

Public Comment
Mary McNamara

I would like to thank CFSAC coordinators for providing phone and webinar access to the December 2013 meeting enabling homebound and severely ill patients to participate. The FDA, Rear Admiral Kweder and her staff are to be commended for recognizing ME/CFS as a serious disease and for publishing “The Voice of the Patient” in September 2013.

ME/CFS is one of this country’s most neglected and serious public health problems. It’s not a new disease-- Thomas Sydenham founder of modern clinical, scientific and public health medicine described a disease spectrum identical to it in 1681. Presently this is what we know about ME/CFS:

- WHO recognized it in 1969 as a neurological disease and incorporated it in the International Classification of Diseases (ICD) under “Disorders of the Brain.”
- The CDC estimates it affects one million people in the United States and seventeen million worldwide.
- It can affect anyone any time—men, women, children, adolescents, the elderly—in all racial/ethnic/socioeconomic groups.
- There are more than 50 outbreaks recorded in the world’s literature.
- Symptoms include extreme weakness and exhaustion; difficulty sitting and standing upright; balance problems, fainting and blackouts; difficulty processing information: slowed thought, impaired concentration, and short term memory loss; widespread pain; exertion-induced flare-ups; difficulty breathing; sleep disturbances; gastrointestinal distress; visual problems; sensitivities to light, sound, and odors; among others.
- Physicians classify cases as follows: very severe, severe, moderate, or mild. The CDC notes severe cases can be as debilitating as end-stage renal disease, heart disease, COPD, lupus, or MS.
- Social Security Administration (SSA) ruling SSR 12-2P clarifies policy for evaluating ME/CFS disability cases and patients who meet SSA criteria for disability are eligible for benefits.
- There is limited availability of medical care and few trained healthcare professionals consequently patients typically consult multiple doctors and suffer for years before receiving an accurate diagnosis. As an example, the wait time to be seen at the Stanford University CFS Clinic is currently four years.
- The estimated economic cost annually in the United States is high: \$17 billion in healthcare costs and \$37 billion in lost productivity are attributed to ME/CFS by CDC epidemiologists.
- It is recognized as a serious issue for the military. Defense Medical Surveillance System records indicate more than 5000 military personnel were diagnosed with ME/CFS between 1999 and 2009.
- The FDA has determined ME/CFS is a serious condition for which there are no approved drug treatments. To fulfill FDA commitments made as part of the Prescription Drug User Fee Act (PDUFA) under Title I of the Food and Drug Safety and Innovation Act (FDAIA) (Pub. L. 112-144), the FDA Center for Drug Evaluation and Research selected ME/CFS as one of twenty diseases to be the focus of workshops under the Patient-Focused Drug Development Initiative.

NIH's "ME/CFS State of the Knowledge Workshop Report" April 7-8, 2011 states "*an infectious disease etiology is plausible because of the frequent abrupt onset of the illness with a classic viral-like syndrome and the similarity of the chronic symptoms to other prolonged infections...there is also extensive focus on the brain as the possible source or residence of the illness.*" Importantly while workshop participants identified key gaps in knowledge as well as research opportunities, former ORWH Director Dr. Vivian Pinn candidly acknowledged past problems in executing a research plan for ME/CFS. And it appears little has changed 2 ½ years later in that regard. To address this problem requires:

- NIH to expand, intensify, and coordinate ME/CFS basic and clinical research activities;
- NIH to allocate sufficient financial resources and personnel to support the research required to close the knowledge gaps. (Note there's a habitual pattern of underfunding and understaffing);
- NIH to ensure leadership and management personnel have the training and experience to guide ME/CFS intramural and extramural activities; and
- NIH to educate its staff on the history and current status of the disease (Ref: Von Salis CFSAC Testimony, October, 2012).

NIH has a track record of success with similar diseases which are generously funded and staffed. Thirteen years ago I wrote: *Now is the time for the leaders of our federal health agencies to deploy our powerful scientific resources to understand this complex illness [ME/CFS] and relieve the suffering it continues to inflict on mankind.*¹ With its "newest" arsenal of high tech tools, engaged world- renowned scientists, and breakthroughs in medical science, NIH can deploy these assets if it chooses to learn how to prevent, diagnose, and treat ME/CFS. I request the Committee ask NIH to take such action.

Turning to the CDC, Dr. Unger is to be commended for her multi-site study, open communication with patients, and CFSAC participation. The September 10, 2013 conference call with Dr. Lipkin was informative and highlighted his need for funding. Because patients cite a high loss of functional capacity, as much as 70-80% in some cases (FDA's "Voice of the Patient"), 2-day CPET testing is critical. Also overcoming logistics and including the severely ill in the CDC study would lead to safe, accurate revisions to the CDC website. Combining Thomas Sydenham's scientific approach to medicine, namely painstaking observation and careful recording, with today's technology will lead to a much better understanding of ME/CFS and ultimately effective treatments.

Finally, the IOM Contract should be canceled. There are no new research findings to warrant it. The \$1 million should be redirected to researchers, specifically Drs. Lipkin, Kogelnik, Montoya, Chia, Enlander, Klimas, Peterson, Fluge/Mella, Bansal, and Tate.

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¹ "Scientific Medicine and Chronic Fatigue Syndrome," *The Scientist*, 13 November 2000

