

Sarah D. Bataka  
1 Glen Meadow Ct.  
Quakertown, PA 18951

September 26, 2011

Center for Drug Evaluation and Research, Approach to Addressing Drug Shortage Public  
Workshop; Patient Testimony

My name is Sarah Bataka and I am a 30 year old woman from Quakertown, Pennsylvania. I'd like to share with you the devastating impact the drug shortage in our country is having on me. In order to do that, I first need to give you an idea of my medical condition. I was born with a mitochondrial disease, which is a form of muscular dystrophy. In addition to chronic pain, muscle fatigue, and the inability to walk, this disease also affects several of my organs and systems. I had a fairly normal childhood with relatively mild symptoms. But as the disease progressed, I went from being very independent to being almost totally dependent on the help of visiting nurses, a team of doctors and specialists, a home infusion pharmacy, medical equipment, many medications, and my mother, who is my sole caregiver.

Today, I am homebound. Both my bed and power wheelchair are surrounded by medical equipment. I take numerous oral medications, and I receive intravenous medications through a port that was surgically implanted in my chest. Medical supplies and injectable medicines are needed to maintain a port.

One of the ways mitochondrial disease affects my body is that my kidneys can't hold onto the electrolytes, such as magnesium and potassium, that are essential for survival. For six years now, I've needed help maintaining my blood levels of these and other critical electrolytes. In addition to receiving them in pill form, I get them through IV's that provide enormous daily doses. I absorb very little of what is taken orally, and it is nowhere near effective at maintaining

my blood levels. I *must* receive my electrolytes in IV form. I cannot survive without them.

In April of this year, I got the worst possible news: I was told by my home infusion pharmacy that their supply of IV magnesium sulfate, a key ingredient in my IV bags and one without which I cannot survive, was dwindling and that they only had enough to fill my IV bags for a few more weeks. To give you some idea of the impact this news had on me, please consider what it would feel like to you if someone told you that there would only be enough air supply left for you for three weeks of breathing. I so depend on this medication for survival that its unavailability would indeed be the same as you having your air supply cut off.

I had been unaware of the nationwide drug shortage crisis until I was personally affected. Because visible particulate matter was found in what is supposed to be a sterile injectable drug, a plant was shut down and this, I was told, created a nationwide shortage affecting individuals like myself who depend on this life-sustaining drug. Even now, manufacturers are just not able to keep up with the increased demand. Magnesium sulfate is needed by many different kinds of patients with many different medical conditions. For us there is no substitute, just as there is no substitute for oxygen, and you can't survive without it.

Because of halted and delayed production, hospitals in my area are in short supply of IV magnesium sulfate. If the product is unavailable and if there is no equivalent substitute, there is simply no way to treat patients who, for whatever reason, have low blood magnesium levels. On a normal day, even prior to this shortage, hospitals tended to be uncomfortable with the amount of electrolytes I require. They surely will not want to use so much of a product that is now in such limited supply to treat just one patient when it could otherwise be used to treat several patients.

Fortunately, in my case, my home infusion pharmacy was, at the last minute, able to get enough IV magnesium sulfate to treat me for a few months. Eventually, if the shortage isn't

resolved and home infusion isn't able to get more product, I will have to be admitted to the hospital until home infusion can provide it for me once again. If the hospital does not have enough IV magnesium for me, my blood level of magnesium will get too low, and I will suffer seizures, cardiac events, and eventually cardiac arrest. I will die.

I sometimes get tired of tubes and wires, weekly blood tests, medications, and noisy equipment, but I don't have a choice. It takes all of these things to keep my body going. I literally work all day, every day, to stay alive. I have hope that science will one day find a cure, and this is the driving force behind why I fight every day to stay alive... only to have to fight again the next day.

Having a complicated, multisystemic disease means that I rely, for survival, on numerous medications and medical products and on those producing them and those supplying them. This makes me much more vulnerable to recalls and shortages than the average person. I won't be healthy until scientists and doctors can use gene replacement therapy to cure me, but if the medications necessary to keep me alive in the meantime are available, I stand a good chance of being around long enough for that to happen.

As I have become aware of just how far reaching this drug shortage crisis is, I have also become aware of new depths of my own fragility. My health is precarious in ways that I hadn't before realized. Now, there is little security in the fact that I live, with a life threatening disease, in America. There are people dying because of drug shortages... in America. I hope I won't be one of them.

Thank you for your time and for giving me the opportunity to be heard.

Sarah Danielle Batalka