Testimony

Mary E. McNamara

I submit this testimony as one of the Founders of the New Jersey CFS Association and its Vice President, Director of Research, Emeritus.

At the NIH "State-of-the-Knowledge Workshop," April 7-8, 2011 participants recommended research to further the scientific understanding of ME/CFS. I request Secretary Sebelius establish within HHS four projects to carry out the following proposals:

1. *Genetics: Whole Exome/Genome Sequencing*
   Proposed by Dr. Michael Dean-- utilize resources currently funded to do this state-of-the-art genetics research and sequence twenty ME/CFS patients. The Lo/Alter PNAS study cohort of MLV-positive patients who were re-tested after fifteen years would be desirable study subjects as would multiple family members afflicted with ME/CFS (Dr. Mikovits) and a twin set (Dr. Klimas.)

2. *Immunology: ME/CFS Immune System Test Panel*
   Proposed by Drs. Klimas and Fletcher-- clinically deploy and evaluate the University of Miami's "ME/CFS Immune System Test Panel" to assist with diagnosis and treatment management.

3. *Neurology: ME/CFS Proteome Biomarker*
   Proposed by Dr. Natelson-- validate and convert his spinal fluid proteome biomarker into a blood test for ME/CFS diagnosis.

4. *Infectious Diseases: Dr. Ian Lipkin's Pathogen Studies*
   Dr. Lipkin did not present at the Workshop, but his NIAID XMRV study was referenced and should be summarized in the Workshop's final report due to its importance. (Note: Dr. Lipkin discussed the study at the *New York Academy* of *Sciences*, March 29, 2011, "Pathogens in the Blood.") If his study design does not include searching for co-infections in addition to retroviruses, it should be expanded to include them. If he, possibly with Dr. Montoya, has a separate study to search for all pathogens using his state-of-the-art technology, it should be described in the final report as well.

Dr. Komaroff emphasized the role of infectious agents, primary and secondary, and central nervous system and immune system abnormalities in ME/CFS in his Plenary Overview reaffirming previous requests which are resubmitted here (Attachment).

Mary E. McNamara
April 18, 2011

ATTACHMENT: Testimony submitted for October, 13-14, 2010 CFSAC Meeting

To the Chairman and Members of the CFS Advisory Committee (CFSAC):

I submit this testimony as one of the Founders of the New Jersey CFS Association and its Vice President, Director of Research, Emeritus.

Regarding the findings of the Lo, et al study (*PNAS*, August 23, 2010) which found evidence of MLV-related viruses in CFS patients which expands upon the Lombardi, et al XMRV discovery in CFS (*Science*, October 23, 2009), I request that:

1. Secretary Sebelius meet with the Whittemore Peterson Institute founders and researchers before the next CFSAC meeting to acknowledge their discovery and to ask them how HHS can help them continue their groundbreaking research and clinical work.
2. The number of human gamma retrovirus cases worldwide be reported at each CFSAC meeting.
3. ME/CFS clinical trials, number of patients enrolled, and health outcomes be reported at each CFSAC meeting.
4. The Trans-NIH Working Group on Chronic Fatigue Syndrome be reorganized with NIAID, NHLBI, NCI, NINDS, NHGRI, NICHD, NCCAM represented; and be re-staffed by individuals with skills, knowledge and abilities focused on: infectious disease (virology, retrovirology, opportunistic infections, diagnostic tests, treatments, prevention); immunology (clinical, acquired immune dysfunctions, diagnostic tests, treatments); neurology; and genetics.
5. The skills, knowledge and abilities of ME/CFS staff, grant peer reviewers, and decision makers be examined to ensure qualification to work on an infectious disease, with acquired immune system dysregulation; infection-related neurological abnormalities, blood

volume loss, orthostatic intolerance, P450 dysregulation, and other debilitating infection-related health issues; and that nonqualified staff be reassigned.

6. Speaking on the *Global Health Initiative* at Johns Hopkins August 16, 2010, Secretary of State, Hillary Clinton, said, "*No nation in history has done more to improve global health. …One of the intersecting goals of being the leader in global health…has to do with the health of our own people.*" Given *GHI's* success in treating millions of people suffering from infectious diseases, I request that Secretary Clinton be briefed on ME/CFS's magnitude, 17 million globally, and societal cost, $9.1 billion annually; and that the *Initiative's* components, namely--

expertise (infectious diseases, including retroviral disease);
principles (improved health and quality of life outcomes);
programs (clinics, diagnostic tests, treatments, prevention);

and

funding levels ($63 billion over the next 6 years)

be used as a blueprint to establish <u>specialized care</u> (i.e., local clinics, trained physicians, standard diagnostic work-ups, treatments) for the men, women, and children suffering from this debilitating disease in the U.S. and abroad.

Mary E. McNamara
September 17, 2010