

Public Comment
Robert Miller

- I would like to welcome the new members to the Committee and thank you for committing yourself to this role. I would ask that you review the recommendations made by this committee over the last 5 years and move the process forward for patients to see results from those recommendations. Retracing the steps of the last few years of this Committee would waste more years of lost time for patients who have lost so much time already. HHS and its agencies have not responded to or performed on the most important recommendations – like multiple recommendations to implement a national network of research centers or centers of excellence for research, treatment and clinical trials in ME/CFS – and it is time to demand a response from the Secretary of Health.
- I would reiterate my call for this Committee to be bold and recommend that the NIH spend \$100 million a year on ME/CFS research, like it does on Multiple Sclerosis, a similar neuro-immune disease with a smaller patient base. The NIH neglects the 1-4 million Americans who have ME/CFS, the vast majority of whom are women. The illness has been the least funded by NIH among widespread diseases, with only \$6 million a year in funding. Yet our nation spends billions in direct costs to keep us ill. The men who run NIH neglect this women’s illness. How much money is spent on erectile dysfunction and prostate issues gentlemen?
- As an American, I am embarrassed to tell you that the most exciting research in this field is occurring in foreign countries. Norwegian researchers are conducting clinical trials with auto-immune treatments like Rituxan, with early but promising results. Researchers in Australia are identifying immune and auto-immune irregularities that may be potential biological markers for ME/CFS patients, because in their country ME/CFS is a disease, not a stigma. The federal health agencies in other countries support real research in the causes and treatments of my illness. If that were true in the US, I would be well, and so would millions of Americans who suffer like me.
- I have personally come before this committee for 6 years seeking clinical trials for ME/CFS treatments. I have told my story about being enrolled 12 years ago in the only clinical trial in this country for CFS treatment – Ampligen. I’ve told how I had to first move to Reno from Las Vegas, NV to find a knowledgeable clinician, who was able to enroll me into the early Ampligen trials. Then later how I had to uproot my twin boys and wife from Virginia to Reno to participate a second time in the Ampligen trial, which makes me lucky, but has placed a large burden on my sons and family. The FDA has failed ME/CFS patients. The FDA should be running clinical trials in conjunction with the NIH and CDC, like they did for HIV. Patients have asked the FDA to hold a

stakeholders meeting to find out why Ampligen has been used for 20 years but still isn't licensed; also to bring other pharmaceuticals to the table whose drugs are being used off label and to promote additional clinical trials; and to bring experienced clinicians, researchers and patients to the FDA's broken process. We need all the stakeholders sitting down together to figure out this most complex illness. This is not a one person or one agency problem, so let's get the best and brightest from all angles to sit down and work this out.

To make the progress needed, we require a significant, sustained and coordinated commitment from HHS to address the following four key priorities:

1. **Resolve the definition, name and classification confusion**
2. **Provide a fair share of research funding, focused on biological pathologies, biomarkers and treatment**
3. **Educate the medical community**
4. **Accelerate the FDA pipeline for ME/CFS**

Thank you,

Robert Miller