Public Comment

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The recent FDA meeting was notable in many ways – among them engagement, collaboration, interactive participation, identifying necessary steps, in this case for successful drug development. I hope this model will be used throughout DHHS and its agencies.

On the Sept 2012 FDA teleconference call, Dr. Kweder said that one of the challenges in getting companies interested in investing in treatments for a condition is that "...you've got to be able to define the condition well..." http://www.fda.gov/downloads/Drugs/NewsEvents/UCM320310.pdf (p.16)

At the CFSAC meeting on **October 3, 2012** Dr. Kweder also said that

"All of this is pretty straightforward—when you have a disease that is well-defined, it has objective, well established measures of disease progression for improvement. That's our challenge with CFS and ME—it's getting there." (p.34) http://www.hhs.gov/advcomcfs/meetings/minutes/cfsac10032012.pdf

But as you and I know, this is not straightforward when we have definitions that range from vague with only a requirement of 6 months of fatigue and no additional symptoms, to a definition like the Canadian Consensus Criteria that specifically describes the disease that is ME.

Dr. Kweder later said:

> **"What Should HHS Do?**
> Use every tool possible to facilitate defining the condition for research purposes in a way that can be widely agreed upon:
> **Include all parties with expertise and interest in this condition.**
> **Include patient representation in the consensus.** Consensus doesn't mean that everyone has to agree on every point. Consensus means we can move forward.
> A research definition is needed so that we can begin to study things. It may be subject to change over time. That's OK. The only way you learn is by starting someplace. Clinical therapeutics are not going to be developed until this is done.
> HHS needs to invest in tools to specifically measure symptoms, signs, and function of the CFS and ME populations." http://www.hhs.gov/advcomcfs/meetings/minutes/cfsac10032012.pdf (p.36-37)

There is considerable overlap between Dr. Kweder's recommendations and CFSAC recommendations that I believe should be on the CFSAC list of high priorities.

As for definition in order to have well-defined patient populations, I urge adoption of the Canadian Consensus Criteria now, across the board.

Regarding research:

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.
And because it does not address appropriate treatment:

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.

Remember that ME experts, including patients and advocates, must be fully engaged in this work as equal partners.