

Testimony

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Over and over again, this Committee has made recommendations to the Secretary of the Department of Health and Human Services and no significant changes have resulted to the CDC's CFS program or the quality of medical care available to patients. There have been no substantial increases in research funding for the disease. Over and over again, it has been shown that after 26 years, the CDC does not even have a workable case definition or appropriate name for this disease. The CDC has no idea of the prevalence rate, the pathogenic agent, the etiology, the transmission, the criteria for a differential diagnosis, or the appropriate treatment for this disease.

This fall, the CDC had the opportunity to appoint a new CFS director and to change the course of its wayward program. This disease and its long suffering patients have been neglected, or put off with unfunded promises, for too long. There is now evidence that a new family of human gamma retroviruses is associated with the disease and may be spreading through the population. The new director needed to be a strong and bold leader with new ideas how to engage with the best minds in the field and attract new talent to develop this important finding. The CFS program needed to be completely redesigned, restructured, and reenergized.

Patients are weary of hearing sorry excuses such as the CFS program can't do virology because that's in another building. The new leader needed to be able to cut through these structural roadblocks and work across disciplines. The diagnosis and treatment guidelines found on the CDC's website need to be completely redone using the best information available based on medical science and clinical experience. Clinical trials of promising drugs need to begin. Doctors, hospitals, and emergency rooms need to be informed of the true nature of the disease and the critical medical issues common to CFS.

There was much to be done to correct the mistakes of the past. The new leader needed to be an exceptional person free of accumulated CFS dogma. But what happened? The CDC chose to continue with business as usual and appointed one of its own as the new CFS director – someone who had participated in the program's past mistakes and who wishes to continue exploring nebulous mind-body phenomena and CFS.

How unproductive, harmful, and oblivious does an agency program have to be before the DHHS takes decisive action to correct it? Clearly, based on the choice of new director, the CDC is incapable of reforming itself. Authority from outside the agency is necessary to stop this waste of public money and waste of desperately ill patients' lives. It is not a question of interference with science. The CDC program only uses the appearance of science to support its biased policy of no specific medical testing or treatment for CFS. Any science which contradicts this policy is ignored or dismissed. With the current CDC structure and policies, there is no chance of making any progress on this disease.

Twenty-six years after the CDC first sent investigators to Incline Village, Nevada, the CDC still does not have a workable case definition for the disease they found there. The CDC's 1994 Fukuda, or International, CFS case definition fails to define the disease usefully for either research or diagnosis. It forces doctors to give a CFS diagnosis to patients suffering from the serious neuroimmune disease myalgic encephalomyelitis. At the same time, the definition – only requiring any four of eight poorly described symptoms plus “fatigue” – allows researchers to select “CFS” subjects with only depressive disorders and none of the characteristic symptoms of the neuroimmune disease.

The problem is that the only required symptom is fatigue. Fatigue is a common symptom of many diseases and is difficult to clearly define. Other specific symptoms must be required for a meaningful case definition. The CDC's 26-year failure to adequately define the disease has created an absurd situation. Patients with a serious neurological disease can only be diagnosed by doctors as having CFS while CFS research and treatment recommendations are based on a groups of subjects largely without the disease.

The CDC's vaunted Wichita and Georgia CFS research cohorts should be abandoned. The CDC squandered millions of dollars developing these population-based research groups composed mostly of depressed, inactive people, which the CDC labeled as having CFS. It has been shown repeatedly by independent research that the subjects in these cohorts do not even meet the CDC's own prior flawed CFS criteria.

The CDC's methodology used in its population studies was biased and inappropriate. The use of random phone calls, questionnaires, and interviews in a clinical setting to identify people with CFS assumes everyone with CFS is not so severely affected they are able to answer phone calls, accurately answer questions, and leave their homes, if selected. This assumption is totally unwarranted. Anyone

experienced with the disease knows that many patients are severely disabled. A significant number are homebound, or completely bedridden. Cognitive impairment and rapid exhaustion performing simple tasks are common features. Some live alone and do not answer phone calls from unknown callers. The severely affected could not participate in days of testing away from their homes, even if they were contacted.

The CDC's population studies were hopelessly biased even before they began. The most severely affected patients are absent from CDC's CFS research groups. The CDC research cohorts are, therefore, unrepresentative and unreliable. Combined with the "empirical" use of questionnaires, which lacked specificity, to select CFS subjects, the CDC has produced useless mixed research cohorts. This mixture of subjects labeled CFS is only useful to psychogenic theorists and others who wish to promote ineffective and harmful behavioral treatments for all CFS patients, such as CBT and GET. The CDC should be prevented by the DHHS from using their Wichita and Georgia cohorts in any further CFS studies, or as part of their five-year strategic research plan.

The consequence of the lack of a coherent CFS case definition was evident at the April NIH ME/CFS State of Knowledge Workshop. The search for biomarkers has produced inconsistent results because inconsistent groups of patients are being studied. It should be clear to the NIH that if ME/CFS research is to progress, the Canadian Consensus case definition, which has symptom requirements beyond fatigue, should be used. It is very important to note that the two potentially most significant studies in the history of CFS, which found a strong association between CFS and a new family of infectious human gamma retroviruses, HGRV, did not rely on the CDC's current case definition to select subjects.

In 2005, the Committee's Recommendation 10 stated: "We would encourage the classification of CFS as a 'Nervous System Disease,' as worded in the ICD-10 G93.3." The upcoming US clinical modification which the CDC controls is proposing to code CFS (Chronic Fatigue Syndrome NOS) in the R codes for unspecific signs and symptoms. The codes for the US version, ICD-10-CM, are scheduled to be frozen beginning October 1 of this year. The Committee must act now if they wish to bring the US into agreement with the World Health Organization which codes CFS with Benign Myalgic Encephalomyelitis in G93.3, Nervous System Diseases. Allowing CFS to be included in the nonspecific ICD R codes of the US ICD-10-CM will detrimentally affect how the disease is perceived and how patients are treated. Patients with the neurological disease myalgic

encephalomyelitis can only be diagnosed with CFS in the US. The US ICD codes should reflect this reality.

The tragedy of the CDC's years of bungling and face saving is that thousands of terribly ill patients, limited and disabled by neuroimmune disease, are diagnosed with CFS by doctors who have no choice but to follow the CDC's guidelines. The CDC recommendation that no tests for immune dysfunction or pathogens be performed to help doctors diagnose and treat the disease has no scientific basis. The handful of doctors in the US who understand the true nature of the disease are not accessible to the majority of patients. If any doctors can be found willing to treat CFS, it is likely they will only follow the CDC guidelines which recommend no specific medical tests or significant treatment.

Doctors need to be provided with clear and specific diagnostic guidelines so that they can catch the disease in its early stages and in children. CFS only as a diagnosis of exclusion is a myth perpetuated by the CDC. Doctors should be advised to strongly caution CFS patients against overexertion and standard exercise to limit the disability caused by the disease. Hospital and emergency room personnel need to be informed and aware of the special medical issues of CFS patients. The much more comprehensive and scientifically based Canadian Consensus ME/CFS clinical guidelines should be recommended to physicians by the DHHS to help counteract the years of unscientific CFS misinformation from the CDC.

What does it take to begin correcting the injustice to CFS patients caused by the CDC's intransigence for over a quarter century? Are they accountable to no one? Doesn't the government care that people are being denied their basic human right to appropriate medical care? Is it only the patients, their advocates, and a few dedicated doctors and researchers who can see what a tragic mess the CDC has made of this disease?

I thank the Committee and hope these comments are useful to them.