

Public Comment

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First, I wish to thank the FDA for last month's Drug Development Workshop/Patient Stakeholder mtg. The meeting was an excellent example of how agencies can engage advocates in positive and productive dialogue. I hope that other agencies will follow FDA's example, particularly as NIH and CDC continue to develop new case definitions and medical education.

However, *HOUSTON....WE HAVE A PROBLEM....or should I say problems!*

I would like to share with you the five recommendations that I believe you should designate as the highest priority for the Secretary. As the FDA meeting showed, these priorities are fundamental to getting new treatments approved and this Committee has recommended many of them more than once. I urge you to include the full wording of these recommendations as originally passed, not the edited versions that appear in the CFSAC Recommendations Chart.

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. **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.
3. **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.
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.

I DO NOT want to hear the same old answers from NIH and CDC. NIH...there is money. We need to find a way to get studies approved and funded – help not hinder. To the CDC, you need to follow the FDA in involving patients or listen to CFSAC recommendations. I don't have Chronic Fatigue Syndrome....I have myalgic encephalomyelitis (ME). Please let doctors who do not know that we can change the name of the disease and not lose past research! In addition, if we change the name, we will be able to get Social Security Disability. These are major reasons why some researchers, patients, physicians are afraid to have the name changed.

I thought we lived in an innovated nation....the greatest nation! Since this disease, I feel I live in a closed society. We all need to work together and find solutions that will help us get well and have a normal future and contribute to our economy. It can be done! Patients have been waiting too many years. Remember, children, teens, and young adults are counting on us!

I am tired of hearing that we have to be at the HILL. We are trying. Remember we are very sick.

It is time that CFSAC start having ME/CFS patient participation in the meeting in some manner such as a Q & A session. We know the realities of this disease – we live with it 365 days a week, year after year after year.

Please let's get things moving and find new ways to get the above recommendations implemented. We are wasting too many peoples' time and money to discuss the same thing over and over. It is our time!

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 us. Also, special thanks go out to the ME/CFS experts!!!