Testimony Submitted by Mrs. Shannon Weston to the
U.S. Senate Special Committee on Aging
for the Hearing on
Sudden Price Spikes in Decades-Old Prescription Drugs
March 17, 2016

Good morning and thank you Chairwoman Collins, Ranking Member McCaskill, and distinguished Members of the Committee for inviting me to testify today.

My name is Shannon Weston and my husband, Joshua, and I met fourteen years ago today. In the three years that followed we bought a house, got married and began dreaming of our future family. After I completed graduate school we began trying to begin our family. Over the past seven years we suffered many losses before becoming pregnant with Isla. My pregnancy was ideal. I never had morning sickness and all of my check-ups were perfect.

Since I was 37 when I became pregnant I was considered to be a mother of advanced maternal age. This meant that I met with a maternal health specialist monthly and each time had an intensive study ultrasound where they performed measurements of Isla's organs, head, etc. Each time they were impressed with how my pregnancy was progressing and never saw anything to worry about. The doctor was even extremely careful never to reveal or show us our baby's sex, as we wanted the surprise of finding out at birth.

Isla was born on May 14, 2015 at 10:51am and she was 7lbs 6 oz with a head full of hair. My labor began normally and progressed as expected. After two and a half hours of pushing, however, the doctor said she had not progressed and was stuck. It seemed my pelvis did not expand as it should have. I was taken immediately for an emergency cesarean section. Since I had a c-section, Isla did not transition well to lung breathing. She then spent the next 6 days in the NICU being weaned off of oxygen and being treated for jaundice. After this emotional time we were finally able to take our amazingly perfect beautiful daughter home.

Over the next couple of weeks we thoroughly enjoyed everything about her. Learning all of her idiosyncrasies, taking lots of pictures, stressing over if we were doing everything right, and trying to survive on no sleep.

When Isla was two months old she developed a fluid pocket between her skull and scalp. We immediately went to the doctor and her concern was that trauma had caused it. We were sent immediately to the hospital for a CT scan. The scan ruled out trauma which we knew it would, but it revealed pin point calcifications in her brain. The next day we met again with her doctor to discuss what could have caused these calcifications. Dr. Mason, her pediatrician, said that it could have come from a number of things and that we needed to investigate further. A TORCH titer test, a screening for certain infections, was ordered and we were sent to a pediatric ophthalmologist and a pediatric neurologist. The TORCH titer test was negative. The ophthalmologist saw a macular scar in her left eye, but was not positive on what caused it. The neurologist performed an MRI which revealed normal brain function and that the fluid pocket was a result of bruising she got when she was stuck at birth (we couldn't tell because of all of her hair).

Once Dr. Mason received these results she ordered a second TORCH titer. She explained to us that all of this could be an overreaction, but that it could also be something much more serious. She said that if it was something much more serious that this was all a blessing in disguise and we could begin sooner to treat before it became something irreversible. The results came in and this time it was positive for the IGg antibody for toxoplasmosis. Dr. Mason then contacted Dr. Belhorn, a pediatric infectious disease specialist at UNC Chapel Hill, whom she had contact with as she had a previous patient with congenital toxoplasmosis. Dr. Belhorn explained that having the TORCH titer run by the local laboratory would not reveal proper results for congenital toxoplasmosis since the proper tests could only be run at the laboratory in Palo Alto, CA.

On August 6, 2015 we met with Dr. Belhorn at UNC. He then explained to us what his thoughts were and that more tests need to be run and sent to the laboratory in California. We were admitted to UNC hospital that day and they proceeded to draw blood, perform a spinal tap on my two month old daughter and make arrangements for a specialty eye doctor to see her. These results came back and they did not specifically point to a diagnosis of toxoplasmosis, but they could not rule it out either. The specialists at the Palo Alto lab asked for repeat blood draws from Isla and from me to be performed. This was done and the results were received in the beginning of October.

The specialist and Dr. Belhorn both diagnosed Isla as having congenital toxoplasmosis at this time. Dr. Belhorn called me immediately and we spent many hours going over what this meant and how we needed to proceed. In all actuality most of the time was spent consoling me as my head was spinning a million miles a minute and every worst case scenario was playing. Dr. Belhorn assured me that at that time Isla was asymptomatic, ignoring the eye scar, and that as long as we began treatment immediately she should remain so. He then ordered the pyrimethamine and sulfadiazine that is the treatment for congenital toxoplasmosis and said it would be compounded in two days. We made an appointment and arranged to go to Chapel Hill for her first treatment which would be monitored to ensure she did not have a reaction.

The morning we were to go for her treatment Dr. Belhorn called to say our insurance company denied covering the medication. He then resubmitted and they denied again. At this point I filed an appeal and he faxed all of Isla's paperwork, his diagnosis, and the success of the treatment to them for review. They reviewed and wrote to Dr. Belhorn stating that since Isla was not HIV positive that there was no medical necessity to treat and that was the reason for the denial; even though the company's CY2014, 2015 and future 2016 formulary did not list it as a drug that required preauthorization.

Dr. Belhorn continued to fight with the insurance company over the necessity of treatment with pyrimethamine. I looked into any way I could think of to come up with the almost $360 thousand necessary to treat my daughter for a year with a drug that she needed, knowing that as long as she was treated before symptoms set in that she would remain asymptomatic. I looked into a second mortgage, cashing in my TSP and even contemplated contacting the local news agency to get our story out there in the hopes that something would change or maybe a benefactor would see it and want to help. I was hopeless and depressed at the thought of what would happen to my perfect little girl if I was not able to help her. I truly felt like I had failed her in the worst possible way.

I spent days researching pyrimethamine and trying to see if there was another way to obtain it even if that meant purchasing it from outside the US. I did find a company here in the US who was formulating a compounded version, but they had not obtained FDA approval. About the time I was drafting letters to doctors in France who perform research studies specific for congenital toxoplasmosis, Dr. Belhorn called to say that the UNC pharmacy was able to obtain enough of the drug that we could be sure Isla would receive treatment for at least a year and that they would compound it into the serum for her to take. Since November 6 we have been purchasing the medication from the UNC pharmacy directly for $218.00 ($48.00 for the pyrimethamine and $170.00 for the sulfadiazine) each month. I am so grateful that this option was found before it was too late for my daughter. I thank the Committee again for the opportunity to participate in today's hearing.