

WRITTEN TESTIMONY  
OF  
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FOR THE

JUNE 6, 2001 NEUROPHARMACOLOGY ADVISORY COMMITTEE MEETING

Prior to my involvement in the Xyrem study, beginning in late 1995, the quality of my life was being destroyed by narcolepsy.

Almost everyone knows that narcoleptics fall asleep at odd times. Unfortunately, daytime sleepiness is just one of a complex of narcolepsy symptoms, all of which are either eliminated or improved by using Xyrem. Not all narcoleptics have all of the symptoms. I have experienced all of the following.

**DAYTIME SLEEPINESS:**

Since the age of 25 (1969), falling asleep at unpredictable times has made it difficult for me to work. As an employee, I learned to hide in the restroom to take 10-15 minute naps when the uncontrollable urge to sleep came over me. No matter when I went to bed at night, no matter how many vitamins I took, I could not stay awake all day at work, and I couldn't plan to make the sleep attacks occur at 10:00 o'clock and 2:00 o'clock for scheduled breaks.

This is a symptom narcoleptics attempt to hide from everyone else. It is almost impossible. Narcoleptics fall asleep in meetings. Jobs that allow for escape for a hidden nap at unpredictable times are rare. Not everyone has an office with a door that closes. Employers notice sleeping employees, and, even with today's protective laws, sleepers lose their jobs.

After the death of my husband in 1976, as my narcolepsy was still relatively mild and undiagnosed, I completed my undergraduate degree and then began law school. Increasingly severe symptoms made completing law school slow and difficult. While taking notes during lectures I would begin to dream. Several times I actually wrote a few words about my dreams before dropping my pen. I began to fear for my sanity. Who was writing these things about helicopters and my mother in the middle of my notes on civil procedure? I sought medical help. After four months of testing my doctor inquired, "Do you ever feel muscle weakness when you laugh or get emotional?" I asked, "Doesn't everybody?" and Eureka! I had a diagnosis: Narcolepsy. The good news was, I wasn't crazy. The bad news: At the time, my doctors knew of no treatment.

I am not easily deterred. I graduated. Not with my class. Not among the top 25%, as had been my goal, but I did, finally, graduate. However, I was afraid to take the job offered, clerking for a District Court Judge, because I feared that I would fall asleep in court, sitting up in front for all to see. In Boulder, Colorado, I established a reputation as a compassionate and effective advocate in family and juvenile law. However, I was unable to serve enough clients as a part-time sole practitioner and mediator, during my wakeful hours, to make a sufficient living to support my children and myself. I paid a charitably small rent to live with generous friends. I had to ask that my student loans be deferred.

For a parent, daytime sleepiness is very troublesome, in fact, dangerous. I was a single parent, a circumstance faced by many narcoleptics whose marriages suffer from this condition. I was lucky. My kids survived. I have fallen asleep in a pediatrician's waiting room; at a production of Hansel and Gretel in which my son played Hansel; while reading stories to my kids; at parks while they played on the swings; and while helping with their homework. They got very good at watching for our stop so they could awaken me to get off the bus.

Things got a bit better for me in 1992 when my physician recommended I try Ritalin for daytime wakefulness. However, Ritalin and other wakefulness medications contribute to my high blood pressure, and have other problematic side effects. Xyrem makes it possible to get good, effective nighttime sleep, so I can take significantly less of the wakefulness drugs. I've taken Xyrem for most of the past 6 years, with no side effects.

#### **HYPNOGOGIC HALLUCINATIONS AND NIGHTTIME WAKEFULNESS:**

While everyone else is sleeping, an untreated narcoleptic alternates between vivid, often frightening dreams, and hours of worried wakefulness.

Falling asleep at night, and sometimes awakening, can be a horrific experience. You believe you are awake. You know where you are sitting or lying, and your awareness of your surroundings is clear and accurate. But you experience hallucinations. For me, often it was hearing the sounds of an intruder entering my home from behind me. I was paralyzed, and unable to turn around to confront my attacker to defend my children and myself. In a real-life experience, an actual intruder had tried to sexually assault me, so these hallucinations were terrifying.

A 16-year old narcoleptic I met at a sleep clinic told me about his horrifying dreams of space aliens and other monsters. His experiences and mine were parallel, in that sometimes we were so aware that we were dreaming that we would attempt to will ourselves into wakefulness, and actually dream that we were awake, doing ordinary

morning things like going to the bathroom or eating breakfast, only to have our attacker jump out at us from the shower stall or the cereal box. Trust me, it was no compliment if either of us said, "I'll see you in my dreams!"

Before Xyrem, I had hypnogogic experiences virtually every night, on my way to sleep. When I lived alone, I dreaded going to bed, knowing that it would happen, and knowing that no matter how I prepared myself, when I was in that experience, I would believe that it was real. When I remarried, I learned to fear for my husband's safety. He would hear me making fearful noises in my dreams, and would awaken me and try to comfort me into more restful sleep. He stopped trying to help in this way after I attacked him and bit him severely, as I thought he was my attacker.

After finally getting to sleep, for the rest of the night I would alternate between dreams and hours of wakefulness, during which I worried about the inevitably sleepy tomorrow. Before diagnosis, the dreams became very vivid and intricate. They repetitively concerned similar themes, developing into stories over time. It was as if I had one life during the day, and another at night. I began to feel unable to distinguish between dreamed events and reality. This contributed to the fear of insanity that drove me to seek medical help.

Prior to Xyrem, anti-depressants helped with the serial dreams, but did nothing for the hypnogogic hallucinations, and I experienced troublesome side effects. On Xyrem, the nightmares are gone. What dreams I have are normal, and rarely recalled, like a normal person. I get good, restful sleep, and no side effects.

#### **AUTOMATIC BEHAVIOR:**

When sleepy during the day, instead of falling asleep, some narcoleptics will continue doing an activity while not fully conscious. Before I was informed of it's clinical name, I named it "going to stupid."

For me, the experience was annoying and embarrassing, but did not cause serious problems. While working on the computer, I have "gone to stupid," finding myself unable to do simple functions, like saving a document, and have had to re-do some work as a result. I learned to recognize the condition and simply stopped and took a nap, losing time instead of ruining or losing a document. I was lucky.

I've heard stories of other, much more dangerous events, such as a woman who brought a pot of oil, rather than water, to a boil, which resulted in severe burns and property damage.

Since I've been on my present medication regimen, including Xyrem, I haven't experienced any events of "going to stupid."

## **CATAPLEXY:**

Early symptoms were just momentary muscle weakness when I laughed. My face felt strange, and my knees felt wobbly. By the time I found Xyrem, my cataplexy was severe. When my granddaughter, Alexis, was a toddler, she kissed my cat while the two of them were sitting in my window seat. I found it so adorable that I collapsed totally to the floor. All muscles go limp. You can't protect yourself from hitting your head on the coffee table on the way down. You just fall.

Walking in the hall at work, then as a mediator for the Colorado Department of Labor and Employment, my supervisor told a joke. Instead of laughing, without warning, I fell to the floor. Employers worry about liability. A couple of cataplexy attacks at work, especially when you work for the Division of Workers' Compensation, are pretty likely to lead to unemployment. I had an unbelievably supportive supervisor, and fortunately, I was only a week away from starting Xyrem when this occurred.

Based on stories my grandmother told, I think my grandfather had undiagnosed narcolepsy and cataplexy. He was not so fortunate as I. He spent a lot of time alone in his room at unpredictable times, demanding silence from his family. When he was about 45, he had become so concerned about the possibility of falling off a roof, in his business as a general contractor, that he tried to change careers. It was shortly after the Great Depression. A potential employer promised to hire him if he purchased a particular kind of truck. He spent all his savings on the truck. When the job fell through, my grandfather decided that his insurance policy would be more helpful to his wife and three daughters than he was, and he ended his life.

I had the good fortune of knowing what cataplexy is before mine became severe. Before I found Xyrem, I did what I could to anticipate problems. As an example, I asked friends to stick close by on Law School Graduation Day, so they could support me if the sheer joy of it put me on the ground. I got pretty wobbly, and my friends kept me upright. I've never been seriously injured by a fall, suffering only some severe bruising. Fortunately, before Xyrem, I never had an emotional experience on the stairs, which at my home present a clear and present danger of a potentially fatal fall.

Many others have not been so fortunate. I've heard stories. The most startling was about a narcoleptic who was not able to escape a house fire because his fear caused cataplectic collapse. When you collapse, the muscles used for speech also fail, so you cannot cry out for help. Cataplexy, at best is hugely embarrassing. At worst, it is extremely dangerous.

Various anti-depressants I've tried had only partial success in controlling my cataplexy, caused distressing side effects, and the pharmacist's warnings threatened worse ones. Going off anti-

depressants resulted in an extreme rebound of cataplexy, far worse than any cataplexy I experienced before trying them.

In contrast, since I began using Xyrem, my cataplexy has been nearly totally eliminated. Only on rare occasions have I had a slight facial relaxation or a tiny knee wobble in response to a very emotional situation. These were so insignificant that no one else noticed them at all. I've experienced no side effects from Xyrem. Additionally, when I had to abruptly stop using Xyrem for a short time, my cataplexy returned slowly, over a three-week period. Other than the return of all the other symptoms of narcolepsy, I had no additional negative symptoms from terminating my Xyrem regimen. Thankfully, the time that Xyrem was unavailable to me was brief.

### **WHAT A DIFFERENCE XYREM MAKES!**

Since going on Xyrem in the fall of 1995, I have been able to function as an essentially normal person in spite of my diagnosis of "Severe Narcolepsy with Cataplexy."

I have had some career success. I am now a full time Administrative Law Judge with the Colorado Department of Labor and Employment. I can work an 8 to 10 hour day, reliably stay awake to hear all my cases, share a funny anecdote with an attorney, and decide emotional issues involving people who are severely disabled by industrial injuries, without collapsing.

Because of my employment, I am presently current on my student loan payments. If I am able to continue to meet the demands of my job, they will be paid off within the next 18 months.

I am a responsible and happy member of a great family that I thoroughly enjoy. I am able to be a full partner to my husband, to whom I've been happily married for precisely seven years as of June 6, 2001, rather than a nighttime endangerment or a financial burden.

I enjoy helping out with my three grandchildren, rather than falling down when they do something cute or have a problem. Three years ago I was able to assist at the birth of Justin, Alexis' little brother, with no cataplexy. I was thrilled to carry him from the delivery room to his first physical examination. Last fall, we traveled to California to get to know my son's firstborn, little Griffin. Later that week, when he became quite ill, I was fully competent to drive him and his frantic parents to the emergency room, and comfort them during his examination and treatment. I was also able to rejoice over his swift and complete recovery. And when I was granted the distinction of being the first to see the empty place after Alexis lost her first tooth, I picked her up, hugged her, and shed a tear of joy, all in an upright position!

I was privileged to be the primary family caregiver for my mother when she suffered a year of dementia. I was with her to provide comfort as she succumbed to pneumonia. I stood up and spoke of the beauty of her life at her funeral.

Without Xyrem, Cataplexy would have robbed me of all of those experiences.

Without Xyrem, I could be unemployable.

Without Xyrem, it would not be safe for me to hold my grandchildren.

Without Xyrem, I would have to try to avoid emotion. Please think about that. Thinking about it makes me very emotional.

The things that make life worthwhile are facing challenges that make us angry, or sad, or frightened, and overcoming them; and celebrating the joy of our successes and our blessings. Xyrem returns the value in life to narcoleptics who have cataplexy. Without Xyrem, my life would be worse than empty.

Please understand. I am a very fortunate narcoleptic. God blessed me with sufficient intelligence to graduate from law school while half asleep, and enough inborn tenacity and stubbornness to never take "You can't!" as the final answer. I live in Denver. My mother's doctor, unlike most physicians in the area even today, heard about the study of the substance we now call "Xyrem," being done in a nearby suburb. That happenstance has allowed me to reclaim a productive life. Thousands of narcoleptics in this country are not nearly so lucky. They desperately need for Xyrem to be available, by prescription, in their towns, in order to complete high school, hold jobs, build successful marriages, and raise children safely.

Xyrem gives back to narcoleptics the bottom-line American Dream, the opportunity to pursue happiness, without falling down when the going gets tough, or when the goal of happiness is attained. As a member of the Narcolepsy Network, and of Orphan Medical's Xyrem Patient Counsel, I am testifying, not only for myself, but also as an ambassador for all those other narcoleptics, and for our children and grandchildren, who may inherit this condition from us. Please find a way to balance the concerns of all persons interested in this drug. Please allow the approval and distribution of Xyrem for treatment of narcolepsy to go forward, now.

Thank you for taking the time to consider our side of this story.

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