

Submission by MEadvocacy.org

Prepared for the Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies

Regarding the Department of Health and Human Services' Myalgic Encephalomyelitis Policy

**There is an urgent need for a systemic overhaul at the Department of Health and Human Services (HHS), including the National Institute of Health (NIH) and the Centers for Disease Control (CDC), in regards to its funding and handling of the disease myalgic encephalomyelitis (ME)**

Dear Ladies and Gentlemen of the Committee:

The Department of Health and Human Services is the U.S. government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. Yet, in the past three decades, HHS, NIH and CDC have neglected and mistreated over a million severely disabled patients suffering from the disabling chronic disease myalgic encephalomyelitis (ME).

Thirty years of malfeasance, misfeasance, neglect, and incompetence by HHS has rendered ME patients frustrated and disgruntled. They remain invisible, misunderstood and extremely sick. Advances in the science of the disease have been mostly squashed by the gross lack of funding by NIH for this severely disabling disease. In addition, misinformation and badly outdated information published by the CDC, along with the lack of education about the disease in medical schools, have caused a dearth of palliative care for patients nationwide. Most importantly, after 30 years, we still are not any closer to finding a possible treatment or cure to help the millions of ME patients.

MEAdvocacy.org is a growing grassroots movement of advocates and patients who are rising up and saying we have had enough of empty promises and lies. We want the right to life, liberty, and the pursuit of happiness that is afforded to us by the Declaration of Independence. We want the same chance at life and health as patients who suffer from other similarly burdened diseases. We are lawyers, laborers, teachers, students, fathers, mothers, and children. Our productive lives have been cut short by this debilitating disease and we have no hope of treatment or cure. We have had enough and are saying, "**No More!**"

### **ME Incidence and Prevalence:**

Myalgic encephalomyelitis, also known in the U.S. as chronic fatigue syndrome (CFS) and myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), is a seriously disabling neuro-immune disease. It sickens an estimated 850,000 to 2.5 million in the U.S. and 17 million worldwide. A majority of patients are disabled, unable to work, attend school or participate in activities of daily life. A quarter are so severely affected as to render them bedbound, unable to care for themselves.

### **ME History, Criteria and Name:**

ME has a long history, appearing worldwide in epidemic and endemic forms. A 1955 outbreak in London resulted in [Dr. A. Melvin Ramsay](#) (1) describing it as an **infectious** neuromuscular illness and coining the term "myalgic encephalomyelitis." Disregarding this, the CDC broadly redefined the disease and renamed it chronic fatigue syndrome (CFS) in response to 1985 cluster outbreaks of the disease in Incline Village, Nevada and Lyndonville, New York. This redefinition resulted in three decades of confused research findings rather than answers to the cause and treatment of this disease. In addition, the undignified name and poor criteria caused stigmatization and marginalization of patients.

HHS had been aware of these problems for years, yet stubbornly refused to act. It disregarded almost all advice from its own Chronic Fatigue Syndrome Advisory Committee (CFSAC)(2). It ignored specific requests by CFSAC, medical experts, patient advocates, patients and their families to adopt ME expert-authored, well-defined criteria for the disease. In direct opposition, HHS announced on September 23, 2013 a secretly negotiated contract with the Institute of Medicine (IOM) to redefine and re-brand this disease despite Dr. Nancy Lee, Director of the Office of Women’s Health, stating earlier that year that Secretary Sebelius had specifically told her that the government was “not in the business of setting criteria for diseases.” HHS disregarded the fact that historically it is the expert medical community, not the government, who delineate criteria for diseases. Case definitions are a clinical decision that should come from the clinical community.

The IOM report was published on February 10, 2015, and outlined new criteria that are again overly broad and unrestricted. They omit exclusionary criteria and even differential diagnostic suggestions to guide clinicians in making accurate diagnoses. Some experts believe the new definition will capture people with major depression, autoimmune diseases and cardiopulmonary disease. At the clinical level, the result will be tragic for patients who receive inappropriate advice and, as our history has already proven, it will be disastrous for the clarity of findings if this overly inclusive criteria is used for research. The new recommended name, “Systemic Exertion Intolerance Disease (SEID)”, repeats the same error that the CDC made thirty years ago, which was attempting to describe the disease by one of its many symptoms.

**Disease Burden and Funding:**

Some ME patients have died prematurely from complications of ME. Others have died at their own hands due to the severity and length of their suffering without proper palliative care, as well as dismissal and stigmatization by the medical community. If we do not act on behalf of these severely affected patients, we are complicit in their suffering and untimely deaths. The patients will not carry this burden quietly any longer and we are looking at Congress to require HHS to properly fulfill their duty to ME sufferers.

In 2009, Dr. Nancy Klimas, the director of AIDS research at the Miami Veterans Affairs Medical Center stated:

My H.I.V patients for the most part are hale and hearty thanks to three decades of intense and excellent research and billions of dollars invested. Many of my CFS patients, on the other hand, are terribly ill and unable to work or participate in the care of their families. I split my clinical time between the two illnesses, and I can tell you if I had to choose between the two illnesses, (in 2009) I would rather have HIV. But CFS, which impacts a million people in the United States alone, has had a small fraction of the research dollars directed towards it.  
<http://consults.blogs.nytimes.com/2009/10/15>

In the intervening 6 years, nothing has changed. It is very clear that real change at HHS regarding this disease will not come about naturally. We have come to you, the Appropriation Committee, for help in addressing this dire need for oversight and investigation.

It is estimated that the burden to the economy for ME is between \$17 to 24 billion, yet NIH funding for research has stagnated at a mere \$5 million a year, less than funding for hay fever. HHS has placed funding for ME at the rock bottom of their [funding budget list](#)(3). The yearly allocation for ME/CFS is a fraction of what other similarly burdened diseases receive.

<u>HHS/NIH funding data for 2014</u>	<u>US patient population</u>	<u>Funding per patient</u>
<i>HIV/AIDS - \$2 billion 978 million</i>	<i>1,200,000</i>	<i>\$2,481</i>
<i>M.S. - \$102 million</i>	<i>400,000</i>	<i>\$255</i>
<i>Parkinson’s - \$139 million</i>	<i>1,000,000</i>	<i>\$139</i>
<i>Alzheimer’s \$564 million</i>	<i>5,300,000</i>	<i>\$106</i>
<i>ME/CFS - \$5 million</i>	<i>1,000,000</i>	<i>\$5</i>

The great divide between NIH funding for ME and other diseases cannot be explained away. Simply advising and recommending that NIH increase funding for ME, has not worked. The Secretaries of Health and Human Services have not responded to most of the 77 recommendations made by the Chronic Fatigue Syndrome Advisory Committee during the past ten years. The department did not heed the call by President Obama as a result of a call out at a townhall meeting by the wife of a patient. It has not listened to the many recommendations by this Appropriation Committee over the past twenty years. In order to fund ME on par with MS, a similarly serious disease, ME would need \$250 million a year. Perhaps a sliding scale of allocation from other diseases related to immune, cognitive and nervous system dysfunctions could be utilized by this committee to find the additional funding needed for ME.

We cannot continue with the same path and expect a different result; that would be insanity. We need a different approach and a complete overhaul at all agency levels. We need an investigation by Congress into the mishandling and neglect of Myalgic Encephalomyelitis by HHS, NIH and CDC and active, ongoing Congressional oversight until HHS' negative bias is rectified.

The following are the recommendations and goals that we at MEadvocacy.org feel the Appropriations Committee needs to require that HHS meet, in order to bring Myalgic Encephalomyelitis back on par with other similarly burdened diseases:

- 1. Fund biomedical research for ME commensurate with its severity and burden to patients and the economy. We are asking for specific funding in the amount of \$250 million, the amount we believe is needed to bring ME on par with other similarly burdened diseases. HHS should clearly allocate funds to study patients from past ME cluster outbreaks as well as the study of the epidemiology of patients with severe ME. The additional funding needed for ME might be accomplished by means of a sliding scale of allocation from other diseases related to immune, cognitive and nervous system dysfunctions.**
- 2. Heed the ME stakeholders' request to adopt the diagnostic and research criteria authored by those experienced in the disease, namely the 2003 Canadian Consensus Criteria ([CCC](#))(4), which has been adopted by the International Association of Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis ([IACFS/ME](#))(5). In a letter to the Secretary of HHS, [50 experts](#)(6) in the disease declared their consensus agreement to adopt the CCC. This was endorsed by a letter signed by [171 advocates](#)(7) as well as a [petition](#)(8) signed by over 6,000 patients. The 2011 revision known as the International Consensus Criteria (ICC) would be an alternatively acceptable criteria for adoption.**
- 3. Retain the historical name for this disease, myalgic encephalomyelitis, which has been coded since 1969 by the World Health Organization under neurological disease with the code G93.3. In addition, ME will appear in the 2015 U.S. ICD Codes as U.S. ICD-10-CM with the same coding.**

**Additionally, we request that the Appropriation Committee recommends HHS:**

- 4. Return ME to the National Institute of Allergy and Infectious Disease (NIAID) or place it in the National Institute of Neurological Disorders and Stroke (NINDS), which also manages similar neuroimmune diseases such as MS, fibromyalgia, and Lyme Disease. The Office of Research on Women's Health, where ME is currently housed, is entirely inappropriate for disease, which also strikes men and children.**
- 5. Provide opportunities for dissemination of information through the development of a curriculum for all U.S.- based medical schools, as well as physician continuing education, about ME as defined solely by disease experts, in order to provide the tools needed for**

physicians and other medical professionals to appropriately recognize and treat this disease. Currently, this would mean using either the 2003 Canadian Consensus Criteria or the 2011 International Consensus Criteria, not the overly broad criteria developed by the non-expert IOM panel. In addition, the [CCC](#) (9) or [ICC](#) Primer(10) should be widely distributed and made available to clinicians, particularly primary care physicians, nationwide in order to facilitate the best care for their ME patients.

6. Partner openly and transparently with stakeholders within one year to establish a comprehensive, aggressive and fully-funded cross-agency strategy and implementation plan, with well-defined objectives and milestones, and to develop a plan to monitor progress and provide for Congressional oversight.

“We’ve documented, as have others, that the level of functional impairment in people who suffer from CFS is comparable to multiple sclerosis, AIDS, end-stage renal failure, chronic obstructive pulmonary disease. The disability is equivalent to that of some well-known, very severe medical conditions.”– Dr. William Reeves, former CDC Chief of Viral Diseases Branch ([2006 CDC Press Conference](#))

Links:

- 1) [http://mecfsforums.com/wiki/Articles\\_by\\_Dr.\\_A.\\_Melvin\\_Ramsay](http://mecfsforums.com/wiki/Articles_by_Dr._A._Melvin_Ramsay)
- 2) <http://www.hhs.gov/advcomcfs/>
- 3) [http://report.nih.gov/categorical\\_spending.aspx](http://report.nih.gov/categorical_spending.aspx)
- 4) <http://www.name-us.org/DefintionsPages/DefinitionsArticles/ConsensusDocument%20Overview.pdf>
- 5) <http://www.iacfsme.org/OrganizationInformation/tabid/124/Default.aspx>
- 6) <https://dl.dropboxusercontent.com/u/89158245/Case%20Definition%20Letter%20Sept%2023%202013.pdf>
- 7) [https://thoughtsaboutme.files.wordpress.com/2013/10/sebelius\\_letter\\_advocates2.pdf](https://thoughtsaboutme.files.wordpress.com/2013/10/sebelius_letter_advocates2.pdf)
- 8) [https://secure.avaaz.org/en/petition/Stop\\_the\\_HHSIOM\\_contract\\_and\\_accept\\_the\\_CCC\\_definition\\_of\\_ME/?pv=4](https://secure.avaaz.org/en/petition/Stop_the_HHSIOM_contract_and_accept_the_CCC_definition_of_ME/?pv=4)
- 9) <http://www.name-us.org/DefintionsPages/DefinitionsArticles/ConsensusDocument%20Overview.pdf>
- 10) [http://www.name-us.org/DefintionsPages/DefinitionsArticles/2012\\_ICC%20primer.pdf](http://www.name-us.org/DefintionsPages/DefinitionsArticles/2012_ICC%20primer.pdf)
- 11) <http://www.meadvocacy.org/>