

Testimony

Lily Chu, MD, MSHS

Dear Sir/ Madam,

Thank you for this opportunity to address the federal government about myalgic encephalomyelitis/ chronic fatigue syndrome (ME/CFS). .

Department of Health and Human Services (Dr. Howard Koh and Secretary Kathleen Sibelius)

Thank you to Secretary Sibelius for her written letter to NIH State of the Knowledge Workshop on ME/CFS Research participants. I hope that the Secretary and Dr. Koh were able to watch the Workshop proceedings. The federal government is a complex entity that I am just beginning to learn to navigate so I do not always know to which agency or department I should direct my concerns. My biggest wish is that Secretary Sibelius and DHHS staff approach ME/CFS with a can-do problem-solving attitude and not allow government bureaucracy, red tape, agency turf divisions, ego, or funding be obstacles in helping patients with this illness. We know from history that the United States government and people can solve seemingly insurmountable problems when we put our minds to it. As one Workshop researcher quipped, we need a “Manhattan Project” for ME/CFS.

The CFSAC agrees: since at least September 2004, CFSAC has requested that Centers of Excellence be established in different regions of the country. Three Centers of Excellence were in existence for a few years back around 2000 but their funding was cut without a clear reason despite no significant progress being made yet in solving this illness. Since then, there has been no institution that performs research, treats patients, and educates healthcare providers about ME/CFS – three common goals of Centers for other medical conditions. .

ME/CFS researchers, clinicians, patients, and advocacy organizations can help inform the government about the illness but may not be well-acquainted with the different government agencies and what each agency can do. For that, we need the creativity and expertise that governmental staff possesses!

In March 2011, Secretary Sibelius wrote a letter to CFSAC stating she had asked agencies to consider CFSAC recommendations and report on them at this meeting. I hope to hear agency responses to these recommendations.

National Institutes of Health (NIH) :

I want to commend Dr. Dennis Mangan and everyone involved in organizing and executing the recent NIH State of the Knowledge Workshop on ME/CFS Research. I learned a lot from the Workshop and it was gratifying to see researchers, clinicians, patients, advocates, and government officials discuss current ME/CFS research as well as gaps in the knowledge base and how to bridge those gaps.

- A. Renew current or construct new funding opportunities specific to ME/CFS. The two current opportunities (PA-08-246 and PA-08-247) specific to ME/CFS expire in September of this year.
- B. Dr. James Baraniuk of Georgetown University mentioned during the Workshop that one persistent obstacle to ME/CFS research was that it did not appear to fit neatly into any particular institute. I agree with Dr. Baraniuk. Since no institute feels any need to “take responsibility” for this illness, this has significantly slowed the pace of research. Without biomarkers or a specific etiology, this becomes a vicious cycle where year after year, ME/CFS continues to fall under no specific grant-making institute. The Trans-NIH ME/CFS Working Group is a step in the right direction but without funding, little will be achieved.

I hope to hear from specific institute or center representatives concerning their agencies’ reactions to the Workshop. If their agencies could sponsor ME/CFS-specific research, include ME/CFS under current funding opportunities already sponsored by the agency, or inform ME/CFS researchers which agency-specific opportunities might apply to them, that would be very helpful.

- C. Include leeway in any funding announcements to explore ME/CFS case-definitions besides the Fukuda criteria. Specifically, the Canadian Consensus Criteria, developed by experienced ME/CFS clinicians, should be considered. One current ME/CFS specific grant (PA-08-246) has language allowing for this and components of it could be retained in any future announcements.
- D. Fukuda et al. in their 1994 paper suggested ME/CFS might be a heterogenous illness and that future studies should consider subgrouping patients. (1) Yet, most studies have not done this and instead, when laboratory or diagnostic test inconsistencies are seen across studies, they are dismissed rather than seeing them as possible candidates for subgrouping patients or as possible factors in the disease process. One exception is Dr. Leonard Jason’s study showing that ME/CFS subjects with a Th2 shift in their immune system or decreased cortisol levels at baseline are less likely to respond favorably to a CBT or exercise program. (2, 3) We need more studies like this. Future funding opportunities should encourage subgrouping of subjects as appropriate.
- E. Consider offering more diverse grant types. Most ME/CFS specific grants have been of the R01 type and it was brought up by researchers at the meeting that

having more types would give them more ways to apply for funding. Would ME/CFS researchers benefit from K-type career development awards that allow them more freedom? Would availability of awards targeting mid-career investigators help recruit already experienced investigators in the field or allow them the chance to train junior scientists?

- F. Researchers at the Workshop also enthusiastically discussed ways they could collaborate on their projects and we have heard about the MAPP network from NIDDK during the October 2010 CFSAC meeting. Specifically, researchers have tended to examine one aspect of ME/CFS (e.g. the immune system or cognitive functioning) according to their area of expertise but it has been rare that researchers have been to work together to explore more than one aspect. Let's break out of the metaphor of several blind men examining different parts of the elephant and coming to different conclusion about this illness! Is there any way to construct a similar network for ME/CFS?

Centers for Disease Control and Prevention (CDC):

I was glad to see Drs. Elizabeth Unger, James Jones, Mangalathu Rajeevan, and Steve Monroe at the recent Workshop. The CDC has made some welcomed changes to their website over the last year and I hope they will consider incorporating some of the information from the NIH Workshop on their website.

In 2006, then-CDC director Dr. Julie Gerberding held a press conference declaring that CFS was a real biological illness: I have always believed in the power of “show, don't tell.” For example, if the CDC website were to include or refer to some of the biological studies showing what happens to ME/CFS subjects' bodies post-exercise as compared to normals, this would “show” physicians and the public WHY physical exercise/ activity needs to be carefully executed and not just “tell” them. It would help back up the assertion that ME/CFS is a biological and not psychological illness.

The CDC should also further review patient, researcher, and clinician concerns about the effects of graded exercise and cognitive behavioral therapy (GET; CBT). Dr. Fred Friedberg's talk on “self-management” and the discussion following at the NIH Workshop was superb. The current CDC website has some precautions about GET and CBT but there is more to the story. For example, surveys of thousands of patients internationally over the last decade have shown that many patients felt that GET and/or CBT significantly worsened their health and a less publicized January 2011 Spanish GET/CBT showed deterioration in physical function and increased pain with these treatments. (4, 5) Indeed, 89-96% of participants in the UK PACE trial suffered “non-serious” adverse events (6, Table 4 in the paper) but details of these events are not given and a high bar (to my clinical eye) for “serious” deterioration was set whereby subjects had to be continuously functionally disabled for 4 weeks to qualify as a “serious” deterioration. (7)

Past GET and CBT trials have several methodological flaws including differing subject selection criteria, short-term follow-ups (less than one year) for a chronic illness, poor assessment of treatment safety, and lack of objective outcome measures that should be considered when assessing their conclusions. (8, 9) Finally, CDC need to be cautious regarding which advisors they utilize: some UK advisors have ties to disability insurance companies which may influence their views. In the UK, patients have had their disability benefit claims rejected or discontinued due to not participating in these treatments (out of fear about adverse effects) or are accused of medical non-compliance when they do not improve. At the very least, advisors should be asked about any possible conflicts of interest before serving on panels, committees, etc.

I understand that Dr. Unger will be meeting with patient advocacy organizations in May and appreciate her willingness to engage with these groups.

Health Resources and Services Administration (HRSA):

According to their website, HRSA's mission is to "To improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs" especially "for people who are uninsured, isolated or medically vulnerable." (10) People with ME/CFS have communicated to the government for years their difficulty with finding/ accessing knowledgeable healthcare providers even in large metropolitan areas and about 25% of patients may be homebound or bedbound, judging by data from the UK since no data is available for the USA. (11) As a physician who made housecalls in the past, I know homebound patients are usually isolated and medically vulnerable. ME/CFS may also affect people of color and those with lower levels of education and occupational levels in greater numbers than white upper-middle class professionals. (12) Historically, people in the former categories have had difficulty accessing care and the problems experienced by more socioeconomically advantaged ME/CFS patients are likely magnified many fold in these groups. This likely contributes to the 80% of the ME/CFS population that has not been diagnosed yet. (13) I am not familiar with HRSA's many programs but could any of their resources or activities potentially be used to help advance care for this underserved population?

Thank you for paying attention to my concerns. As I mentioned, I am new to government processes and programs and would appreciate any guidance from federal officials. Together, we can solve this illness!

Sincerely,

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