

Dear Sirs and Mesdames,

Thank you for this opportunity to address the CFSAC and other participants at this meeting.

Centers for Disease Control

During the May 2009 CFSAC meeting, the committee's top recommendation to DHHS was to "establish progressive leadership at the CDC that can achieve efficient meaningful progress in CFS research, clinical care and education." I heartily endorse this recommendation.

I participated in the May 2009 CDC stakeholder meeting and have reviewed the CDC's CFS 5-year strategic plan. While there are many goals outlined and buzzwords used, I have yet to see any meaningful action out of the CDC.

During the stakeholder meeting, a major concern of people with CFS and researchers was the empirical definition of CFS used by the CDC. The empirical definition muddies the results of studies since subjects with other illnesses could be misclassified as CFS. Jason et al. recently showed that up to 38% of people diagnosed with major depressive disorder could be misdiagnosed with CFS using CDC criteria. (1) Conversely, studies (2,3) that have attempted to narrow the subjects selected, e.g. to those with acute onset CFS after a flu-like episode, have been able to produce more consistent results. Yet, the CDC has not acknowledged this as a problem and does not plan to address this issue at all until 2010.

Secondly, the CDC does not seem to have any interest in interacting with other CFS researchers. The 5-year strategic plan mentions establishing an international workshop in Summer 2009 but it does not seem this was done. CDC staff were invited but none showed up at either the March 2009 International Association for CFS/ME meeting or the CFIDS Association of America/ NIH-sponsored September 2009 meeting at Cold Spring Harbor. CDC has also not shared data collected over the years on CFS patients with other researchers. Science is a collaborative enterprise but the CDC is behaving like an ostrich with its head stuck in the sand.

When I was a medical student many years ago, I respected the CDC greatly and even thought about joining its Epidemic Intelligence Service but my experience as a physician disabled by CFS has been troubling. I would like to see the CDC CFS section re-establish itself as a trusted agency for those who are affected by and who care for people with CFS.

NIH

It's been a long time in the making and CFS research still needs more funding but I would like to commend the National Institute of Allergy and Infectious Disease for approving \$1.4 million for Dr. Judy Mikovits and Dr. Jonathan Kerr's research. I want to thank Dr. Eleanor Hanna for her effort and care.

I also hope NIH review staff will seriously consider funding other groundbreaking studies including examining biomarkers of mental/physical fatigue, pain that are elevated greatly after exercise in CFS patients (4) and the use of rituximab to relieve CFS symptoms, currently being studied in Norway (5).

While I am excited by these studies, they point out the need for establishment of federally-sponsored regional centers dedicated to CFS. (CFSAC May 2009 Recommendation #3) Results of pilot studies need to be replicated with large national samples. Many people with CFS are interested in participating in studies and willing to travel some distance despite illness but when there is only ONE center (the Whittemore-Peterson Institute at the University of Nevada, Reno)

in the entire United States, it becomes cost-, physically-, and logistically-prohibitive. Furthermore, no location currently offers all the available testing that is being studied. Finally, any interview of CFS sufferers shows that finding a primary care physician to diagnose or manage CFS is still very difficult.

FDA

The CFS patient community has been waiting many months to hear from the FDA about the approval status of Ampligen. As a former medical researcher, I would also like to see the final results of the open-label Ampligen study. (6) I hear bits and pieces about the trial but have yet to see it written up anywhere. Clinicaltrials.gov has the study listed as completed but no study results are posted.

Thank you to the CFSAC and Dr. Wanda Jones for your hard work. Thank you for your attention.

Sincerely,

Lily Chu, MD, MSPH

1. Jason LA, Najar N, Porter N, Reh C. Evaluating the Centers for Disease Control's Empirical Chronic Fatigue Syndrome Case Definition. *Journal of Disability Policy Studies*. 2009 Sept; 20(2): 93-100.
2. [Lombardi VC, Ruscetti FW, Das Gupta J](#), et al. Detection of an Infectious Retrovirus, XMRV, in Blood Cells of Patients with Chronic Fatigue Syndrome. *Science*. 2009 Oct 8.
3. Kogelnik AM, Loomis K, Hoegh-Petersen M, et al. [Use of valganciclovir in patients with elevated antibody titers against Human Herpesvirus-6 \(HHV-6\) and Epstein-Barr Virus \(EBV\) who were experiencing central nervous system dysfunction including long-standing fatigue](#). *J Clin Virol*. 2006 Dec;37 Suppl 1:S33-8.
4. Light AR, White AT, Hughen RW, et al. [Moderate exercise increases expression for sensory, adrenergic, and immune genes in chronic fatigue syndrome patients but not in normal subjects](#). *J Pain*. 2009 Oct;10(10):1099-112. Epub 2009 Jul 31.
5. Fluge Ø, Mella O. [Clinical impact of B-cell depletion with the anti-CD20 antibody rituximab in chronic fatigue syndrome: a preliminary case series](#). *BMC Neurol*. 2009 Jul 1;9:28.
6. <http://www.clinicaltrials.gov/ct2/show/study/NCT00215800?term=chronic+fatigue+syndrome&rank=3> (Website accessed 10/12/2009.)