

Prepared by MEadvocacy.org for the Senate Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies; Department of Health and Human Services.

Dear Ladies and Gentlemen of the Committee:

MEadvocacy.org (1) is a project of the non-profit organization May12.org and is asking Health and Human Services to fund \$250 million for research into the disease myalgic encephalomyelitis (ME).

There is an urgent need for a systemic overhaul at the Department of Health and Human Services (HHS), including the National Institutes of Health (NIH) and the Centers for Disease Control (CDC), in regard to its funding and handling of this disease.

ME is a chronic, disabling, neuroimmune disease that affects an estimated one million American men, women and children in the U.S. Yet, the past three decades, since the Lake Tahoe outbreak where the disease was redefined, there have been few biomedical scientific advances and no FDA approved treatments for this heavily burdened disease. This is due to the fact HHS, NIH and CDC have had an institutional bias leading to marginalization, neglect, underfunding and mistreatment of this patient community.

Advances in the science of the disease have been repeatedly squashed by the gross lack of funding by NIH for the disease. In addition, misinformation and badly outdated information published by the CDC, along with the lack of education about the disease in medical schools, has caused a dearth of palliative care for patients nationwide. Most importantly, after 30 years, we still are not any closer to finding an FDA approved treatment or cure to help the estimated 17 million ME patients worldwide.

MEadvocacy.org is a non-profit grassroots movement of advocates and patients who are rising up and saying it is time for a change. We are lawyers, laborers, teachers, students, fathers, mothers, and children. Our productive lives have been cut short by this disease and we currently have no hope of treatment or cure. We have had enough and are saying, "No More!"

ME Incidence and Prevalence:

ME, also known in the U.S. as chronic fatigue syndrome (CFS) and myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), sickens an estimated 1 million people 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, an estimated 250,000 people, 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 what Dr. A. Melvin Ramsay (2) described it as an infectious neuromuscular

illness and formally used the term “myalgic encephalomyelitis.” Disregarding this, the CDC broadly redefined the disease and renamed it the marginalizing name 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 causes stigmatization and marginalization of patients.

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 no longer carry this burden quietly 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.”* (3)

In the intervening 7 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 subcommittee for Labor, Health and Human Services, Education, and Related Agencies, 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 to \$6 million a year, less than funding for hay fever. HHS has placed funding for ME at the rock bottom of their funding budget list (4). The yearly allocation for ME/CFS is a fraction of what other similarly burdened diseases receive. Dr. Francis Collins, the director of NIH, has promised increased help, but the proposed funding for ME/CFS is only \$7 million.

HHS/NIH funding data for 2015 for several diseases: HIV/AIDS \$3 billion; M.S. \$94 million; Parkinson’s \$146 million; Alzheimer’s \$589 million; ME/CFS \$6 million.

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 nearly 100 recommendations made by the Chronic Fatigue Syndrome Advisory Committee (CFSAC) (5) during the past ten years. 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 and calls for RFAs and increases in NIH funding.

HHS 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 Appropriations 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 to bring them on par with other similarly burdened diseases yet, gets a mere **\$6 million**. This is just on a premise of equality, not equity. If evaluated based on equity, a disease with no FDA approved treatment and an abysmal quality of life (lower than AIDS and MS), it should be getting much more funding to bring it up to par. To be equitable ME should be funded at greater than \$3 billion.

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 ME by HHS, NIH and CDC and active, ongoing Congressional oversight until HHS' negative institutional bias is rectified. We are therefore coming to you for help in this matter.

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) (6), which has been adopted by the International Association of Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis (IACFS/ME) (7). In a letter to the Secretary of HHS, 50 experts (8) in the disease declared their consensus agreement to adopt the CCC. This was endorsed by a letter signed by 171 advocates (9) as well as a petition (10) signed by over 6,000 patients. The 2011 revision known as the International Consensus Criteria (ICC) (11) 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 and is similarly coded in the 2015 U.S. ICD Codes as U.S. ICD-10-CM.

Additionally, we request that the Appropriation Committee recommends HHS:

A- Ensure that NIH completes their 2015 promise of placing ME into 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 a disease which also strikes men and children.

B- 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 which the CDC is defiantly implementing in their educational materials. In addition, the CCC (6) or ICC Primer (11) 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.

C- **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://www.meadvocacy.org>
- 2) <http://www.name-us.org/DefintionsPages/DefRamsay.htm>
- 3) <http://consults.blogs.nytimes.com/2009/10/15>
- 4) https://report.nih.gov/categorical_spending.aspx
- 5) <http://www.hhs.gov/advcomcfs/recommendations/index.html#>
- 6) <http://www.name-us.org/DefintionsPages/DefinitionsArticles/ConsensusDocument%20Overview.pdf>
- 7) <http://www.iacfsme.org>
- 8) <https://dl.dropboxusercontent.com/u/89158245/Case%20Definition%20Letter%20Sept%2023%202013.pdf>
- 9) https://thoughtsaboutme.files.wordpress.com/2013/10/sebelius_letter_advocates2.pdf
- 10) https://secure.avaaz.org/en/petition/Stop_the_HHSIOM_contract_and_accept_the_CCC_definition_of_ME/?pv=4
- 11) http://www.name-us.org/DefintionsPages/DefinitionsArticles/2012_ICC%20primer.pdf