

## The Lykins Family Statement

### **Steve**

In September of 2001, our son Brian had orthoscopic surgery to remove a bone chip in his knee. It went very well. Afterwards, Dr. Mulawka, the surgeon, showed us pictures of Brian's knee, which revealed a quarter-sized divot in the bone. He told us that Brian should have follow-up surgery in order to prevent future arthritis in his knee. He also explained that a piece of bone from a cadaver would be used in the procedure and told us about the effort and testing that went into ensuring the donated bone tissue would be clean and safe. It was supposed to be a routine surgery, one that Brian could have lived a completely normal life without. In other words, it was a strictly a preventative and elective procedure. The recovery from the procedure was expected to take a little longer than the previous one, but no one expected any significant complications.

On Wednesday, November 7<sup>th</sup>, Brian had the follow-up surgery, which went well. Dr. Mulawka told us that Brian might become a little sick from the medications and possibly experience more pain than the previous surgery, but, otherwise, the recovery should go well.

After the operation, Brian was experiencing a lot of pain. He had a horrible headache, upset stomach and felt like he was burning up. The nurses, however, said his temperature was normal. The doctor decided to keep him overnight for observation. Leslie and I drove home to Willmar for the night.

We did not expect any complications, so I left for work the next morning and was scheduled to work in Minneapolis for the next five days.

### **Leslie**

After Steve left, I drove to St. Cloud Hospital to pick up Brian. When I got there I found he was sick to his stomach and in excruciating pain. The pain pack the doctor had inserted into his knee during the operation wasn't working. The purpose of the pain pack was to administer medication directly to the knee to help control the pain.

After Brian was released from the hospital, I drove him to the St. Cloud Orthopedic Clinic where they removed the pain pack. Brian was originally scheduled to go to the doctor on Friday, the following day, but the doctor thought he could wait to see Brian until Monday morning. So, instead we drove to my home in Willmar where Brian stayed with me overnight. Throughout the evening Brian began to feel better. His knee was still sore and he felt warm at times, but otherwise felt fine.

On Friday morning, Brian woke up feeling much better. Of course, his knee was still sore, which was to be expected. That afternoon, he said he felt well enough to go home. At his home, he rested, ate and drank a bit, used the exercise machine and occasionally iced his knee. His recovery was going exactly as we thought it would. That evening, we watched a movie together and he told me that he felt fine and if I wanted to go home, I should, which I did.

On Saturday, I had previous plans to be out of the house most of the day, so I was up early. Brian called me, told me he felt fine, and asked some questions about when he was supposed to take his medication. He said his leg was still sore, but otherwise felt fine. I then went out, returned home at about 5 p.m. and called Brian. He told me he had been sick to his stomach for a while, which we had expected. I told him I would come over to his house after I took care of a few things, and he said that was fine. I got to his house about 6 p.m. As soon as I arrived, I realized that he was in worse shape than he had let on. He was throwing up and told me he almost passed out twice walking to the sink. He complained about feeling warm, but he did not feel warm to the touch.

I called Dr. Mulawka's office right away and got the answering service. They told me they would call the doctor and have him call me back. Shortly after, someone else from the clinic called. When I explained how Brian was feeling, he told me to change the dosage on one of the medications, which was the likely culprit of his stomach problems. Brian told me he would like to spend the night at my house; so, we packed up some of his things and started to drive to my house, which was only two and a half miles away.

On the way, Brian said he would like to stop at the hospital and have them check him out. We got to the emergency room about 8 p.m. When the nurse and doctor on duty examined Brian, they suspected that he was simply dehydrated and put him on an IV. I think they also gave him something in the IV to help settle his stomach. He still complained about "burning up" and stripped off his shirt and blankets, but he still did not register a fever. Brian also complained about his knee hurting but the nurse could not find any unusual swelling, redness or hot spots. A couple of times he doubled over with an upset stomach before the medication seemed to help him. The nurse and doctor thought he would feel better once he was more hydrated from the IV. His vital signs seemed to be okay. The doctor also ordered chest x-rays and had blood drawn. After that was done, Brian was back in his room and resting better. No one seemed alarmed about anything and they told us that he could go home soon. Brian finally appeared to be dosing off to sleep. I was tired and told the nurse that I would go out into the emergency waiting room to get some rest. At that point, it was about 1 a.m.

I was in the waiting room for about fifteen to twenty minutes when someone came in and told me to come right away. Brian had suddenly taken a turn for the worse. He had been moved to a larger room in the ER where several people

were anxiously working around him. He was awake. After a few minutes, a doctor told me that Brian's vital signs had changed all of a sudden and they were trying to find out what was wrong. Then the doctor asked me if there was anyone in town who I wanted to call to be with me. I began to worry. He told me that I should call my husband who, thankfully, was in Minneapolis and not on a trip. I called Steve and the doctor explained to him that he should come to hospital immediately, that things didn't look good for Brian. I hadn't expected any of this when I brought Brian to the hospital. We thought he was just dehydrated and nauseous from the strong medicine. The doctors were now planning to move him to the intensive care unit.

I made my way to the ICU when Brian was being wheeled into a room. The doctor was trying to ask Brian questions. He answered in short statements. We hadn't been in the room long when Brian had a convulsion. He sat straight up and gave a loud, long groan. I think that's when he went into a coma. The doctors and nurses got me out of the room and attended to Brian. Some time passed and a nurse came and got me and brought me back to Brian's room. I wasn't in there for long before he had another convulsion. It appeared as though he stopped breathing until the doctor put some sort of respirator on him. I was then led back to the waiting room.

Steve got the hospital about 4 a.m. The doctor filled him in on Brian's condition and told him that they weren't exactly sure what was happening, but that it was life threatening.

## **Steve**

Brian was in a coma when I got to the hospital. His blood pressure had been at zero for several hours. All the organs in Brian's body were failing. His heart was the last organ to fail and at 6:21 a.m. on November 11<sup>th</sup>, our son died.

Shortly after Brian's death, we learned that the tissue put into his knee was infected with a deadly bacteria. This infected tissue was allowed to be implanted in Brian's knee due to several industry and government failures.

1. There were no federal guidelines for the automatic rejection of high-risk cadavers. The cadaver that supplied the tissue for Brian's operation should have been rejected for at least 2 reasons. First: He died due to suicide so the time of death was uncertain. Second: The body was allowed to remain un-refrigerated for at least 19 hours before tissue harvesting began.
2. Cryolife procedures for preparing the tissue to make it clean and safe were flawed.

The Center for Disease Control began an investigation into the cause of Brian's death because two other men from the same area died within about 1 week of each other after having routine knee surgery. One of the men had his surgery in the same hospital as Brian. The CDC found the other two men died from blood clots. They did not have cadaver tissue put into their bodies. Their knee operations were completely different from Brian's. However, due to the presence of the deadly bacteria found in Brian's body, the CDC continued with a lengthy investigation into the cause of our son's death.

Over the next 6 months I talked on a regular basis with Dr. Kainer from the CDC who was running the investigation. I could not believe the things that I was hearing about the tissue industry as a whole and Cryolife in particular. How could a medical industry in the United States of America be allowed to operate like this? A medical industry allowed to operate with little or no state and or federal regulation, how could this be? The FDA had known about the problems in this industry for years and for some reason was dragging its feet in bringing about the necessary regulations. The CDC had clearly defined the problems in this industry and the FDA would do nothing about it.

It became very clear at that point that the CDC had no power to bring about change in this industry and the FDA was not going to do its job. Cryolife was going to continue to operate in the unsafe manner that caused the death of our son. So at that time we decided to bring a lawsuit against Cryolife. The purpose of our suit was to bring about change in this company and this industry. Money was never the motivation for the suit; it was only the vehicle that would get people to pay attention. We did not sue Dr. Mulawka, and we did not sue the hospital. We only sued the people responsible for Brian's death because they would not fix the problems on their own. All we ever wanted was for the people involved in Brian's death to learn from what happened and fix the problems. It became clear that Cryolife and the FDA would not fix the problems without the lawsuit. Less than 30 days after we filed the suit, the FDA shut Cryolife down due to their unsafe practices. Unfortunately, there are still no federal regulations to prevent companies like Cryolife from operating in unsafe ways.

One and a half years after Brian's death, the FDA is still only proposing regulations for the tissue industry. Nothing has changed! The tissue industry can still operate anyway they want, with little or no federal regulations. What is taking the FDA so long? In our lawsuit, we listed seven areas of meaningful reforms that are needed in this industry.

1. REJECT HIGH RISK CADAVERS
  - o Diseased Cadavers i.e. cancer, meningitis
  - o Over 70 years old
  - o Cadavers un-refrigerated over 10 hours
  - o Suicide Cadavers
2. TESTING OF TISSUE WHEN CADAVER IS RECEIVED
3. STERILIZE TISSUE BEFORE DISTRIBUTION

4. DISCARD CADAVER IF ANY CONTAMINATION FOUND
5. MANDATORY REPORTING OF CONTAMINATION TO:
  - o Federal Agencies
  - o End User Doctor
6. CERTIFICATION OF CADAVER HARVESTING PERSONNEL
  - o Uniform Basic Qualifications
  - o Uniform Training
7. MANDATORY ANNUAL PROCEDURE/INVENTORY AUDIT

Had these reforms been in place at the time of Brian's operation, our son would not be dead and many other people would not be dealing with some very serious medical conditions. How much longer is it going to take the FDA to do its job and bring the tissue industry into the 21<sup>st</sup> century? This industry has been allowed to operate like something out of the Wild West for too long. Too many people have had their lives ruined and too many people have died. We need reforms and regulations in this industry now, not someday. There is no question that the tissue industry is necessary and important for the advancement of quality of life, however, there is no need for it to operate in such a dangerous manner.