

Testimony to the Chronic Fatigue Syndrome Advisory Committee of the
Department of Health and Human Services
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[I hereby give permission to use my full name as stated above.]

Thank you for allowing me time to speak.

I was in the *Science* article last October, and I tested positive for the retrovirus XMRV.

I first fell ill in 1990 while living in Delaware. I was a tenured professor at Villanova University outside Philadelphia. I had giardia followed by Epstein-Barr during an outbreak at my university. In the four years that followed, I had bronchitis eight months out of the year; I lost my sense of balance; the slightest bit of alcohol made me sick; I had increasing trouble falling asleep; and I could not do my usual Nautilus circuit and aerobic exercise without my pulse skyrocketing. Yet I had periods of health; I skied every winter.

Then, on October 24, 1994, I had a blackout in my office. When I came to, I could not understand a word of the essays in the bluebooks in my lap. It took fifteen minutes to be able to stand. I do not know how I made it home. My chair put me on short-term leave, which eventually became long-term disability. Although I was “resting,” I got worse instead of better. After a blackout while driving close to home left me and my car on top of a stone fence (and no memory of how I got there), I gave up my car keys. At first I could walk across a room; eventually I could only move about the house by leaning on walls, furniture, and my golden retriever. When outside my house, I was in a wheelchair. Increasingly, however, I could not go outside because I could not sit up that long. This is a very isolating disease.

I continued to have a social life on internet, because nobody could tell how long an email or website took to complete – and other brainfoggy patients didn’t mind misspellings or wrong words inserted into a sentence. By fall 1998, however, even internet was too hard.

About a year into my illness I developed Hashimoto’s thyroiditis. I also was found to have NMH/POTS. My Washington specialist, Dr. Marsha Wallace, treated the sleep problems, the thyroid problems, and the disautonomia, but I continued to deteriorate. Eventually I spent most of my time curled up in bed, in the dark, listening to a favorite movie (because it was too painful to look at the tv); severe pain behind my eyes, in the back of my neck; migraine-level headaches; and general muscle aches everywhere.

In 1996 I heard Dr. Robert Suhadolnik of Temple present on his new discovery, 37kDa Rnase-L, and I was fascinated. Two years later, Dr. Wallace, arranged for Dr. Dharam Ablashi to have my blood spun down into a PMBC pellet to be sent to Redlabs in Belgium for testing; at the same time, Dr. Ablashi tested me for HHV-6, Variant A, which he had co-discovered at NCI. I was positive for both.

I had read that abnormal Rnase-L was a good predictor of success with an experimental immune modulator, Ampligen, an asymmetrical double-stranded synthetic RNA. I had also read a study

by Dr. Ablashi and Dr. Paul Levine that had shown Ampligen inhibited the growth of HHV-6 in vitro. With that evidence to work with, I made the decision to go on the experimental drug. I was too sick for the double-blind study then being set up, but that was just as well – I wanted to know I was getting the drug.

I responded extraordinarily well. My brain began behaving normally within four months; soon I was driving and reading again. Eventually I would return to research, but I have never regained normal stamina. The slightest illness would set me back for weeks. Nevertheless, I could go places again with my husband; travel and see things; walk – walk on a beach, walk on a trail far enough that I did not hear the sound of automobiles anymore. If you have ever been confined to a wheelchair, you will know what that meant, to be able to walk again. I had dreamed of walking. And now I could stride.

Ampligen was expensive. After 20 months I quit taking it. I experienced what we Ampligen patients sometimes refer to as the “Ampligen Honeymoon” – I felt *so* normal and was *so* happy. I even negotiated with Villanova to return to teaching.

And then, on October 6, 2001, at Cal Ripken’s last baseball game, I had a blackout. The usher, who knew us, got me to First Aid and found Bob (who was visiting friends). Bob got the car while a nurse took me out in a wheelchair. The Disease was back.

The next morning I forgot what had happened and went to get out of bed as usual – but I fell to the floor. Six weeks later Dr. Ablashi confirmed that HHV-6, Variant A, was back. I could not send blood to Belgium, but the HHV-6 results were enough. I knew I had to get back on Ampligen.

The physician who had provided Ampligen in 1999 was no longer doing so, but I learned that I could receive Ampligen infusions at Hahnemann Hospital in Philadelphia, where they had permission for double-blinds because of Phase II’s on rare blood diseases. It took seven months, but I finally was on Ampligen again. I had deteriorated terribly, however. It was as if I had never been better at all.

So I had to climb back out again. After that, I was afraid to go off the drug. I remained on it from May 2002 to February 2008. Dr. Wallace had retired, so in 2005 I began seeing Dr. Dan Peterson at Incline Village (joking that the price of a ticket on Southwest Airlines was cheaper than Amtrak to NYC, my other choice).

The money is a problem – but it is roughly the same as my after-tax disability pay, so I live on the largesse of my husband, who is a chaired professor in a business school and does a *lot* of moonlighting – everything from teaching banking in executive ed programs to college lacrosse officiating and odd jobs for Major League Baseball. We manage.

But so few of my friends could afford the testing I’ve had, let alone the treatment. Every test for which I am positive is on the CDC’s hit list – that paragraph that states the test is inappropriate for CFS. Consequently, insurance won’t pay for those tests. At roughly \$500 apiece, the

expense adds up. Nobody can get tested, nobody can say they have what I have, and if they could, they couldn't get treatment anyway. Pretty neat deal. For the insurance companies.

I continued to do well on Ampligen and made great progress on a book. Then my worst nightmare came true. In January 2008, dear Dr. Brodsky, now in his 80s, passed away. In February I received a phone call: FDA had taken away the drug. Hahnemann applied twice to get it reinstated, and I am not sure where the bottleneck was, but they were denied. Which means I was denied.

All the places where it used to be possible to get Ampligen on the East Coast were no longer in the program. Now I began to panic. I knew I was a ticking time bomb – I hoped perhaps I could stay relatively well for more than a year because I had been on it for so long, and I was so much better. I was wrong.

Seven months after losing Ampligen, in September 2008, I had my third episode of sudden onset. Once again I descended into hell. I lost the ability to walk normally and we had to bring the wheelchair back up from the basement. I dropped things, and when I tried to load the dishwasher I crashed one glass against another. The exertion of five minutes of testimony at the October 2008 CFSAC meeting sent me to the floor; my friends helped me lie down softly as I had once been able to help them. It made no difference that now I knew the names of the various symptoms – ataxia, expressive aphasia, short-term memory loss, central auditory processing dysfunction, etc. My brain had disappeared. And there was the exhaustion. And the pain. Pain, pain, pain.

I went to see Dr. Peterson at the end of September, and he put me through a series of tests. My MRI results were negative but I had an abnormal SPECT scan. My VO2 MAX stress test was below the level Social Security lists as an automatic disability for people far older than me. My Holter Monitor test was abnormal, and a 24-hour blood pressure and pulse test showed an NMH/POTS event when I was standing in line at the pharmacy – suddenly my systolic dropped 40 points while my pulse skyrocketed 40 points. (That was the first time I had ever seen a readout of it.)

I was active for Epstein-Barr (it goes dormant and reactivates over and over again if I am not on medication). I can now add a low natural killer cell count and a very low natural killer cell function (3%). More viruses had appeared – most seriously, HHV-7 and cytomegalovirus (CMV). I was also weakly positive for Cocksackie B2, B3, and B6. We did not find HHV-6 in my plasma, however.

During this period I went back to see Dr. Peterson every couple of months. I could do this only because of the kindness of the people who push wheelchairs for Southwest Airlines, the airport limo drivers and Tahoe taxi drivers, and the kind people who run a motel on the north shore of the lake, who have a family member with The Disease. When I was scheduled for a lot of testing, my daughter would fly up from Los Angeles to drive me around. Somehow we made it work. But I always came back home.

In the fall of 2008 Dr. Peterson tried Vistide, a drug that is approved for CMV. I had my first two doses a week apart while staying at Tahoe. He had then set up a dose at an infusion center connected to the only infectious disease practice in northern Delaware – but when I came for the infusion, they refused to give it to me. “I’m sorry,” the doctor said, “we can’t give you this. It’s a strong drug, and all you have is CFS.” But I have cytomegalovirus, and Vistide is approved for cytomegalovirus. “We know. And if you had something serious, like AIDS, or were on chemo from cancer, we would give it to you. But all you have is CFS.” But you told my specialist you would administer it to me. “Yes, but we hadn’t seen your files yet. We didn’t know you have CFS.”

I had to fly to Reno, spend the night, get my dose, and fly home.

But Vistide was not in the works for me. Ironically, while I seem to be the poster child for Ampligen, Vistide made my liver function tests go off the charts. My SGOT and SPGT counts were 500 times what they should ever be. They returned quickly to normal, so we tried a half dose of Vistide and then halved it again, but each time SGOT and SPGT spiked just as before. Vistide was out of the question.

In July 2009 I had a spinal tap - my daughter and her boyfriend came up from L.A. to help me again (Bob was just trying to earn money!). Aha – that’s where HHV-6 had been hiding out. So now I could say I ran the table – HHV-4, 5, 6 and 7.

At one point I remember saying to Dr. Peterson, it has to be my immune system. Something has to be really wrong with my immune system. Otherwise this does not make sense. He agreed, and then he said, “Oh, there are things I would like to tell you!”

Now, I will admit here that the very well-kept secret did not turn out to be what I was hoping for. I hoped desperately that Ampligen had by some miracle been approved. The finding that there was a retrovirus in 2/3 of a sample of 101 CFS patients completely bowled me over. *That* one I had *not* expected. And a few weeks later, by email, came the suggestion from a fellow patient that I ask WPI if I had been in the study. I assumed it was the Tahoe-Truckee cluster outbreak of 1984-85. Instead, they had deliberately picked zip codes from all over the place – so my Delaware zip code had bought me a free XMRV test. I was afraid to call and find out – not afraid to have it (I had plenty!) – afraid that I would *not* have it. Just as I had been afraid of the Rnase-L test 11 years earlier. The epithet of diagnosis-seeker only has meaning to someone who has never struggled to find treatment for a severe illness. XMRV means two things to me: an explanation for why I can’t go off Ampligen without getting sick, and the possibility of a substitute for Ampligen if FDA refuses to approve it. It means hope.

One more anecdote: During this period I fell, resulting in a slipped disk. (I fall a lot when sick.) I have a good neuro-spine surgeon at Penn, and he shaved a piece off quite neatly. But I was amazed at the response from the anesthesiologist, and later the nursing staff, to my warning that I had been diagnosed with a newly discovered retrovirus and they needed to take precautions. I was treated very differently than in the past – same symptoms, same litany of diseases and abnormalities, but now we had added a recognized disease (CMV) and a retrovirus (XMRV), and

everything had changed. They were very happy to get me out of the hospital as fast as possible – so was I.

CMV and XMRV represent the first diagnoses I have ever had which turned heads among hospital staff.

But as my daughter said when I told her about my new diagnoses, “you were sick long before anybody said what you had, Mom.” And she should know. She spent five years taking care of me.

Last year my husband, Dr. Peterson, and I decided that because I responded so well to Ampligen, I had to go back on it. That meant I was going to have to live in Incline Village, NV, until Ampligen became available at home again. It’s ironic – I live in the Northeast Corridor – 10 minutes from I-95, 5 minutes from a train station. I’m within driving and/or easy Amtrak distance from 40 percent of the nation’s population. But I had the choice of western North Carolina or a resort town on Lake Tahoe to be able to go back to the only medication that has ever worked for me. Since Dr. Peterson was my specialist, the choice was obvious. And I imagine I won’t get much sympathy for having to live at beautiful Lake Tahoe. But I have been married 35 years, and I miss my husband terribly. At our age, you feel like two heads of the same body. It’s awful. Thank heavens for unlimited long distance calling, MLB.com’s internet package, and Southwest Air.

I know that XMRV is “hot” right now, and dominates the discussion. But please remember that there are a number of immune biomarkers and viruses that we have that CDC also pretends don’t exist. They couldn’t find XMRV? I’m not surprised – they never could find HHV-6, natural killer cell dysfunction, mycoplasma, or NMH/POTS, either. It’s been the same thing for years: A quick study with a few patients chosen in a creative manner and then they can announce that X, Y, or Z is not “The Cause” of CFS. Why should it have been any different with XMRV?

But look at my history – and I am no different from many, many others with my disease who have also been able to get testing and treatment. I have some things others don’t have; others have things I don’t have. There’s a young man getting Ampligen with me who shares HHV-6 and the 37kDa Rnase-L (and XMRV) – but he also has parvo, which I don’t have, and myocarditis, which I hope I don’t have. But there’s a pretty standard array of testing that works for us – that demonstrates a very serious set of biomedical abnormalities. What matters right now is not finding The Cause, but identifying patterns that can lead to treatment and improvement. That can turn around the downward spiral.

When you go to test whether XMRVs or PMRVs are related to the condition known as CFS (Fukuda 1994), please go back to everything else CDC has ruled out for the 25 years they have hidden this disease. This is important. Our lives are in your hands.

Thank you.