

November 2, 2018

The Honorable Anna Eshoo
241 Cannon Building
Washington, DC 20515

The Honorable Jim McGovern
438 Cannon House Office Building
Washington, DC 20515

The Honorable Zoe Lofgren
1401 Longworth House Office Building
Washington, DC 20515

The Honorable Jamie Raskin
431 Cannon House Office Building
Washington, DC 20515

Dear Representatives Eshoo, Lofgren, McGovern, and Raskin:

We, the undersigned ME/CFS advocacy and research organizations, request that the House of Representatives pass legislation that would (1) create a federal advisory committee, interagency coordinating committee, or federal working group for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) and (2) address critical issues preventing proper diagnosis, treatment, and care for the approximately 1 to 2.5 million Americans afflicted with this horrific disease.

As you know, the Department of Health and Human Services (HHS) abruptly announced the charter would not be renewed for the Chronic Fatigue Syndrome Advisory Committee (CFSAC) in September 2018. We believe legislation is urgently needed to fill the void left by CFSAC and address other key needs of the ME/CFS community.

Basic Facts about ME/CFS:

- In a 2015 report¹, the National Academy of Medicine (NAM) found that ME/CFS “is a serious, chronic, complex, and multisystem disease that frequently and dramatically limits the activities of affected patients.”
- ME/CFS affects both sexes and all ages, races, ethnic groups. Preliminary data suggests the prevalence and severity of ME/CFS in patients who are ethnic minorities and/or poor may in fact be worse, yet these populations are even more underdiagnosed and undertreated
- ME/CFS results in more functional impairment than many other chronic diseases with many patients unable to work or attend school. People with ME/CFS have the lowest quality of life scores of any disease measured.²
- Americans with ME/CFS face a clinical care crisis. Fewer than 30% of medical textbooks and curricula mention ME/CFS, while mainstream clinical guidance recommends treatments that can cause harm to patients.
- 84-91% of patients remain undiagnosed. Of patients who have received a diagnosis, the majority report that it took over 4 years to receive it. In the United States, there are fewer than 12 experienced clinical care specialist centers available to serve up to 2.5 million patients.

¹ IOM (Institute of Medicine). 2015. *Beyond myalgic encephalomyelitis/chronic fatigue syndrome: Redefining an illness*. Washington, DC: The National Academies Press.

² Hvidberg et al (2015) The Health-Related Quality of Life for Patients with ME/CFS. PLoS ONE

- ME/CFS costs the economy \$17-24 billion annually in direct medical expenditures and lost productivity.
- NAM found “remarkably little research funding,” a “paucity of research” and a healthcare profession which has been falsely persuaded that ME/CFS is a psychological problem. Further, NAM also notes a lack of diagnostic tests and FDA-approved treatments leaving patients with nowhere to turn.

CFSAC History:

Created in 2003 as a discretionary committee, CFSAC’s purpose was to provide advice and recommendations to HHS on issues related to Myalgic Encephalomyelitis (ME) and Chronic Fatigue Syndrome (CFS). The Committee’s charter was broad-ranging, covering the need to (a) improve knowledge and research about ME/CFS and its diagnosis, treatment, and clinical management; (b) improve medical education and the dissemination of up to date information about ME/CFS; and (c) provide avenues for input from patients and caregivers.³

The charter expired on September 5, 2018. Despite working group meetings and other committee work scheduled past this date, on September 6, 2018, HHS announced the charter was not renewed. There was no prior notice about this decision – not even to CFSAC members or agency ex-officios from NIH and CDC. HHS stated that the Department feels that the Committee accomplished the duties outlined in its charter. This announcement was a shock to the community; we strongly disagree with HHS’ decision and explanation. To our knowledge, CFSAC is the only HHS committee to have been terminated under the current administration.

Why CFSAC or a CFSAC Replacement is Needed:

1. Contrary to HHS’ statement, CFSAC had not completed its mission. Substantial work remains, as outlined below, and no transition plan or substitute mechanism was developed to ensure the ongoing work would continue. Working groups were actively engaged in the following projects on the date of termination:

- The Medical Education Working Group was developing recommendations for programs and materials that agencies would utilize to educate health care providers about ME/CFS, to address the persistent disbelief and stigma about the disease, and to address the increased risk of suicide in this patient population.
- The Pediatric Education and Parent Information Working Group was developing additional guidance for parents of children with ME/CFS, for

³ HHS Office. “Charter.” *HHS.gov*, US Department of Health and Human Services, 9 Sept. 2016, www.hhs.gov/ash/advisory-committees/cfsac/about-cfsac/charter/index.html. Chronic Fatigue Syndrome Advisory Committee Charter - Expired September 5, 2018

navigating individualized education plans and medical needs accommodation plans pursuant to Section 504 of the Americans with Disabilities Act.

- The Clinical Trials and Treatment Working Group was developing plans to improve engagement with the pharmaceutical industry by addressing known challenges in executing drug trials and identifying key opportunities for clinical trials.

2. CFSAC represented a unique place where multiple government departments and agencies, clinicians, researchers, patients, caregivers, and advocates could discuss needs, share information, establish priorities, and coordinate actions. Indeed, it was the only federal entity solely focused on ME/CFS.

3. CFSAC was also an important platform facilitating ME/CFS community engagement with government agencies. Patients, caregivers and the public could attend public meetings and webinars and stay informed on important agency initiatives. Part of each meeting was set aside for public comment, where anyone from the community could bring an issue to the attention of the participating agencies. Now, there is no formal mechanism for community input or engagement with HHS agencies on ME/CFS.

4. Historically, the community has expressed frustration about HHS' failure to address the vast majority of CFSAC recommendations. However, CFSAC and HHS were finally beginning to produce real results and achieve collaborative success just as it was disbanded. The National Institute of Medicine completed a comprehensive report on ME/CFS (2015); the NIH conducted a Pathways to Prevention Workshop (2015); the Agency for Health Care Review and Quality (AHRQ) published an Evidence Review (2014) and an Addendum (2016) on diagnostics and treatments. Additionally, CDC made substantial revisions to its website.

For all these reasons, the community strongly believes that CFSAC must be continued. Creating a new committee or working group by statute and facilitating Congressional oversight will ensure that HHS and other agencies make a real commitment to combating ME/CFS and address the unfinished work to improve the lives of people with ME/CFS.

Proposal for CFSAC Replacement

While HHS has not formally rejected the community's request to reinstate CFSAC, preliminary feedback from the Department indicates that HHS does not intend to reconsider its position. Given the manner in which CFSAC ended – abruptly and without advance notice, with no planning for finishing ongoing projects, and no plans for further engagement – the community has significant concerns about HHS retaining substantial discretion over another advisory committee. Accordingly, specific parameters defined by statute would substantially increase a new committee's standing and effectiveness. Therefore, we request that Congress create by statute an

Interagency Federal Advisory Committee, Coordinating Committee, or Working Group [Interagency Committee] for ME/CFS, as it has done in the past for other diseases.⁴

Based on those models, we propose a Committee or Working Group that:

- reports to Congress and the President
- includes all pertinent HHS agencies such as the CDC, NIH, and FDA, as well as relevant non-HHS agencies and departments such as the Social Security Administration, the Department of Defense, the Veterans' Administration and the Department of Education.
- dictates that members of the ME/CFS community, such as patients, caregivers, clinicians, scientists, and ME/CFS organizations comprise at least half of the committee or working group membership
- carries out specific responsibilities such as:
 - identifying gaps in disease research, tracking, and clinical care, and providing recommendations to relevant federal agencies for addressing those gaps
 - developing a strategic interagency plan for conducting and supporting research and education, including proposed budgetary requirements
 - providing a summary report for public distribution of ongoing and current disease-related research and federal activities related to the disease
 - soliciting input from states, localities, and nongovernmental entities, including organizations representing patients, health care providers, researchers, and industry regarding scientific advances, research questions, surveillance activities, clinical care access, and emerging issues in the disease space
 - establishing a process for full public participation in decisions relating to the disease

Other Legislative Solutions for ME/CFS:

Due to decades of tragic neglect of ME/CFS by science, medicine, and our government, progress in understanding the disease, finding diagnostic measures, devising treatments, and approving drugs has been minimal. While the NIH and CDC have increased their work on ME/CFS in the last two years, their commitment lacks the urgency and scale that is desperately needed given the disease prevalence and severity.

⁴ See examples 1) 42 U.S. Code § 280i-2 - Interagency Autism Coordinating Committee, 2) PUBLIC LAW 107 - 84 - Muscular Dystrophy Community Assistance, Research and Education Amendments Of 2001", OR the MD-CARE ACT, 3) 29 U.S. Code § 765 - Disability, Independent Living, and Rehabilitation Research Advisory Council

ME/CFS legislation also could address key areas of need for people with ME/CFS, using the statutory mechanisms described below. We would be happy to provide more specifics - we see this as the start of a dialogue with your offices about the best way to achieve the community's goals.

1. NIH:

- A. Allocate Sufficient ME/CFS Funding: Broaden and accelerate NIH activities to expedite the delivery of diagnostic tools and treatments and appropriate the necessary funds in fiscal years 2020 to 2024 to accomplish these outcomes. The funds provided need to include new, multi-year RFAs to incentivize researchers to enter the field and to address key pivotal research topics such as validation of diagnostics. [Studies have found](#) that research funding of roughly \$200 million per year would be commensurate with disease burden.
- B. Create a Multi-year Research Plan: A key role of the Interagency Committee should also be to work with the NIH to develop a strategic plan for ME/CFS research and reach consensus on the criteria and methods for selecting ME/CFS participants for research.
- C. Authorize a ME/CFS Program: There should be a ME/CFS specific program authorized at the NIH specifically to address the recommendations of the Committee on Appropriations in H. Rept. 115-952 which states *"the Committee recommends that NIH significantly increase research funding to be commensurate with disease burden and use that funding to further accelerate the research field through a set of intramural and extramural investments such as (a) RFAs for biomarkers and treatment trials, (b) additional funding for investigator initiated studies and early stage investigator awards, (c) an initiative to reach consensus on the case definition, and (d) mechanisms to incentivize researchers to enter the field."*

2. CDC:

- A. Conduct National Epidemiological Research: The CDC should conduct proper epidemiological studies, using appropriate patient selection and epidemiological methods. This data should be publically available, published in epidemiological papers, and used to inform the Interagency Committee. Such studies will improve understanding of prevalence, risk factors, natural history, and prognosis to inform better public health policies.
- B. Create A National Public Health Agenda for ME/CFS: This model has been successfully completed in other diseases. It is a public/private partnership which produces a comprehensive disease specific public health agenda. The agenda is

intended to be a blueprint for all stakeholders to guide public health actions in policy, planning, and advocacy to improve care and quality of life for people living with ME/CFS.

- C. Improve ME/CFS Tracking Data: Currently, ME/CFS is approved as an optional module for the state-based 2019 [Behavioral Risk Factor Surveillance Survey](#) (BRFSS). In 2016, only three states elected to incorporate the optional ME/CFS module in their survey. All states, districts, and territories need to include the current ME/CFS module in the annual BRFSS survey through FY 2025, and the Interagency Committee and other agencies should utilize the data collected to inform agency policy and planning.
- D. State-Based Medical Education Grant Programs for ME/CFS: The CDC needs to implement a competitive medical education grant program for ME/CFS medical education at the state level. The CDC also needs to include ME/CFS in the list of chronic diseases for which it currently provides grants to states and encourage States to incorporate ME/CFS into ongoing programs and activities regarding chronic diseases.
- E. Online Training and Continuing Education for ME/CFS: The CDC, in consultation with affected individuals, expert clinicians, ME/CFS organizations, and other stakeholders, needs to develop a comprehensive ME/CFS continuing education program to be offered within the Training and Continuing Education Online (TCEO) system.

3. **FDA**: Utilize Existing Grant Programs: Direct the FDA to include an RFA under the Orphan Products Grants Program for a natural history model of ME/CFS in FY2020.⁵

4. **HRSA**: Designate ME/CFS as a Medically Underserved Population (MUP): People with ME/CFS experience the lowest quality of life of any disease measured and lack access to basic, appropriate, and specialized care for ME/CFS. The MUP designation would open up over 25 government programs within HRSA and other federal agencies for the ME/CFS population.

5. **HHS**: Create and Fund Centers of Excellence for ME/CFS: Congress should direct the Secretary of HHS to create no fewer than 12 Centers of Excellence to support research and care for the estimated 1 to 2.5 million Americans afflicted with ME/CFS. In coordination with the Interagency Committee, the CDC and the appropriate NIH Institutes should award grants and contracts for these Centers of Excellence.

⁵ Last year, the [FDA in partnership with the NIH's National Center for Advancing Translational Sciences \(NCATS\)](#) announced a \$6 million investment in natural history models for six diseases, and in some cases, aimed to identify biomarkers or clinical endpoints. In FY 19, the [president's budget](#) included a request for an additional \$20 million dollars to establish more of these models. The funds could be used to develop 20 more such models including one for ME/CFS.

Thank you for providing us with the opportunity to explain our needs and concerns.

Respectfully yours,

Carol Head
President and CEO
Solve ME/CFS Initiative



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Executive Director
#MEAction



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