Public Comment

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Thank you to the FDA for the meeting on April 25-26, 2013. Some of the positives from the FDA meeting were that people felt listened to, engaged with and respected.

So I urge all DHHS agencies to:

Listen to us as the FDA did. We will listen to you.

Engage with us as the FDA did. We will engage with you.

Work with us as the FDA did. We will work with you - as equal partners.

We trust that your presence here is indicative of your wanting to move things forward for people affected by ME.

We too want to move things forward for people affected by ME.

Let's do this together as equal partners.

The FDA meeting made it evident that there are things that need to be done in order to successfully get drug development for ME underway. Many of these are things the CFSAC has included over the years in its recommendations.

My focus here is the ones I feel should be on the CFSAC 2013 High Priority Recommendation List in order to help move things forward.

Let's start by using the Canadian Consensus Criteria to define ME.

I urge you to include these previously made recommendations:

Three regarding NIH and funding:

NIH should fund ME/CFS research commensurate with the magnitude of the problem, and issue an RFA specifically for ME/CFS. ME/CFS is an illness with enormous economic and human costs. The April 2011 NIH State of Knowledge Workshop identified a number of gaps in what is known about the illness. To address these gaps warrants an interagency effort comprising, but not limited to, NIH,CDC, and AHRQ. Further, the focus should be on interdisciplinary discovery and translational research involving interacting networks of clinical and basic science researchers. Areas to be examined would include the following: identification of patient subsets for detailed phenotyping and targeted therapeutic interventions, biomarker discovery, systems biology approaches and disability assessment. To facilitate the above goal, CFSAC recommends that ME/CFS research receive funding commensurate with the magnitude of the problem and that the NIH (and/or other appropriate agencies) issue an RFA specifically for ME/CFS. (5/11)

Pool resources to create Centers of Excellence, using physical or virtual locations. CFSAC would like to encourage and support the creation of the DHHS Interagency Working Group on Chronic Fatigue Syndrome and ask this group to work together to pool resources that would put into place the “Centers of Excellence” concept that has been recommended repeatedly by this

advisory committee. Specifically, CFSAC encourages utilizing HHS agency programs and demonstration projects, available through the various agencies, to develop and coordinate an effort supporting innovative platforms that facilitate evaluation and treatment, research, and public and provider education. These could take the form of appropriately staffed physical locations, or be virtual networks comprising groups of qualified individuals who interact through a variety of electronic media. Outreach and availability to underserved populations, including people who do not have access to expert care, should be a priority in this effort. (11/11)

NIH should issue a $7-10 million RFA for outcomes measures, and biomarker discovery and validation. CFSAC recommends that you instruct the NIH to issue an RFA (funded at the $7-10 million range) for projects to establish outcomes measures for ME/CFS diagnosis, prognosis and treatment which would include but not be limited to biomarker discovery and validation in patients with ME/CFS. (10/12)
and

Removal of the CDC Toolkit. CFSAC asks that the Centers for Disease Control and Prevention (CDC) remove the CFS Toolkit (both English and Spanish versions) from the CDC website. (6/12)