

Outside Witness Testimony prepared for Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies

Addressing National Institutes of Health, the Centers for Disease Control and Prevention, Department of Health and Human Services, and Assistant Secretary for Health

Charmian Proskauer, Chair
U.S. Action Working Group
April 15, 2016

We request:

- **CDC: Restore funding for ME/CFS in FY17 budget - \$6 MM**
- **HHS/Assistant Secretary for Health – Office of Women’s Health: Continue funding for Chronic Fatigue Syndrome Advisory Committee - \$300,000**
- **NIH: Follow through on recent statements to patients by providing significant and specific funding for ME/CFS research, including RFAs**

I present this testimony on behalf of the members listed below of the U.S. Action Working Group, a coordinating committee for a number of non-profit organizations and patient/advocates working to advance research on the disease **Myalgic Encephalomyelitis/Chronic Fatigue Syndrome** (known as ME/CFS). ME/CFS affects up to 2.5 million people in the U.S., according to the Institute of Medicine, and approximately 17 million more around the world and has been reported in people younger than 10 years of age and the elderly (over 70 years). We represent organizations which provide information on governmental and other programs to patients and advocates; educate government officials, medical professionals, and patients about ME/CFS; and provide direct services to patients.

About ME/CFS

Two major reports, both funded by government agencies, were published in 2015, the NIH’s Pathways to Prevention (P2P) report, *“Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome,”* and the Institute of Medicine (IOM) report, *“Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness.”*

Myalgic encephalomyelitis/chronic fatigue syndrome, commonly referred to as ME/CFS, is a disease characterized by profound fatigue, cognitive dysfunction, sleep abnormalities, autonomic manifestations, pain, and other symptoms that are made worse by exertion of any sort. ME/CFS can severely impair patients’ ability to conduct their normal lives, yet many struggle with symptoms for years before receiving a diagnosis. Fewer than one-third of medical school curricula and less than half of medical textbooks include information about ME/CFS. Although many health care providers are aware of ME/CFS, they may lack essential knowledge about how to diagnose and treat it.

The Institute of Medicine report states:

“Myalgic encephalomyelitis (ME) and chronic fatigue syndrome (CFS) are serious, debilitating conditions that impose a burden of illness on millions of people in the United States. At least one-quarter of ME/CFS patients are house- or bed-bound at some point in their lives. The direct and indirect economic costs of ME/CFS to society have been estimated

at \$17 to \$24 billion annually...High medical costs combined with reduced earning capacity often have devastating effects on patients' financial status." (IOM, pp. 1-2)

"Patients with ME/CFS have been found to be more functionally impaired than those with other disabling illness, including type 2 diabetes mellitus, congestive heart failure, hypertension, depression, multiple sclerosis, and end-stage renal disease." (IOM, p. 31)

This devastating disease is not limited to adults. Children and adolescents also get ME/CFS, but there are almost no existing trained medical professionals to give them proper care. One mother writes,

"Both of my children have ME/CFS. As a parent, it has been heartbreaking to watch them suffer from this debilitating illness. My son, now age 20, became sick when he was 12. He missed most of junior and senior high school because he was too sick to physically attend school. My daughter, now age 17, also became sick at the age of 12 and is also too sick to attend school. My children have lost an enormous amount—their health, the social experience of high school, and the ability to participate in things they love like sports and music. It took years of doctor visits and consultations with specialist to receive a diagnosis, and the utter lack of treatments for ME/CFS is incredibly frustrating."

For most of the last 30 years, patients with this disease have received little support from the federal agencies with the most power to help them – NIH and CDC; only very small amounts of funding have been dedicated to researching or finding treatments for the disease or educating the medical community about it. In addition, some of the treatment recommendations provided by the CDC were based on research that is now under review, and have been harmful to patients.

Because of the lack of medical care providers who are properly educated about ME/CFS, and the lack of medical research leading to better understanding of the disease and effective treatments, patients with ME/CFS are often stigmatized or "treated with skepticism, uncertainty, and apprehension" (P2P, p. 4). **As a result, most patients are not able to obtain adequate medical care for their illness, either not getting an accurate diagnosis or receiving inappropriate or no treatment, thereby leaving more than 2 million citizens largely disabled for decades.**

CDC

The patient community was very disturbed to see that the already tiny allocation of \$5.4 million for the CDC's ME/CFS program was zeroed out in the President's budget for FY17, a year in which the CDC is scheduled to complete its 4-year multi-site study and begin a new initiative to educate medical professionals about ME/CFS based on the recent findings of Institute of Medicine. The multi-site study will provide a tremendous amount of new information regarding this disease and it is critical that it be completed.

We, therefore, join in asking this Committee to recommend a restoration of the CDC budget for ME/CFS at a level of no less than \$6M and urge the CDC to use that to complete its multi-site study, and leverage the recommendations from both the Institute of Medicine and the Chronic Fatigue Advisory Committee to provide to develop and execute a new, broad-based medical education campaign.

To address the lack of access to clinical care, we also ask the Committee to urge the CDC to work with the NIH and other agencies within the Department of Health and Human Services

to find creative ways to fund multiple Centers of Excellence (there are none now) and include in them a clinical care component so that patients nationwide might have improved access to expert ME/CFS medical professionals.

NIH

There are NO FDA-approved drugs to treat this disease. In 2014, there were at least 32 FDA-approved drugs to treat HIV/AIDS and nine for Multiple Sclerosis. Why is this? **Because essentially no research dollars are going toward finding new treatments, new drugs, and other useful symptom-reducing interventions.**

Today, research funding from NIH for ME/CFS is far below funding for similarly disabling illnesses with similar or lower prevalence:

- ME/CFS (2 million patients): **Only \$3 per patient in NIH funding** - \$6 million in 2015
- Multiple sclerosis (400,000 patients): About \$235 per patient; \$94 million 2015
- HIV/AIDS (1.2 million patients): About \$2500 per patient (\$3 billion in 2015)

ME/CFS patients are cautiously hopeful to see the recent focus on this disease at the National Institutes of Health, with support from Dr. Francis Collins, Director, and Dr. Walter Koroshetz, Director of the National Institute of Neurological Diseases and Stroke. A Trans-NIH Working Group has been established for this disease, and NIH has also begun planning for an intramural study to begin in the summer of 2016. We recognize the intention of the NIH to expand the extramural research program and applaud the goal of bringing new researchers into the field. However, this will not happen without **funding allocated specifically to this disease.**

We join in asking this Committee to recommend that the NIH make funding for ME/CFS research commensurate with disease burden. This funding is necessary to jump-start the field through a set of intramural and extramural investments that include Requests for Applications (RFAs) for biomarkers and treatment trials, set-aside funding for investigator initiated studies (including for hypothesis generation), regional Centers of Excellence, and support for a network of researchers to develop a research strategy with defined milestones and to reach consensus on a research case definition and research standards.

We further ask that NIH act aggressively to implement these required actions and to collaborate with disease researchers, clinicians, and patients and their advocates in doing so with full transparency for best results.

Department of Health and Human Services (HHS) and Assistant Secretary for Health

The Chronic Fatigue Syndrome Advisory Committee is a Federal Advisory Committee with 11 members of the public, including one patient representative, and non-voting representatives from 7 agencies within HHS. In addition there are up to 3 non-voting “liaison members” from ME/CFS patient or research organizations. It is an important vehicle by which patients can communicate face-to-face and engage in discussions with the agencies. Its charter must be renewed every two years, or it will cease to exist.

We join in asking this Committee to urge HHS and the Assistant Secretary for Health to continue support of the Chronic Fatigue Syndrome Advisory Committee (CFSAC) with a budget of \$300,000 including direct expenses and staff support, to renew its charter in

September, 2016, and to accelerate progress on CFSAC's recommendations to strengthen research, education, training, care, and services to better address the needs of two million Americans living with ME/CFS. Further, to address the gaps in medical care highlighted by the recent Institute of Medicine Report, we ask the Committee to urge HHS to find creative ways to fund regional Centers of Excellence that include both a research component and direct clinical care component.

We close with Cheryl's story.

“CFS is an invisible disability. When you look at me, you won't see my broken aerobic metabolism that has cost me my muscle strength, flexibility and endurance. You won't see that taking a shower or preparing a simple meal causes me to exceed my anaerobic threshold, creating lactic acid build-up, exhaustion and pain. You won't see how my sleep is disrupted every night, restless and unrefreshing. You won't see the chronic and debilitating muscle and joint pain, headaches, sore throat, or the intolerance to noise, bright lights, chemicals and foods that were easily tolerated before CFS. You won't see my lost sense of productivity, accomplishment and contribution that I got from career that I loved and was so much of my identity. Or my lost sense of connection with others because socializing exceeds my energy limits. Or that I can no longer be counted on to help family or friends in need, or be an equal partner and companion to my husband. You can't see my uncertainty about the future. You can't see my heart yearning to live fully, while my body and brain deteriorate. But it's real, and it's my CFS story.”

On behalf of Cheryl and all other ME/CFS patients, we urge this Committee to take the actions we have outlined above. Thank you.

Members of the U.S. Action Working Group

Massachusetts CFIDS/ME & FM Association
New Jersey ME/CFS Association, Inc.
Open Medicine Foundation
Solve ME/CFS Initiative
Adriane Tillman, California
Claudia Goodell, Race to Solve ME/CFS, New Mexico
Denise Lopez-Majano, Speak Up About ME, Pennsylvania
Erica Verrillo, Executive Director, American Myalgic Encephalomyelitis
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