

Written Testimony for the May 2010 CFSAC Meeting by Jerrold Spinhirne

First, I would like to thank the Committee for their service. I hope these meetings can continue to provide valuable input to the CDC's CFS program. I request that the Committee's charter be renewed and outgoing members be replaced in a timely fashion. I would prefer that the time allotted to each person testifying be increased to a combination ten and five minute slots. I don't think three minutes is adequate. I, also, would like to thank Dr. Wanda Jones of the Department of Health and Human Services for conducting last October's meeting and providing a webcast which allowed me to see the meeting on my bedside laptop. The videos from that meeting are now available on the Internet and are a valuable resource.

I will be using the term ME/CFS to refer to the actual disease, as defined by the 2003 Canadian criteria (Caruthers, 2003), and CFS to refer to the syndrome created by the CDC that has various case definitions.

I believe I acquired ME/CFS in October 1996. I say "believe" because I could not find a doctor in Chicago who could come up with a diagnosis for my symptoms – severe cognitive impairment, frequent muscle and joint pain, recurrent swollen and tender lymph nodes, disturbed sleep, dizziness on standing, and lack of stamina when performing mental or physical tasks. Whenever I would exert myself at some task beyond a certain level, I would need several days of rest before being able to resume my normal level of activity.

I was a licensed structural engineer in charge of the structural design of large buildings. After one week of a flu-like illness in October 1996, I returned to my job and was no longer able to make any sense of my work. I have never been able to work full-time again. I was unable to pursue my career after nine years of university education and many years of experience. I wasn't able to take part in many of the activities that I enjoyed. None of the treatments I was offered had any lasting benefit. Several doctors encouraged me to exercise. I had been an amateur marathoner so I resumed my running.

Unlike before my illness, I experienced no "training effect." Formerly, every spring after a winter layoff and some de-conditioning, I was used to experiencing several uncomfortable weeks before running became enjoyable again. I would gradually increased my usual run before work to six miles and my weekend run to ten miles. By the end of summer, I gradually increased my weekend run to over 20 miles in preparation for the fall marathon. After my illness in 1996, none of this applied. Running never became enjoyable. After jogging a mile one day, it was several more days before I could attempt

to run again, and then it was like starting from scratch. So, I started walking. Any attempt to increase my walking distance resulted in days of incapacity.

In the fall of 2004, my symptoms started to become more severe. I was suddenly unable to read, which was one of my greatest pleasures, and could write only with great difficulty. Any exertion put me in bed for days. I read about something called chronic fatigue syndrome and sought help from a doctor, who claimed to have a special interest in CFS, at a downtown university medical center. I was greeted with contempt and disbelief when I presented my symptoms to this doctor. I was barely able to stand, and he told me to “get some exercise.” In January 2006, ten years after my illness began, I finally found an integrative physician in Chicago who recognized my symptoms and diagnosed me with CFS.

I was initially relieved to be diagnosed with CFS. I naively thought I was finally going to get some real help. I soon learned that the majority of the medical community regards CFS as a wastebasket diagnosis and no effective treatment is available. I told my dentist, when I was having difficulty getting up from her chair, that I had chronic fatigue syndrome. She replied, “You should take some Geritol.” Now, if someone needs to know about my illness, I say it’s a form of MS or a neuro-immune disease. Most people in Chicago, in my experience, still have never heard of CFS, and if they have, they think it doesn’t really exist or it’s some kind of mental disorder. This, unfortunately, is true even with friends and family.

I have yet to find a doctor in Chicago who understands the seriousness of ME/CFS and treats it according. I am physically unable to travel to the handful of doctors in the US who are experienced in treating ME/CFS. If I were, I could not afford the financial costs.

I believe the failure of most doctors to recognize ME/CFS and strongly warn patients against over-exertion stems from the CDC’s flawed case definition of CFS. The most commonly used case definition is the 1994 Fukuda (Fukuda, 1994) “Unexplained persistent or relapsing chronic fatigue” is required and any four of the following eight symptoms.

- substantial impairment in short-term memory or concentration
- sore throat
- tender lymph nodes
- muscle pain
- multi-joint pain without swelling or redness
- headaches of a new type, pattern, or severity
- unrefreshing sleep

- post-exertional malaise lasting more than 24 hours

Note that post-exertional malaise is not a requirement, if four of the other seven symptoms are present in addition to chronic fatigue. Post-exertional malaise is required for a ME/CFS diagnosis using the Canadian criteria. Post-exertional malaise, or exacerbation of symptoms, is the defining feature of the disease. How can the CDC still not make PEM a requirement in its case definition?

Chronic fatigue and two of the eight symptoms, concentration impairment and sleep disturbance, overlap with the symptoms required by DSM-IV for a diagnosis of Major Depressive Disorder. Therefore, some patients with *only* Major Depressive Disorder with muscle and joint pain would meet the Fukuda criteria for CFS. The CDC's definition of CFS lacks specificity – patients with more appropriate diagnoses are included, as are patients with idiopathic chronic fatigue and somatic complaints. How is a doctor to make a differential diagnosis with only guidance from the CDC?

In 2005, the CDC attempted to operationalize the flawed Fukuda case definition for research (Reeves, 2005). This was the so-called empirical definition. A study has shown that the empirical definition allowed 38% of those with Major Depressive Disorders to be classified as having CFS (Jason, 2008). This definition produced a 10-fold increase in prevalence rates for CFS (Reyes, 2004; Reeves, 2007). With such a stunning increase, it is difficult to believe this attempt was made in good faith. One has to wonder just what it is that the CDC has been studying for over 20 years.

Case definitions are vitally important in research. The empirical definition was used in a 2009 study (Heim, 2009) allegedly linking childhood abuse and CFS. What validity can such a study have when most of the subjects didn't even meet the Fukuda criteria for CFS? Yet, the CDC features the Heim study on its Chronic Fatigue Syndrome web page (<http://www.cdc.gov/cfs/>) as if it were a meaningful piece of research .

Researchers outside of the CDC are now beginning to use the Canadian criteria in selecting a research cohort. Any subject meeting the Canadian criteria will also meet Fukuda. However, subjects experiencing only common fatigue and somatic symptoms are more likely to be excluded if the Canadian criteria is used. The Whittemore Peterson Institute, where the study finding an association between the human retrovirus XMRV and ME/CFS (Lombardi, 2009) was done, uses the Canadian criteria. The CFIDS Association of America in its promising BioBank research program uses the Canadian criteria. The CDC should follow their lead.

The lack of specificity in defining CFS has allowed psychiatrists in the UK, with no special expertise in neuro-immune diseases, to claim their anachronistic theories of CFS are supported by science. A research cohort can be deliberately selected in which very few subjects actually have any physical disease. A study on this cohort then finds CFS has psychosocial causes and that behavioral treatments are appropriate. The lack of a rigorous case definition by the CDC, which has a worldwide influence, makes this possible.

The most common behavioral treatment offered is graded exercise therapy (GET), usually combined with a form of cognitive behavioral therapy (CBT) that encourages patients to overcome their “illness beliefs.” If CBT/GET were a drug, it would not be found to be safe or effective for ME/CFS by the FDA. Yet, the CDC links on its website a paternalistic GET pamphlet by St. Bartholomew’s Hospital, London which states,

You may be worried that any increase in exercise or physical activity could make your condition worse. Be reassured - research has shown that a guided, gradual exercise programme can help people who suffer from CFS/ME without causing ill effects.

The research referred to would not meet CDC standards so why should the CDC legitimize it? CBT/GET, in fact, has great potential for harming ME/CFS patients. The risks involved simply do not justify anyone recommending it for ME/CFS. The necessary activities of daily life are already more than many patients can safely handle. I believe if I had been properly diagnosed with ME/CFS in 1996 and warned against the possibility of causing serious damage by continuing to exercise, I would not be as severely disabled today.

I hope under new leadership the CDC’s CFS program will begin to correct the tragic mistakes of its past. There needs to be a reemphasis on the pathogenic theory of disease and alterations in the immune system. The CDC should carefully review the information on its Chronic Fatigue Syndrome website. Research using the empirical definition should be removed or clearly marked that the empirical definition was used. Links to the inappropriate UK NICE guidelines should be removed. Patients and doctors should be warned not only to avoid the “push-crash cycle” but that over-exertion of any type, including graded exercise, runs the risk of causing serious harm.

I believe current XMRV research holds great promise. I would like to see a dramatic increase in ME/CFS research funding. I hope that the CDC can be a part of that future.

References

Carruthers B, et al: Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Clinical Working Case Definition, Diagnostic and Treatment Protocols. *Journal of Chronic Fatigue Syndrome* 2003, 11:7-115.

Fukuda K, Straus SE, Hickie I, Sharpe MC, Dobbins JG, Komaroff A. The chronic fatigue syndrome; a comprehensive approach to its definition and study. *Ann Int Med* 1994, 121:953-959.

Heim C, Nater UM, Maloney E, Boneva R, Jones JF, Reeves WC: Childhood trauma and risk for chronic fatigue syndrome: Association with neuroendocrine dysfunction. *Archives of General Psychiatry* 2009; Vol. 66 (1): 72-80.

Jason, LA, Najjar N, Porter N, Reh C. Evaluating the Centers for Disease Control's empirical chronic fatigue syndrome case definition. *Journal of Disability Policy Studies* 2008, doi:10.1177/1044207308325995.

Lombardi VC, Ruscetti FW, Das Gupta J, et al.: Detection of an infectious retrovirus, XMRV, in blood cells of patients with chronic fatigue syndrome. *Science* 2009, 326:585–589.22.

Reeves WC, Wagner D, Nisenbaum R, Jones JF, Gurbaxani B, Solomon L, Papanicolaou DA, Unger ER, Vernon SD, Heim C. Chronic fatigue syndrome – a clinically empirical approach to its definition and study. *BMC Med.* 2005 Dec 15;3:19.

Reeves WC, Jones JF, Maloney E, Heim C, Hoaglin DC, Boneva RS, Morrissey M, Devlin R. Prevalence of chronic fatigue syndrome in metropolitan, urban, and rural Georgia. *Popul Health Metr.* 2007 Jun 8;5:5.

Reyes M, Nisenbaum R, Hoaglin DC, Unger ER, Emmons C, Randall B, Stewart JA, Abbey S, Jones JF, Gantz N, Minden S, Reeves WC: Prevalence and incidence of chronic fatigue syndrome in Wichita, Kansas. *Arch Int Med* 2003, 163:1530-1536.