

Submission by MEadvocacy.org - FY 2018 written testimony for the record.

Prepared for House Committee on Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies.

Dear Ladies and Gentlemen of the Committee:

I am, Colleen Steckel, a volunteer member of the **MEadvocacy.org** (1) advisory committee, a project of the non-profit organization May12.org.

MEadvocacy is asking Health and Human Services to **fund \$250 million** for research into the devastating 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 the funding and handling of the disease ME.

Myalgic encephalomyelitis is a chronic, serious, 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 which has led to lack of public and private funding.

Misinformation and badly outdated information published by the CDC, along with the lack of education about the disease in medical schools, has caused a dearth of palliative care for patients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 a 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. An estimated 250,000 people, are so severely affected as to render them bedbound, unable to care for themselves.

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.

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.” (2)

It is estimated that the burden to the economy for ME is between \$17 to \$24 billion. However, 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. 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 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) (4) during the past 14 years. They’ve continually ignored specific requests by CFSAC, medical experts, patient advocates, patients and their families to adopt **ME expert -authored well- defined** criteria for the disease, calls for significant RFAs and **significant increases** in NIH funding.

In order to fund ME on par with MS (a similarly serious disease) ME would need **\$250 million** a year, yet historically ME has received a mere **\$6 million**. 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 an investigation by Congress into the mishandling and neglect of ME by HHS, NIH and CDC. An active, ongoing Congressional oversight is also needed until HHS' negative institutional bias (5) 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 meets:

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**. 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.
2. Heed the ME stakeholders' request to adopt expert diagnostic and research criteria. MEadvocacy recommends the 2011 International Consensus Criteria (ICC) (6). In a letter to the Secretary of HHS, 50 experts (7) in the disease declared their consensus agreement to adopt the CCC (8) which the more current ICC was based on. This was endorsed by a letter signed by 171 advocates (9) as well as a petition (10) signed by over 6,000 patients.

3. Retain the historical name **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) Direct dissemination of information about ME as defined by disease experts such as the ICC primer based on the International Consensus Criteria-

Links:

- 1) www.meadvocacy.org
- 2) <http://consults.blogs.nytimes.com/2009/10/15>
- 3) https://report.nih.gov/categorical_spending.aspx
- 4) <http://www.hhs.gov/advcomcfs/recommendations/index.html#>
- 5) http://www.meadvocacy.org/nih_sidesteps_critical_problems_with_the_me_cfs_study
- 6) http://www.name-us.org/DefintionsPages/DefinitionsArticles/2012_ICC%20primer.pdf
- 7) <https://dl.dropboxusercontent.com/u/89158245/Case%20Definition%20Letter%20Sept%2023%202013.pdf>
- 8) <http://www.name-us.org/DefintionsPages/DefinitionsArticles/ConsensusDocument%20Overview.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_CC_definition_of_ME/?pv=4