

## Testimony

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First, I want to thank Wanda Jones and this committee for giving us a chance to speak, and in particular, for livestreaming this meeting so that patients who cannot travel (which would be most of the ones I know) and patients who are housebound (which would encompass too many of those I know) can view the meeting from their homes, both in the United States and abroad.

I also want to thank Dennis Mangan, the NIH committee that I was privileged to be a part of, and all the participants, for the outstanding State of the Knowledge workshop on such short notice.

I want to focus on the Centers for Disease Control and Prevention (CDC) today. CDC has been studying this disease for over a quarter of a century, and haven't gotten very far. It is time that they caught up with 2011.

First I want to make clear that when I refer to CFS, I mean the Fukuda definition (1994), and when I refer to ME/CFS, I mean the Canadian definition (2003). When I refer to M.E., I use the Ramsay and World Health Organization definitions.

### **1. CDC's Portrayal of the Disease**

Suppose you broke your leg really badly. You knew it, your family knew it, your friends who were with you knew it. Somebody called emergency, and the ER techs came out. They had already been told by your family that you had a broken leg, but they said they had to find out for themselves. They came up to you and said, "Why do you think you have a broken leg?" Startled by the question, you said, "because it is obviously broken!" (Self-reported, one says to the other.) How about you stand up and we can see what's going on with that leg. "NO!" you responded! "That's going to hurt!" (Catastrophizer, they murmur among themselves. People who catastrophize about pain are more likely to feel pain.) Then they write a prescription for Prozac, say "Take this until you feel more comfortable about the prospect of standing up," and they leave.

Now, of course that was a silly story. But it is exactly how I was treated by the first specialist I saw for this disease. "Self-reported" is an insurance term that is used by British psychiatric "experts" on CFS; and there is a published paper out there about CFS and fibromyalgia that uses the correlation between these diseases and fear of pain to conclude that people who fear pain are "catastrophizers," and "catastrophizing" causes pain. There is a large body of psychiatric research on this disease that is just plain silly.

So don't be surprised if patients are a bit worried about what researchers say about them, or what the government does about them. If you had a badly broken leg and nobody in

the medical profession would believe you, you'd be a little cranky too. Indeed, when scientists injected lab monkeys with HHV-6, Variant A, the poor things hid in the corners of their cages looking supremely miserable, and one would drag his left arm and leg when they made him walk. Poor baby. Been there. At any rate, the scientists working with the monkeys said that they got a little cranky toward the end. No kidding.

Ever since CFS was abandoned by NIH, CDC has been the central agent of promoting views that are diametrically opposed to our experiences. For 25 years they have insisted this disease as caused by some sort of "stress," – at first the stress of yuppie women "trying to have it all." Today they claim the stress is caused by having been abused as children – but they're still saying the same story. It's just caused by an inability to handle stress.

Something else I have faced when coming here or when at a conference on my disease, is the phrase "Oh, I don't believe that." I recently wanted to talk with a well-respected virologist about HHV-6, Variant A, which I is a vicious disease, and which I have in both my blood serum and spinal fluid unless I am on Ampligen. The researcher stopped me as soon as the words came out of my mouth, "I have HHV-6, Variant A." "Oh, no you don't," he said, cheerfully. "There's probably just some artifact in your blood that makes it look as if you have HHV-6, Variant A." That's pretty much the same thing Stephen Straus said to me when I testified here twelve years ago about HHV-6, Variant A. And my response is the same now as it was then: I was part of a study of a handful of CFS patients conducted by Dharam Ablashi, the co-discoverer of HHV-6 and its two variants, while looking at samples from AIDS patients at NCI. Ablashi *saw* the virus in my lymphocytes. It was no artifact. But ... "Oh, I just don't believe that" is something I often hear. Hardly a scientific response, don't you think?

In the meantime, we remain sick. So let me offer my first suggestion: *if the approach hasn't helped anybody with the disease in a quarter of a century, time to change the approach.*

## **2. When is CDC going to begin to identify subgroups using biomarkers?**

The Fukuda article from 1994 that gave us the most commonly used research definition also strongly urged CDC to begin identifying subgroups using objective biomarkers. That was 17 years ago. But if you look on CDC's website, when they discuss biomarkers or microbes associated with The Disease, they always put them in the context of "The Cause" of CFS. No, that's not the point, guys. A biomarker does not have to be "The Cause" to be useful. It just has to correlate. And when we are trying to identify subgroups, it doesn't have to correlate with everybody who has ever had a diagnosis of CFS.

I belong to an identifiable subgroup. When in relapse off Ampligen, I have, among other things, immune biomarkers and activated opportunistic viruses. There is a

subgroup of patients who have precisely what I have, though I have more viruses than many, and some have viruses I don't.

My immune biomarkers would be the 37kDA Rnase-L defect, which always shows up when I am off Ampligen and disappears when I go back on it, and natural killer cell dysfunction. During my most recent relapse, from September 2008 to the summer of 2010 (after having been on Ampligen for several months), I had a natural killer cell function of 2%. I also have an abnormal cytokine profile.

During relapse, I had active viruses in both my blood serum and my spinal fluid. I hold a flush in herpes viruses – Human herpesviruses 4-7. My relapses usually start with Epstein-Barr, which comes and goes while I am really sick. I test positive for active HHV6, Variant A, cytomegalovirus, and HHV-7. I also have Coxsackie B. I have friends who have parvo or an adenovirus, and I have friends who do not have HHV-6 or cytomegalovirus. As for the immune biomarkers, there's a pretty strong correlation between those who were in cluster outbreaks and natural killer cell dysfunction.

I think we're a subgroup, and I'd be very grateful if that could be recognized. The researchers who work with HHV-6 have been asking for years that Variant A and Variant B be recognized as different viruses, with one renamed HHV-9. CDC has turned a deaf ear to their research and requests. Intriguingly, Variant A is found in AIDS, CFS, and in the lesions of MS patients. Variant B, which causes roseola in children, is the virus that reactivates when patients are put on immunosuppressant drugs. While Variant B is endemic (it is the childhood disease roseola), in 90 percent of the adult population, Variant A is found in only 7 percent of the population. These are different diseases, but we need CDC to recognize that.

Finally, outside scientists at the NIH State of the Knowledge workshop strongly urged researchers to adopt the VO2 MAX score as an objective marker of the disease. Mine were significantly abnormal during the relapse – 14.5 – and even now, at 16, not a whole lot better. I have a lot of recuperating to do.

**3. NCHS, within CDC, is overseeing the development of ICD-10-CM. We need to keep CFS in the same code as in ICD-10 – under neurology, at G93.3.** That's where it is in WHO's index to ICD-10 – adopted by over one hundred nations. It's also under G93.3 in the tabular versions of the clinical modifications produced by Canada, Germany, and Australia. It should not be placed in R53.82, under "vague signs and symptoms." We would be the only nation to have CFS in R53.82. Why?

**4. CDC needs to stop using British psychiatrists as consultants and guides to the definition and treatment of CFS.** I am speaking specifically of Simon Wessely, Michael Sharpe, Peter White, and nurse Trudie Chalder. The latter is a specialist in "factitious illness" and "factitious illness by proxy." Is THAT what CDC thinks of us and our disease?

It should be noted from the outset that the British psychiatrists do not use the Fukuda (1994) definition. They use the Oxford definition to diagnose CFS. The Oxford definition requires six months of debilitating fatigue and NO physical conditions that could explain that fatigue. Conversely, psychiatric conditions are NOT excluded from Oxford. I had an email exchange with Simon Wessely in 1996 when he told me that I did not have CFS because I have NMH and Hashimoto's thyroiditis. They also consider a failed Romberg test as exclusionary because it is a sign of neurologic abnormalities – in contrast to my original specialist, Dr. Marsha Wallace, who used my inability to pass a Romberg test as diagnostic for The Disease (as is also true for the Canadian Consensus Definition of ME/CFS.)

The British psychiatric view of CFS is that it is an “inappropriate illness belief.” That is why they prescribe Cognitive Behavior Therapy – not to help patients adjust to the disease, but – in their own words – to “reverse” the disease, to cure the disease. Graded exercise is recommended to get these poor women who have been deconditioned by their inappropriate illness beliefs back into shape and able to return to work and household.

Is THIS what CDC thinks of our disease? If not, why does CDC's website suggest cognitive behavior therapy and graded exercise, perhaps with an SSRI added and something to help patients sleep, as the appropriate treatments for this disease? Why is there a direct link to the website for Peter White's psychiatric practice at St. Bart's hospital in England?

There is another reason that CDC needs to stop using Peter White, Michael Sharpe, and Simon Wessely. All three have close ties with insurance companies. I'm not talking about doing IME's – I'm talking about serious ties. Wessely has been on the Board of Directors of UNUM. Michael Sharpe has written position papers on the disease for UNUM as well. Peter White has been Chief Medical Officer of Scottish Provident the whole time he has been advising CDC. That company was eaten by a British company that was eaten by Swiss RE, and now he is Chief Medical Officer of THAT company. Most recently, White was part of the three-person committee that evaluated the CDC's 5-year-plan for CFS. I looked at his disclosure statement. It said he consulted for insurance companies – but did not say he held an executive office with one. Peter White was also the chief investigator in the multi-million pound disaster called the PACE studies – there isn't enough time for me to explain everything that was wrong with those studies, but I have a copy of a good critique that I'd be happy to give to anyone who wants to read it. The *Lancet* has refused to publish critical letters about PACE, even from the oldest M.E. association in the U.S., the MEA.

What are insurance companies doing with CDC? Could there possibly be a connection between the need for insurance companies to make us disappear – who wants to pay out for a million people needing disability? – and their close ties with the British psychiatrists who have captured the disease in the UK and advise the CDC?

Finally, it was insurance companies who first came up with the name “medically unexplained diseases” (MUS) which has been used by British psychiatrists to label this disease. British psychiatrists regularly use the diagnosis “neurasthenia” (based on an 1869 book called “American Nervousness” that is typical of its day – sexist, racist, and nativist),

but you won't find either neurasthenia or its flip side, hysteria, in DSM-IV because it was deemed heavily gender biased. So Michael Sharpe is chairing a committee that is trying to place a new concept, "CSSD", or "Complex Somatic Symptom Disorder," in ICD-11 and DSM-5. Broken leg time again. I do NOT have a complex somatic symptom disorder. Forgive me if I am displeased with this development. As my husband says, if you can cure her, you can call it anything you want. But a closer look at the PACE trials shows that the combination of CBT and GET has cured NO ONE, even when the Oxford Definition was used to choose most of the subjects in the study.

**5. CDC is going to have to abandon the Reeves questionnaires, which do not diagnose Fukuda 1994 but something else entirely.** They are copies of questionnaires developed by Simon Wessely and Trudy Chalder (says so in the article where Reeves describes them in the first place). It should not be a surprise that they operationalize the Oxford definition, not the Fukuda definition.

CDC has been headed in the wrong direction for a long time. While they have rephrased some of their website so it is not so obviously inappropriate, they still refuse to identify subgroups and they still portray the disease as resulting from stress. **Of everything I have said here, the most important is to change the direction at CDC. Recognize subgroups, because then you can start diagnosing and treating people.**

A million adults have this disease, and untold numbers of teenagers and children. Back in the 1980s, CDC came out to Incline Village, NV, where there was a cluster outbreak, and decided the disease originally thought to be chronic EBV (closer than they knew, actually), SHOULD BE mainly characterized by fatigue. They made this decision in WASHINGTON, not on the site. Then when a group of researchers met to rename the disease, they chose the one coined by Stephen Straus in 1986: chronic fatigue syndrome.

Congress did not charge CDC with defining and identifying a name! They were supposed to be looking at a DISEASE. But patients with the disease, at Incline Village, Lyndonville, Rockland, Atlanta, Miami, Boston, Cherry Hill, and many other places, were left behind while CDC wandered off. Time to return to the patients and what they actually have – not what British psychiatrists and multi-national insurance companies want to SAY we have.

A broken leg is a broken leg. You treat it. There are clinicians in the United States, such as my own specialist Dan Peterson – Nancy Klimas, Lucinda Bateman, Jose Montoya, John Chia, Derek Enlander, Sue Levine, Paul Cheney, Charles Lapp, and very few others – who diagnose and treat the subset of patients who have immune defects and active pathogens, but only those of us who make enough money can afford them. I think that is criminal. It is well past time for CDC to admit to give up on the psychiatric depiction of the disease produced by insurance company hacks, and identify existing subgroups of patients, so that nation can start diagnosing and treating the disease. We lose billions of dollars a year in productivity, billions of dollars a year in income tax revenues, because so many people are too sick to work. Surely we can afford some money to begin to fix it.