn't afford not getting a paycheck, but the pain was so unbearable that I ended up in the ER. The doctor in the ER did a CT scan only to find nothing. That is because the mesh is transparent and cannot be seen on X-rays. The doctor in the ER told me that I probably had Diverticulitis and that I needed to follow up with a GI specialist. That test came back negative also.

I decided to get a second opinion from another surgeon and asked if he could remove the mesh from inside of me. He told me that he couldn't remove the mesh but could do an exploratory surgery to see if the nerves were stitched up. This surgeon did cut and tie off one of the nerves in my groin and thought that it would ease my suffering. After returning to him for 6 weeks in unbearable pain he told me that there was nothing else he could do for me. So I was on my own. I continued to be in unbearable pain and still tried to work. I continued to try to find a surgeon who knew what was happening to me.

I finally did find a surgeon in another state and he agreed to see me. When he examined me he told me that he knew exactly what was wrong with me but to be sure sent me to have an MRI. I went back to this surgeon and he showed me the problem. There it was a hardened synthetic mesh. This surgeon told me that he has been removing these products for 20 years because of problems similar to mine.

So finally after almost 2 years of unbearable pain I found someone who could give me some answers. The surgery to remove the mesh took 3 ½ hours. When I awoke in the recovery room, the surgeon was at my bedside. He told me that he was sorry and that I would be in pain for the rest of my life.

The surgeon explained to me that he had removed a balled up piece of concrete from my groin, that the mesh had hardened and balled up, and had encapsulated the other 2 main nerves in my groin. In order to get the mesh out the nerves had to be severed. He explained to me that the mesh was so hard, that when I moved it was acting like a saw and cutting into the surrounding tissue. I had a 3 inch gash in my pelvic floor along with hundreds of smaller cuts and tears.

In 2008 I was diagnosed with a degenerative nerve condition, which I believe was caused by the mesh. The pain that I suffer through on a daily basis consists of constant burning and sharp pains in my groin and upper thigh. My groin and upper thigh are a purple and brown color because of the nerve condition I now have. It is a constant battle every day. I must take three strong medications Oxycontin, Percocet, and Tramadol just for the pain alone. Every 6 months I have to have radio frequency ablation done at the spinal level where the nerve roots are located. This just to relieve 50 percent of the burning. It is very uncomfortable for me to sleep at night without the help of medication.

Because of this product I am no longer able to work as a printer. I loved my job; where else can you take 12 different components and put them all together and make what I considered art. I am now on New Jersey State Disability, which is about to run out. I have applied for Social Security Disability but have not heard back from them yet.

When I was a teenager, I had a hernia. That hernia was not repaired with mesh, but was stitched back together – 34 years later and I still have no problems with that repair, while the repair that I had when I was 42 went bad immediately and I now face a lifetime of pain and struggles because of it.

All of this I have to go thru because of a piece of hernia mesh that was supposed to be inert and not cause any problems. The mesh that was put inside of me caused so much damage that none of the nerves will ever be able to be repaired and will never grow back. I live a life of pain because of a product that never had any kind of clinical trials and slipped through the back door of what you know as the 510K process based on the use of predicate devices. Did you know that the mesh that was inside of me used only sutures as a predicate device? I am left disabled because the FDA considered surgical mesh equivalent to sutures and allowed it to be implanted in patients like me.

After years of people reporting problems and investigations in to synthetic meshes, the FDA published a Public Health Warning. Unfortunately, the warning was only for Synthetic Trans-vaginal meshes that are used in woman for Pelvic Organ Prolapse, Incontinence and Bladder Slings, which have caused problems every bit as terrible as mine.

There was no Public Health Notification for the Hernia Meshes. Which are just as tragic and cause horrible complications for men and woman alike. In my research I found that in the United States alone there are 750 thousand to 1 million hernia surgeries each year. Failing to address the hernia mesh issue puts too many people in danger. I think synthetic mesh should not be on the market because it is unsafe and I have proudly taken the challenge to work to prevent this from continuing to happen to others.

In closing I would just like to say that I am only one face in thousands of people that this has happened to and the sad part of it all is that I feel that I may be one of the lucky ones. This committee can change the laws to improve the safety of medical devices and put patients first. Surgical mesh and other medical devices should be tested for safety before they are allowed to be implanted into people like myself. We also need a national system to track what happens to patients like me after devices are implanted, to catch these problems as soon as possible.

Thank you.

