

## Public Comment

### Gabby Klein

Hi, I'm Gabby Klein. Thank you, Dr. Nancy Lee and the committee for the opportunity to speak in front of you. I am a 58 year old mother, wife and grandmother. At age 48, I was gainfully employed, cared for my household and was an active member of my community. All this came to a halt on February 11, 2003 when I came down with stomach flu which went on for weeks. Eventually, the stomach issues went away but, new symptoms emerged. I had low grade fever, difficulty sleeping, headaches, muscle pain, noise and light sensitivities. After six months of feeling this way, I was forced to go on disability since I could not even stand at the bus stop waiting for my bus to take me to work.

It took almost two years to get a diagnosis of Chronic Fatigue Syndrome. At that point, I was mainly house bound because my condition was so severe. I was one of the lucky ones in that I found a specialist here in NY who understood my illness and started to treat me for it. He started me on injections of heparin – an anti-viral and B12 for my very high titers of EBV, CMV and HHV6. Unfortunately, they did not do much for me. My doctor explained that had I come to him sooner, my chances of the treatment working would have been greatly increased.

The reason why it took so long to diagnose and why my condition had deteriorated so fast is due to the CDC toolkit for physicians. Based on the toolkit, my GP told me that I either suffer from depression or CFS and it really doesn't matter which one because it is treated the same way: with antidepressants. In addition, he said, I should get out and exercise. I thought that by putting myself in the hands of knowledgeable medical practitioners, I would come to no harm. Yet, this was the start of my downfall. Not only did the antidepressants not work, I became more ill. It just wasted precious time. I tried to push myself physically which started the many crashes that were to become part of my life. This trivialization and misrepresentation of this disease can cause a lot of damage.

For this reason, I feel that the NIH recommendation **of removing the toolkit from the CDC website** is so critical. It is not just a matter of it having some erroneous features, it is a matter of "first do no harm" that any physician takes an oath with. This same toolkit has caused me harm and I am sure thousands of others patients who suffer every day.

I am fortunate that today I am able to deliver this oral testimony. Last year, I couldn't. I was too ill to deliver an oral speech without stuttering and making mistakes. I was bedbound, in severe pain. I would like to speak about this severity because I feel that there needs to be a voice for the estimated 25% of most severe cases of ME/CFS in this country. They have been ignored for too

long. They are not part of the statistics that Dr. Unger talks about when she spoke at the FDA about the latest statistics taken by patients in several clinical settings. Why do we leave them out as if they don't exist? I cannot think of any other lengthy chronic illness which renders their patients bedbound for 10, 18, 30 years! This brings me to the recommendation for the **NIH to fund ME/CFS research commensurate with the magnitude of the problem, and issue an RFA specifically for ME/CFS.** ME/CFS is the most underfunded illness if one compares it to the size of the patient population and the severity of its effects on patients. To compare with MS and Lupus, ME/CFS was budgeted for 2012 with \$6 million dollars compared with \$135 million for MS and \$114 million for Lupus. If one calculates the funding per patient for each of these illnesses, it will show \$270 per patient for MS, \$76 per patient for Lupus and for CFS, there is a mere \$6 per patient.

The third and last recommendation which I feel needs to be addressed is **to hold a stakeholders' workshop to reach a consensus on case definition.** This is so vital because if we are not studying and doing research of patients with the correct criteria, it is all worthless and a waste of money, time and effort. This work should start with the Canadian Consensus Criteria of 2003. One of the reasons that the CCC improved on the CDC's 1994 definition is the fact that it made the symptom of PEM – post exertional malaise a hallmark of the illness. It also takes into account that besides fatigue, other symptoms become aggravated with exertion.

When I was 15 years old, I came down with Crohn's disease. I suffered with the active form for 15 years. I was on a constant dose of steroids and azulfadine drugs. I had to be hospitalized over 20 times in that period. Yet, I finished high school, went to college, got married and gave birth to three children while having Crohn's. Even though, I suffered a lot, I was a functional human being. With Chronic Fatigue Syndrome, my functionality, my dignity and my hope has been taken away from me.

