

# Request for Congressional Action

## Brief picture of the Myalgic Encephalomyelitis/Chronic Fatigue Syndrome situation:

In 20 years time, the toll has risen to over 1 million victims in the US alone & millions more worldwide. US health agencies have not addressed this danger to public health nor sought to find the cause or remedies for the suffering. These health agency policies have ignored past research in this disease, patients are systematically denied medical services, and US MDs are misinformed about this disease. These policies impact the health of those disabled by M.E./CFS and continue to place everyone at risk. **A principal issue must not be overlooked: Why has M.E./CFS exploded into a worldwide epidemic, and what is the inordinate fear of the DHHS to recognize this and discover its cause?**

All Americans would benefit by our government health agencies using their publicity contracts effectively to distinguish between idiopathic chronic fatigue of undetermined pathology and the neurological disease Myalgic Encephalomyelitis/CFS delineated in the 2003 Consensus Criteria for ME/CFS (see international consensus criteria at: [http://www.mefmaction.net/documents/me\\_overview.pdf](http://www.mefmaction.net/documents/me_overview.pdf)), which supports historic worldwide M.E. definitions.

*"I have treated more than 2,000 AIDS and CFS patients in my career. And the CFS patients are MORE sick and MORE disabled every single day than my AIDS patients are, except for the last two months of life!" Dr. Marc Loveless who testified under oath in testimony before Congress in 1995*

*"In my experience, (ME/CFS) is one of the most disabling diseases that I care for, far exceeding HIV disease except for the terminal stages" Dr. Daniel L. Peterson: Introduction to Research and Clinical Conference, Fort Lauderdale, Florida, October 1994*

The neurological coding for Myalgic Encephalomyelitis has been in the WHO International Classification of Diseases since 1969 (first identified in 1934), but it was ignored by the CDC epidemiologists when a few notable outbreaks of the disease occurred in the late 1980s, one of the outbreaks among children in Lyndonville, NY. Instead of making use of a half-century of research & clinical information available about Myalgic Encephalomyelitis and its epidemic nature, the CDC and NIH chose

to focus on the non-medical criteria "fatigue," leading to the mistaken impression both within and without the agencies that "CFS" was a psychosomatic or minor illness when ample evidence to the contrary was available (ref: Osler's Web, by Hillary Johnson).

The coining of the term "chronic fatigue syndrome," was a way to ignore a fully recognized international disease and instead substitute a very common symptom in many serious disorders, and a symptom healthy people recover from easily. And there is now a public relations campaign taking place at the CDC that ignores the neurological coding & historic epidemics, & instead places the disease in the all-encompassing category of "fatiguing illnesses" which buries solid research into the clearly defined disease, Myalgic Encephalomyelitis/CFS. The research case definition for CFS (Fukuda et al., 1994) developed by CDC encompasses a very heterogeneous population. Dr. Jason has requested removal of the present case definition and drafting a new one based on actual observations, rather than vague impressions, which is what the CDC committee has done.

For 20 yrs., CDC and NIH have not responded to many requests by ME/CFS patients, caregivers, researchers & clinicians for truth-telling & proper recognition of this serious neuroimmune disease.

Ignored by the very agencies that are charged with addressing public health issues such as this, we remain disabled, misunderstood, denied sensible treatment, & unable to return to economic productivity, a burden on our families & society as a whole. Dr. Leonard Jason recently showed the economic impact of ME/CFS in a community based versus tertiary based sample, estimating that the direct and indirect costs of ME/CFS in the US are \$22-28.6 billion annually.

*Dr. Leonard Jason from DePaul University, Chicago, wrote that it is regrettable that the disorder is portrayed in such a narrow way, and that flaws in the case definitions of 'CFS' have led to "inaccurate and biased characterization of ME/CFS which incorrectly favors a psychiatric view of the illness". He correctly pointed out "the erroneous inclusion of people with primary psychiatric conditions in ME/CFS samples will have detrimental consequences for the interpretation of treatment efficacy findings". (This has happened, with many research patient pools mistakenly including people who have primary psychiatric conditions & do not meet the internationally-accepted Consensus Criteria for ME/CFS.)*

## What can be done by Congress in this situation?

### 1. What to do about CDC misinformation & mismanagement of research:

#### Name & Criteria & ICD Coding

CDC needs to relinquish the “fatiguing illness” construct for patients who meet the criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) & allow the development of solid criteria based on the 2003 Consensus Criteria for ME/CFS so that clear patient cohorts can be identified for research purposes. (Note: The terms Myalgic Encephalomyelitis or ME/CFS are used internationally to ensure the distinction between Chronic Fatigue Syndrome (CFS) as classified in the World Health Organization’s International Classification of Diseases (Re: severely debilitating organic neurological disorder Myalgic Encephalomyelitis—ICD9 CM 323.9/ICD10 CM G 93 .3) versus the politically & financially motivated, all-encompassing & broadly-defined ‘fatiguing’ version of CFS—R53.82, a wastebasket code, or Ill-Defined Conditions 780.71--two entirely different problems.)

*Expert Testimony: "The worst cases have both an MS-like and an AIDS-like clinical appearance. The most difficult thing to treat is the severe pain. Most have abnormal neurological examination. 80% of cases are unable to work or attend school. We admit regularly to a hospital with an inability to care for self." Paul Cheney, Professor of Medicine, Capital University, USA: Testimony Before the FDA Scientific Advisory Committee, 18 February 1993*

*"The NK (natural killer) cell is a very critical cell in (ME)CFS because it is clearly negatively impacted. The most compelling finding was that the NK cell cytotoxicity in (ME)CFS was as low as we have ever seen it in any disease. This is very, very significant data. (In (ME)CFS) the actual function was very, very low --- 9% cytotoxicity: the mean for the controls was 25, In early HIV and even well into ARC (AIDS related complex, which often precedes the fully developed condition), NK cytotoxicity might be around 13 or 14 percent. (ME)CFS patients represent the lowest cytotoxicity of all populations we've studied."*

*Nancy Klimas, Professor of Medicine, University of Miami School of Medicine; Director of Immunology; Director of AIDS research and Director of the Allergy Clinic at Miami.*

The CDC’s coining of the phrase “chronic fatigue syndrome” was an attempt to ignore outbreaks of a real disease, Myalgic Encephalomyelitis, as well as an attempt to downgrade the condition to a stress-based psychological condition. This misinformation continues & was part of a recent public awareness campaign about CFS by the CDC to try to distract with their latest flawed research attempting to place the blame for the disease on genetic inability to handle stress. In contrast gene studies in the UK have shown immune system problems (Dr. Jonathan Kerr’s team has identified viruses that may perpetuate the disease, which fits with some current thinking that it results from a persistent infection. And, in fact, the two medications shown to bring about improvement in most patients are both antivirals, thus demonstrating that the problem is viral and not psychiatric in origin. Dr. Kerr’s gene expression studies are finding three main abnormalities in ME/CFS patients: these involve the immune system, mitochondrial function and G-protein signaling. There are seven genes upregulated in ME/CFS - those associated with apoptosis, pesticides, mitochondrial function, demyelination and viral binding sites.)

The false CDC construct of “fatiguing illnesses” and their 1994 Fukuda criteria (and their recent telephone questionnaire) become a wide net that catches a large number of patients who experience the symptoms of burnout, thyroid problems, or other medical issues which are incorrectly mixed with the clear and identifiable criteria of the

*Expert Testimony: "I take great issue with the current recommendations that no additional testing should ever be done. I believe there are indications for more advanced testing" Dr. Daniel Peterson: [a Diplomat of the American Board of Internal Medicine who first identified CFIDS during an outbreak in Incline Village, Nevada, in 1984] JCFS 1995: 1:3-4:123-125). At the Second World Congress on ME/CFS and related disorders, held in Brussels in September 1999, Peterson said he was amazed at the misconceptions that existed about ME/CFS; he said that ten years ago, he believed ME/CFS would be resolved by science; he had now changed his mind and believed it could only be resolved by politics)*

neuroimmune disease Myalgic Encephalomyelitis/CFS, i.e., muscle myopathy (loss of muscle power) diagnostically tested by means of bicycle ergometry testing, neurological diagnostic testing (brain SPECT scans, PET scans & QEEG scans) showing brain hypoperfusion, the neurocognitive abnormalities definitively identified through neurocognitive testing, and the immune system dysregulation (several tests). In contrast, the CDC website counsels doctors that there is no definitive diagnostic testing and that the above listed tests are unnecessary. **This is an ever-present danger for patients and a**

**disservice to medical doctors who would like to treat the disease properly.**

## 2. What to do about Placement of ME/ICD-CFS at the NIH:

*Proper placement & recognition of neurological coding of M. E. & appointment of a standing committee for approval of research projects*

The NIH places the disease in the area of Office of Women's Health even though **25% of patients are male**. Just as in 1950, MS patients asked Congress to have the disease MS (formerly called Faker's Disease or Hysterical Paralysis) placed in the area of Neurological Disorders, so also Myalgic Encephalomyelitis, exhibiting detrimental effects on the central nervous system, has a neurological ICD coding and should be placed in this section of the NIH and given a standing committee to approve research projects rather than an ad hoc approval committee as things now stand. (In 1950, the MS Society persuaded Congress to establish a special section of the National Institutes of Health, now called the National Institute for Neurologic Disorders and Stroke (NINDS).

In the case of Myalgic Encephalomyelitis/CFS, there is ample evidence of neurological abnormalities: (<http://www.co-cure.org/neuro.pdf>) and also ample evidence of immunological abnormalities: (<http://www.co-cure.org/immuno.pdf>). Thus, this disease at NIH is misplaced in the Office of Women's Health.

## 3. What immediate actions need to be taken

Require the CDC and NIH to formally adopt the 2003 Myalgic Encephalomyelitis/Chronic Fatigue Syndrome Clinical Working Case Definition Diagnostic and Treatment Protocols; A Consensus Document: ([http://www.mefnaction.net/documents/me\\_overview.pdf](http://www.mefnaction.net/documents/me_overview.pdf)) to replace the present inadequate and inaccurate 1994 Fukuda criteria (proven ineffective by Dr. Leonard Jason in the study cited above. At the same time, implement the internationally accepted name Myalgic Encephalomyelitis/CFS to accurately describe what is currently known about the disease.

Instruct the CDC to update the information it disseminates to reflect the World Health Organization classification (Myalgic Encephalomyelitis/CFS in the ICD-10 under the neurological classification G93.3)

*Expert Testimony: "Abnormalities of immune function, hypothalamic and pituitary function, neurotransmitter regulation and cerebral perfusion have been found in patients with (ME/CFS). Recent research has yielded remarkable data. The symptoms of (ME)CFS have long been viewed as a neurologic pattern, as confirmed by other names such as myalgic encephalomyelitis. A link is being forged between the symptoms pattern of (ME)CFS and objective evidence of central nervous system dysfunction. The view that (ME)CFS is a primary emotional illness has been undermined by recent research" Dr. David S Bell: Instructor in Pediatrics, Harvard Medical School: Chronic Fatigue Syndrome update: Findings now point to CNS involvement: Postgraduate Medicine 1994;98:6:73-81) Dr. Bell was the M. D. dealing with the epidemic of Myalgic Encephalomyelitis/ICD-CFS in Lyndonville, New York involving both children and adults.*

## **Why doing this makes sense & Why Congress needs to intervene now**

1. Clear research cohorts can be identified in order to find the cause of the disease, so that the small amount of research money can be used wisely and without resorting to psychiatric explanations for a biomedical condition.
2. Early detection can be established rather than waiting for six months of fatigue in the CDC criteria which can result in less disability and less money lost by the country in regard to lost productivity
3. Patients can be treated more efficiently and correctly, and MDs can be presented with clearly defined criteria so they are not in the position of disbelieving patients and being confused by CDC "fatiguing illnesses" constructs. The 2003 Consensus Criteria can be used to clearly diagnose patients rather than the present scattershot approach of the CDC, and also three or four definitive tests can be run to clearly identify patients as Myalgic Encephalomyelitis/CFS: brain neuro SPECT or PET scan, neurocognitive testing, Natural Killer Cell Function test, and the Rnase-L antiviral dysregulation testing.