



Solve M.E.

September 8, 2020

Lowell J. Schiller
Principal Associate Commissioner for Policy
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. FDA-2020-N-1391: Public Comments Regarding Office of Women's Health Strategic Priorities

Dear FDA and HHS agency partners,

Please consider this letter as public comments and recommendations regarding the upcoming strategic priorities for the Office of Women's Health (OWH). These comments are submitted on behalf of the Solve ME/CFS Initiative (Solve M.E.) and the community of people affected by Myalgic Encephalomyelitis (ME), previously called Chronic Fatigue Syndrome (CFS).

ME/CFS is a chronic, complex, neuro-immune disease that profoundly limits the health and productivity of millions of individuals. About 80% of cases of ME/CFS are reported to follow an acute infection (like COVID-19) and 75% of ME/CFS cases are in women. Because ME/CFS is an invisible illness, it can be difficult for family members, the public, and even healthcare professionals to understand the challenges and true extent of this serious disease. The causes of ME/CFS are unknown and there are no FDA approved drugs or treatments for the disease. ME/CFS affects between 1 and 2.5 million Americans and costs our economy up to \$24 billion every yearⁱ.

Recommendations for OWH

In 2008, agency leadership placed ME/CFS in the jurisdiction of OWH and coordinating interagency efforts regarding ME/CFS, as a disease that predominantly impacts women, remains one of the Office's responsibilities. New evidence connecting COVID-19 to ME/CFS makes a clear case that *OWH must increase the investment, planning, and prioritization for ME/CFS next year.*

ME/CFS can be triggered by COVID-19ⁱⁱ and initial reports show the increasing numbers of COVID-19 "Long Haulers" are predominantly women. Experts are predicting significant increases in cases of ME/CFS following COVID-19ⁱⁱⁱ. Furthermore, 89% of people who get ME/CFS end up losing their job as a result of the disease^{iv}. Since ME/CFS predominantly impacts women, the expected increase in cases following COVID-19 coupled with the devastating economic impact of ME/CFS could create a serious health and economic crisis which will hit women the hardest. ME/CFS research and medical education must be a strategic priority for the OWH in the future.

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OWH is in a unique position to address this upcoming crisis with key leadership actions and cost-effective solutions. Specifically, we encourage the OWH to implement these recommendations:

1. **Reinstitute the Chronic Fatigue Syndrome Federal Advisory Committee (CFSAC), with a new name, to fill the “void in both intra-departmental and inter-agency collaboration” and provide a “one-stop-shop” for stakeholders and Members of Congress.^v**
2. **Implement the published recommendations of the Institute of Medicine’s (IOM) 2015 report “[Beyond Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome: Redefining an Illness](#)” with new information regarding post-COVID-19 cases of ME/CFS, such as:**
 - **A new ICD code should be assigned, especially for tracking post-COVID-19 cases of ME/CFS**
 - **Develop a toolkit appropriate for screening and diagnosing ME/CFS in general and expand this toolkit to include expertise regarding ME/CFS cases following COVID-19**
 - **Convene a multidisciplinary group to reexamine the diagnostic criteria for ME/CFS (including new reports and information regarding post-COVID-19 cases of ME/CFS)**
3. **Reconvene the “Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome,” who were responsible for publishing the initial 2015 IOM report, and publish an updated edition of the report with new scientific findings and new data relating to COVID-19.**

Regarding Reinstating CFSAC (Recommendation #1)

Generally, I strongly encourage you to recognize three important facts regarding ME/CFS and the OWH:

- From 2008 until 2018, The Office of Women’s Health (OWH) was responsible for managing and supporting the [Chronic Fatigue Syndrome Advisory Committee](#) (CFSAC), whose membership included representatives from the FDA.
- [CFSAC’s charter was allowed to sunset](#) without any advance notice to the ME/CFS community, key stakeholders, or even committee members, who were notified that the committee was disbanded shortly after scheduling meetings for the following year.
- [Forty-Four \(44\) bipartisan members of congress](#) jointly signed a letter of concern to HHS regarding the continued need for CFSAC and asking for clarification on the future of CFSAC projects, left unresolved.
- To fill this interagency void, the National Institutes of Health (NIH) and Centers for Disease Control (CDC) have formed an “[Interagency ME/CFS Working Group](#),” which met for the first time in August 2020, yet is unable to provide formal recommendations to HHS.

Reforming CFSAC is an essential, extremely low-cost, and urgent first step to facilitating improved federal government responses to new ME/CFS cases caused by COVID-19. Without such an advisory committee, federal agency response will be piecemeal, hindered, and lacking expert stakeholder input. Additionally, with such a committee easily available as an agency resource, OWH will be exceptionally placed as a leader on this emerging issue, especially as increased congressional attention is focused on the extended ramifications of COVID-19.



Regarding Implementing IOM Published Recommendations (Recommendation #2)

It is essential for the strategic planners at OWH to be aware of the facts about ME/CFS published by the 2015 IOM report. Up until the publication of this report, many government agencies were not aware of the seismic shifts in the field and the realities of this disease. It is shocking that five years later, the report's key recommendations have still not been implemented. If OWH and other government agencies are going to be even marginally prepared for the predicted increase of ME/CFS cases following COVID-19, implementing these 5-year old recommendations are a critical and necessary first step. Specifically, Solve M.E. recommends implementing Recommendations numbers 1, 2 and 3.

Specifically, from the 2015 IOM report:

“Recommendation 1: Physicians should diagnose myalgic encephalomyelitis/chronic fatigue syndrome if diagnostic criteria are met following an appropriate history, physical examination, and medical work-up. A new code should be assigned to this disorder in the *International Classification of Diseases, Tenth Revision (ICD-10)*, that is not linked to “chronic fatigue” or “neurasthenia.”

Solve M.E. strongly and urgently recommends that OWH act as a facilitator with other agency partners to assign a new ICD code to ME/CFS. Millions of women have and will remain in “healthcare limbo” until more clear coding guidance is implemented. ICD coding is fundamental and critical for insurance billing, disease tracking, data collection, improving patient experience, expediting treatments and more. Without a clear ICD code for ME/CFS, or post-viral chronic illness, federal agencies will lack key tools for tracking the lasting impacts of COVID-19.

From the 2015 report:

“Recommendation 2: The Department of Health and Human Services should develop a toolkit appropriate for screening and diagnosing patients with myalgic encephalomyelitis/chronic fatigue syndrome in a wide array of clinical settings that commonly encounter these patients, including primary care practices, emergency departments, mental/behavioral health clinics, physical/occupational therapy units, and medical subspecialty services (e.g., rheumatology, infectious diseases, neurology).”

Solve M.E. recommends that OWH lead the implementation of this recommendation and include expanded knowledge from experts regarding post-COVID-19 cases of ME/CFS.

From the 2015 report:

“Recommendation 3: A multidisciplinary group should reexamine the diagnostic criteria set forth in this report when firm evidence supports modification to improve the identification or care of affected individuals. Such a group should consider, in no more than 5 years, whether modification of the criteria is necessary. Funding for this update effort should be provided by nonconflicted sources, such as the Agency for Healthcare Research and Quality through its Evidence-based Practice Centers process, and foundations.”

Solve M.E. recommends that OWH lead the implementation of this recommendation in partnership with the Agency for Healthcare Research and Quality (AHRQ). Solve M.E. especially encourages OWH to be



a leader for updating these criteria with COVID-19 information because OWH was instrumental in executing the original 2015 IOM report.

Regarding Reconvening the IOM Committee (Recommendation #3)

Even before the pandemic, several federal agencies and committees recommended a revisiting of the 2015 IOM report in 2020 to update this critical information with the most recent published data and findings. With the newest reports and the rising cases of post-COVID-19 ME/CFS, this revised report becomes even more critical.

In 2015, only 30% of medical textbooks covered ME/CFS. We know that medical professionals were woefully ill-equipped to treat cases of ME/CFS in 2015. And, while some positive steps have been gained, most American ME/CFS patients are still experiencing years of delay in getting a diagnosis and medical professionals that are completely unable to meet their needs. Wait times at the few specialty clinics have only gotten longer, only 3 collaborative research centers exist, and the FDA still has not approved a single treatment for ME/CFS. And, there still is not a single federally funded center of excellence or clinical trial for ME/CFS in the United States. Five years later, progress has been negligible and, OWH cannot allow that negligible progress to continue in the post-COVID-19 healthcare system.

Consolidating and disseminating the latest science on ME/CFS and COVID-19 is critical in the coming years as millions of COVID-19 survivors seek post-viral and long-term care.

I hope these recommendations are helpful and that the OWH will take these into account consideration in your strategic planning for the upcoming year.

Please don't hesitate to contact me or my organization if there is any way we can assist.

Sincerely,

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Addendum: About ME/CFS

ME/CFS is a complex disease with an array of debilitating symptoms including cellular energy disruption, orthostatic intolerance, unrefreshing sleep, memory loss, joint pain, inflamed lymph nodes, severe headache, sore throat, neurological abnormalities, and even complete organ system shutdown. The cause of ME/CFS is unknown, and there is no existing cure nor FDA-approved treatment for the disease. Here are a few facts about this serious and



often misunderstood condition from the 2015 Institute of Medicine Report “[Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness.](#)”

- An estimated 836,000 to 2.5 million Americans have ME/CFS
- Nearly 80% of ME/CFS cases are reported to follow an acute infection, typically viral infections
- Coronaviruses can trigger ME/CFS^{vi} and ME/CFS-like symptoms
- ME/CFS affects four times more women than men
- One quarter of ME/CFS patients will become house- or bedbound in their lifetime
- ME/CFS can strike anyone at any time; onset has been reported from ages 8 to 80
- Recovery from ME/CFS is rare and symptoms often persist for life
- Many with ME/CFS have comorbid disorders, such as irritable bowel syndrome, dysautonomia, and fibromyalgia
- Patients with ME/CFS have the lowest median and mean quality of life scores of any disease tested, including lung cancer, rheumatoid arthritis, and brain stroke

In short, **ME/CFS is often a life-long disease** resulting in an extreme reduction of every-day function, long term disability, and moderate to severe chronic pain, manifesting most often in neurological pain, joint pain, musculoskeletal pain and headaches. 89%^{vii} report job loss as a result of their illness. For many with ME/CFS, living with severe chronic pain is a daily struggle.

ⁱ Institute of Medicine. 2015. *Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/19012>.

ⁱⁱ (September 2, 2020) Patient Report. *I'm a COVID-19 Long-Hauler and Was Just Diagnosed with Chronic Fatigue Syndrome. Will I Ever Start Feeling Better?* CreakyJoints arthritis digital community. <https://creakyjoints.org/living-with-arthritis/coronavirus/patient-perspectives/covid-19-long-hauler-chronic-fatigue-syndrome/>. Accessed 9/8/20

ⁱⁱⁱ Vastag, Brian and Mazur, Beth. “**Researchers warn covid-19 could cause debilitating long-term illness in some patients**” May 30, 2020. *The Washington Post* Retrieved from https://www.washingtonpost.com/health/could-covid-19-cause-long-term-chronic-fatigue-and-illness-in-some-patients/2020/05/29/bcd5edb2-a02c-11ea-b5c9-570a91917d8d_story.html

^{iv} Institute of Medicine. 2015. *Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/19012>.

^v (December 17, 2018). Letter from Congress. *Regarding HHS Decision to Disband CFSAC* Senator Ed Markey et al. <https://solvecfs.org/wp-content/uploads/2020/09/SIGNED-MECFS-letter-to-Azar-12.17.18.pdf> Accessed 9/8/20

^{vi} Moldofsky H, Patcai J. Chronic widespread musculoskeletal pain, fatigue, depression and disordered sleep in chronic post-SARS syndrome; a case-controlled study. *BMC Neurol*. 2011;11:37. Published 2011 Mar 24. doi:10.1186/1471-2377-11-37

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