

Public Comment

Anonymous

I am a 38-year old former attorney with ME/CFS. My sudden onset in 2008 destroyed my ability to work. I have been disabled every day for the last 5 years.

I have not had access to some ME/CFS treatments I have read about, other than Vitamin B12. The only prescription drug that I take is for sleep. My doctor does not know what else to do.

Despite every “lifestyle change” treatment imaginable, I am no better today, in 2013, than when ME/CFS struck 5 years ago. My doctor and I have stopped pretending that I am getting better. I need something better than medical advice to eat and sleep well, stay as fit as possible within limits, and taking pills to sleep.

FDA’s recent focus on ME/CFS has been encouraging. Useful ideas appear to have been exchanged at the recent FDA meeting in an area of immediate need: drugs to treat ME/CFS patients today. However, one or two meetings are insufficient to bring together the strong strategic vision, coordinated efforts, and commitments of resources that are needed to get treatments to ME/CFS patients unless much more is done, and more consistently, by FDA and the other health agencies.

This lack of momentum has been mirrored in CFSAC proceedings. I have watched parts of every meeting online since 2009. Each meeting seems to involve a re-invention of the wheel with respect to formulating Recommendations, or a plan to make a plan at the next meeting yet another six months later.

Importantly, there appears to be a lack of a focused strategic vision for CFSAC (or short-term or long-term milestones towards such a strategic vision) that guides or informs the group in making recommendations from one meeting to the next. Isolated recommendations seem to disappear into a vortex of inaction between meetings. Please do more to ensure that the recommendations are prioritized, presented, and monitored in a way that facilitates action by HHS on each of the recommendations.

I believe the following 5 past Recommendations should be designated as the highest priority for the Secretary.

1. **NIH should fund ME/CFS research commensurate with the magnitude of the problem, and issue an RFA specifically for ME/CFS.** You made this recommendation in May 2011, and included an edited version of it in your original High Priority List. This Committee has made recommendations to increase NIH funding into ME/CFS research many times, but this recommendation asks for “funding commensurate with the magnitude of the problem,” and I believe that is critical language to be included in the high priority list.
2. **NIH should issue a \$7-10 million RFA for outcomes measures, and biomarker discovery and validation.** You made this recommendation in

October 2012. An RFA with set aside funding to attract a greater number of proposals is a critical and immediate need to jump start research.

3. **Pool resources to create Centers of Excellence, using physical or virtual locations.** You made this recommendation in November 2011, and included it in your original High Priority List. Creating regional centers for research and treatment has been recommended by this Committee many times, and I believe these centers are an essential part of any plan to make progress against ME/CFS.
4. **Hold a stakeholders' workshop to reach a consensus on case definition.** You made this recommendation in October 2012. We cannot wait two or more years for the current CDC and NIH case definition processes to unfold. We need immediate action to achieve consensus on the appropriate case definition for this disease so that research, treatment development and patient care all reflect what we have learned since the 1994 Fukuda case definition was published.
5. **Remove the CDC Toolkit for healthcare providers from the CDC website.** You made this recommendation in June 2012. Despite CDC's point-blank refusal to follow this recommendation, I ask that you include it in your High Priority list. The Toolkit does not reflect best clinical practices, and patients experiences show that the information in the Toolkit is misused and can be harmful to patients.

For those recommendations that simply sit on the list from year to year, HHS input should be sought regarding why there has been no action, and what can be realistically be done on the recommended items, along with a specific timeframe for action.

Thank you for your efforts on behalf of people affected by ME/CFS. I hope your High Priority list will reflect what will do the most good to help patients.