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Senator Durbin and members of the Committee,

Thank you for taking the time to both hear and read my testimony. It is my hope that by sharing with you, others will be spared from the serious and life-changing effects of taking unregulated diet supplements containing ephedra and guarana (herbal caffeine). As conditions of a legal settlement, I will not be permitted to reveal the name of the company or the names of the supplements I took.

It was February of 1996 that I used supplements containing ephedra and guarana. I was in my fifth year of marriage and had two small children. My son was just over two years of age and my daughter was six months old. I was exploring the possibilities of home-based businesses when I came across a "Moms Wanted" ad. I called the 1-800 telephone number and heard pre-recorded messages with amazing testimonials of quick weight loss, increased energy, greater physical endurance, and financial security. Still not sure what the product was, but drawn in by the claims of being "all natural", I called a second number given "for those still interested". I was referred to a local meeting that would be taking place later that evening.

While my first objective had been to find part time income, I was now interested in shedding the extra baby weight. Also, being a mom of two small children, I wanted to learn more about the extra energy the testimonials on the phone had referred to. Upon arrival, each first time guest was given a beverage sample. This was one of the more popular caffeine containing products and touted as a "healthy alternative" for coffee. By the time I left two hours later, I had heard more amazing testimonials, seen very professional videos, and listened to the head facilitator make incredible statements about this product line. I was most impressed with the claim that these products were "all natural" and that even medical doctors were unaware of the healing potential these products offered. While medical doctors push pills to fix problems, these products would work to stop the problems in the first place. The facilitator even implied some of the products could reverse major illnesses like diabetes and cancers. These statements were impressive to say the least.

The brochures I was presented with used phrases like "Doctor recommended", "scientific approach" and "quality assurance". I was very impressed with the entire presentation and found myself feeling very comfortable. At one point, I asked what ingredients were in the weight supplements that made it so effective. The response was something like this.

"Do you ask what is in a Snickers candy bar or a McDonalds hamburger before you put it in your mouth? I could tell you the names of the ingredients but it would not mean anything to you. But I will tell you that the Chinese have been using these natural herbs for thousands of years safely." (Later I would learn that this was the answer many distributors used.)

I do wish it had been explained at this point that some of the herbs were stimulants and were responsible for the extra energy that would be felt. But the extra energy and weight loss was always attributed to the overall greater health one would achieve.

At home, my husband and I read through all the literature I had been given and didn't see anything which raised any doubts in our minds. I was excited about what I'd heard and was anxious to get started. My plan was to try these supplements for myself, then sell them if it was all they claimed them to be. The only warning on the labels that did apply to me was that I was a nursing mother. When I inquired about the reason for this specific warning, I was told that while it was probably safe, there had been no studies done on children. With my daughter already on solid foods, she was close to being weaned anyway. So I took the next few days to stop nursing completely, and then purchased my first products from this company.

I was specifically interested in the products for weight loss and enhanced workouts. This included herbal tablets containing ma huang (the Chinese name for ephedra) and two caffeinated beverage mixes I would mix with water. With my first purchase came a brief explanation how to take them. It was also important to take them together to maximize results. Never was I given any verbal cautions, warnings, side effects to watch for, or any other clue these dietary

supplements could be unsafe. How could I know that seven days later I would be in a psychiatric ward at the Anaheim Medical Center in Irvine, California?

At this point, I feel I need to make it very clear, that I had never in my life experienced any kind of mental illness. With no family member or friends having a mental illness, I did not even really know what the term referred to. I had also never done any kind of illegal substances in my youth that would have given me a reference point of being "HIGH". I believe this is why I did not stop taking the supplements when I started to experience the bizarre behavior and thought patterns. In fact, thinking I was taking the equivalent of a vitamin, I never made the connection between the product and my changing behavior.

I started the first day as directed with 1 herbal tablet in the mid-morning and 1 in the mid-afternoon. Day 2, as directed, I increased to 3 times a day, each tablet taken 45 minutes before each meal. I never did increase my dosage after that even though it was recommended to work up to 2 tablets, 3 times a day. I also began the beverage mixes according to instructions. Over the next six days, the pace of my life would speed up, and my mood would elevate to a psychotic state.

I remember feeling the lift in my energy immediately and for the first time in months I did not need to sleep while the children took their afternoon naps. In fact, it was such an amazing feeling, that I knew after the first couple days this stuff would be easy to sell. Thoughts began to flow and I became very consumed with setting up my new part time business. On day three after starting the product, I woke very early and actually went to the gym before daybreak. Then, I proceeded to go home and completely clean the house before the kids woke up. My days were full with every minute being used and I felt so productive. There seemed to be no limit to my energy. By day four, I had come up with a new marketing plan for this company and was seeking legal advice on how to patent it. In hindsight, I realize that my thoughts were becoming grandiose and irrational.

It was around day five that I began to feel something *BIG* was happening to me and I still made no connection to the product. Running on little sleep by then, I remember feeling that I was very in tune with a spiritual realm. At one point, I felt that I was being watched, and I remember being suddenly convinced that one of my neighbors was demonically possessed. Thinking she was spying on me, I shooed her out of my house when she tried to help me carry in my groceries. I was flipping in and out of paranoia, followed by what I thought were divine thoughts from God, and I somehow became convinced I was being chosen. Initially in my psychosis, I thought I was being chosen to warn people it was the end of the world. One way I acted on these thoughts was to begin passing out twenty-dollar bills to the homeless and telling them they would be going home soon. Later, and this is embarrassing, I thought I was being chosen to be God's wife. Eventually, I just thought I was supernatural myself. There was no other explanation for feeling the way I did and knowing all that I knew (or thought I knew). To this day, I will admit it was a euphoric and incredible way to feel. As a side note, I now understand why some continue to take these ephedra-containing products even when they are informed of potential side effects. It also does not surprise me to hear that teens everywhere use these supplements as legal ways to get high.

By day five or six, my husband knew something was very wrong, but I could not be reasoned with. I was argumentative and mad whenever he tried to slow me down and discuss my behavior. I felt he was holding me back from my mission. He had called my mom and aunt to ask for help, but they too could not get through to me. My mind was racing so quickly that I could not stay focused on anything for more than seconds, and I grew more and more agitated as thoughts raced from point to point. My children were being neglected and some of the things I was saying made my husband afraid to leave them alone with me. Bottom line, you cannot reason with someone who is irrational. On the morning of the seventh day, and following more bizarre behaviors, my husband drove me to the hospital. While in the hospital, the only reason that I did not walk out was because I thought God wanted me to heal the others that were there. I was hearing voices in my head, seeing visions in the clouds, and convinced of demonic plots around me that wanted me and my family dead.

Because my husband had noticed that the change in behavior coincided with starting these supplements, he brought the products with us to the hospital. It was there that the psychiatrist assigned to me first pointed out the ephedra and guarana herbs. A prior emergency room physician, he had seen cases like me before. He explained to us that when combined, these herbs had an amphetamine effect that could lead to psychosis. We were lucky to have him given that most medical physicians are not very familiar with the herbs. Of course I could not comprehend what he was talking about at that time,

but for my husband, it confirmed what he suspected. The products were to blame.

While I remained in the hospital for the next ten days, I was given strong sedating medications and had extensive counseling. The super feelings of the spiritual did begin to subside, but I was not able to give up the ideas and beliefs of who I was. I could not understand how I could have made it all up, and I believed that what I'd seen and felt while on the product was still very real. It would take two to three months before my mind would allow me to believe that all I'd experienced was a result of an amphetamine like high. Slowly, the ability to think logically did return, only to be followed by a severe and life threatening depression. From beginning to end, recovery was a nine-month process.

While I had set out to help increase our financial base, now we were completely wiped out and had outstanding medical bills. But this hardship could not compare to the emotional consequences of taking these products. My marriage was severely affected. My husband could not help but second-guess everything I said. In the episodes of depression, I would lose all confidence and find myself unworthy of his commitment to me. I often felt he and the children would be better off with someone else. Trust and healing, for both of us, have taken years to regain. And nothing can make up for the lost time with my children. Especially since the damage has turned out to be permanent. Two years later, I would have a second episode of psychotic behavior followed by depression. And one year after that, it would happen for a third time. With each incident came fear, uncertainty, and months of medication. To stop these cycles, I now remain on a small amount of medication and have been well for almost three years. But I keep additional medications in the cupboard just in case.

Following my initial incident, we reported what had happened to my direct uplink distributors. While very concerned for me, they personally had "never seen anyone react to the product that way". There was no effort to find out details of my reaction or document it for future use. Next, we filed a lawsuit and felt lucky to have John Tiedt, an attorney who took our case on a contingency basis. Knowing me personally, he was very upset with the devastation this product had wreaked on my family. I was also determined to make a difference for future moms who would respond to that ad. It was later I would realize how many different products, containing these same controversial ingredients, were on the open market.

In his pursuit of our case, our attorney found that the labels on my products were very inaccurate. Lab tests revealed that there was more ephedra and guarana in the product than the label specified. In response to this finding, there was finger pointing between the company and the lab that actually manufactured the products for them. So each hired separate lawyers. Can you imagine the difficulty of trying to fight a case against a company with unlimited financial resources and not accountable to anyone? Their lawyers searched in vain for evidence of a pre-existing mental condition, family history of mental illness or history of drug use. There was none. But in the end, we felt we should settle. There had been no trial cases before us, and we did not have the financial capability, or endurance, to fight this giant. The money we received was just enough to cover our medical bills and replenish our small savings.

My doctors and psychiatrist have concluded one of the two following explanations.

- #1. I somehow had a pre-disposition toward mental illness (which had never shown up before), and the supplements triggered its appearance.
- #2. The supplements actually altered my natural brain activity and caused me to have symptoms similar to bi-polar illness.

Either conclusion is scary. Whichever way you look at it, these kinds of products are very dangerous and carry with them high risk. I have been fortunate to share my story in news clips and magazine interviews. Every single time, I receive calls from people going through the same experience. These are the lucky ones. At least they have identified the source of the problem and can discontinue use. But I worry about the victims rushed to the hospitals and mental facilities that never make the connection between starting these supplements and mental disturbances. Most patients do not think to tell their doctors they are taking "natural" supplement products. It doesn't occur to them that the supplements they are taking to achieve better health are actually causing debilitating side effects.

I know for a fact I am not alone in my experience. In addition to the people that call me, my psychiatrist sees new patients with similar symptoms regularly. With these new patients, my psychiatrist now knows to go beyond the question, "Are you taking any kind of prescription medication or illegal substances." The initial answer is usually "no", because

most herb users do not think of these products as drugs, but rather as vitamin equivalents. His further questioning often reveals that the individual has been taking ephedra and guarana containing products that coincide with the on-set of mental symptoms. These include symptoms of psychosis, panic attacks, paranoia, and even schizophrenia. Each time I visit him for my check ups, his cupboards contain additional supplement products that patients have brought in. From weight loss to workout supplements, they all contain ephedra and a caffeine source.

In conclusion, I would like to mention my thoughts on what might have helped my situation. Even the improved labeling standards today would not have stopped my incident. At 26, I was healthy and had no medical concerns. I can see no other way to stop others from being hurt other than to place strict federal regulation on ephedra-containing products. With new product lines coming to the market regularly, these products continue to be advertised as “all natural” and “healthy”. Since I took these supplements, similar products have now become available in grocery stores, coffee shops, gas stations, and the many health stores that have popped up around town. Never do I see posted warnings. The over the counter drug combination of synthetic ephedrine and caffeine has been banned by the FDA since the 1980’s. Why is the herbal equivalent allowed on the market?

I would also recommend that the “cautions” portion of labels, nation wide, immediately be required to include the phone number of the FDA. There needs to be a place, other than the individual manufacturers, where consumers can report adverse affects. I can only hope that the money these companies donate to campaigns and supportive political leaders will not keep the issue at a stand still. The evidence of harm is abundant. How many victims will it take to finally place the burden of proof in the hands of the manufacturers? In articles I read, representatives for the industries repeatedly claim that cases like mine cannot be scientifically proven. Yet, it is the industry, which should have the requirement to prove their products are scientifically safe. Until that can be done, and the medical communities and manufacturers *both agree* on safe standards, the public should no longer be subjected to the lack of information and false claims. Please use your power of influence to make a difference.

Thank you,

Karen Ruiz