Public Comment

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I watched the recent FDA meeting with great interest and want to say thank you to the FDA for great engagement and commitment. This is a great model for engagement across DHHS and the community.

I am eagerly anticipating the FDA's action plan to continue moving things forward. I am sure you are aware, the patient community is ready to collaborate as partners and key stakeholders with all of DHHS – including NIH and CDC.

And we are ready to collaborate despite our severe disabilities and our lack of financial and social resources. We do work hard.

It was clear from the FDA meeting that there are priorities that must be set in place to successfully get drug treatments for ME. The issue of priorities brings me to the CFSAC and the CFSAC High Priority Recommendations list.

Regarding definition: The most expedient and effective thing to do is to adopt the Canadian Consensus Criteria – now!

I strongly urge you to include the following recommendations on the CFSAC list of high priority recommendations:

NIH should fund ME/CFS research commensurate with the magnitude of the problem, and issue an RFA specifically for ME/CFS. Recommendation made May 2011 - 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.

Pool resources to create Centers of Excellence, using physical or virtual locations. Recommendation made November 2011 - 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.

NIH should issue a $7-10 million RFA for outcomes measures, and biomarker discovery and validation. Recommendation made October 2012 - 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.

Remove the CDC Toolkit. Recommendation made June 2012 - CFSAC asks that the Centers for Disease Control and Prevention (CDC) remove the CFS Toolkit (both English and Spanish versions) from the CDC website.

Each of these would help us move forward in ways identified at the FDA meeting as priorities in order to get to successful drug development for ME.