

## **Public Comment**

### **Mary Dimmock**

*I am reading this letter on behalf of a group of ME/CFS patient organizations and patient advocates who have written this letter to Secretary Sebelius, Dr. Koh, Dr. Lee and the CFSAC to express their dismay with how ME/CFS has been handled in this country.*

Dear Secretary Sebelius, Dr. Koh, Dr. Lee, and CFSAC

We strongly believe there is an urgent need for the Department of Health and Human Services to undertake a strategic, coordinated, and fully-funded effort to address the critical priorities for adequate ME/CFS research, treatment and provider education. Therefore, we respectfully request a meeting to discuss the concerns raised in this letter and to begin formulating a comprehensive plan to address those concerns. We request your response by August 1, 2012.

For more than 25 years, DHHS has known about the devastating impact of chronic fatigue syndrome (CFS, known as myalgic encephalomyelitis or ME/CFS), a disease that the CDC has said “can be as disabling as multiple sclerosis, lupus, rheumatoid arthritis, heart disease, end-stage renal disease... and similar chronic conditions.”(1) ME/CFS has obliterated the lives of more than one million Americans. Patients can be sick for decades, often homebound and bedridden and more likely to die prematurely from cancer, heart failure or suicide than those without ME/CFS. (2)

Former CFSAC member Dr. Nancy Klimas stated: “My H.I.V. patients for the most part are hale and hearty thanks to three decades of intense and excellent research and billions of dollars invested. Many of my C.F.S. patients, on the other hand, are terribly ill and unable to work or participate in the care of their families.” (3)

Compounding the personal devastation is the effect on our country’s economic well-being. ME/CFS drains our workforce and costs our country an estimated \$18 - \$23 billion annually. (4)

In spite of all this, virtually nothing has been done, compared to other similar diseases.

The problems are clear: confusion resulting from the definition and name, paltry and misapplied NIH funding, inadequate CDC physician education and an FDA pipeline that has failed to deliver any treatments to address such a serious and life-robbing disease.

We acknowledge some progress has been made. But it has been far too little and far too slow for many patients who have suffered for decades. To make the progress needed, we require a significant, sustained and coordinated commitment from DHHS to address the following four key priorities:

1. **Resolve the definition, name and classification confusion** (5) (6) (7) (8) (9)
2. **Provide a fair share of research funding, focused on biological pathologies, biomarkers and treatment** (10) (11) (12) (13, 14)

3. **Educate the medical community** (15)
4. **Accelerate the FDA pipeline for ME/CFS** (16)

*See Appendix 1 for specific details on the issues associated with these priorities.*

While there are other priorities, these four are the most critical priorities today. And they have been for the last 25 years.

Many of us have literally lost decades of our lives from this lack of progress. As patients, family and friends of people with ME/CFS, we cannot allow our lives to be destroyed any longer. As a country, we can ill-afford the economic costs.

It is time for the United States government to embrace this disease with the seriousness and vigor that characterized the fight against HIV/AIDS. The Department of Health and Human Services is the one organization positioned to provide the leadership needed to undertake a strategic, coordinated and fully-funded response to the challenge of ME/CFS. We ask you to schedule a meeting between a group of ME/CFS patient representatives and key representatives from across DHHS to discuss the concerns raised in this letter and begin to formulate a comprehensive plan.

Please respond to Mary Dimmock by August 1, 2012 regarding the scheduling of this meeting or if you need additional information.

Signed

**ME/CFS Patient Organizations**

CFS Solutions of West Michigan	New Jersey CFS Association, Inc.
CFS Knowledge Center, Inc.	PANDORA
CFS/Fibromyalgia Organization of Georgia, Inc.	Phoenix Rising
Chronic Fatigue Syndrome, Fibromyalgia and Chemical Sensitivity Coalition of Chicago	Rocky Mountain CFS/ME and FM Association
Coalition 4 ME/CFS	Speak Up About ME
The Connecticut CFIDS & FM Association, Inc.	Vermont CFIDS Association, Inc.
Massachusetts CFIDS Association, Inc.	Wisconsin ME/CFS Association, Inc.

**ME/CFS Patient Advocates**

Lori Chapo-Kroger, R.N.	Mike Munoz
Lily Chu, M.D., MSHS	Donna Pearson
Laurie DeDecker, R.N.	Mary Schweitzer, Ph.D.
Mary Dimmock	Meghan Shannon MS MFT
Pat Fero, MEPD	Rivka Solomon
Suzan Jackson	Jennifer Spotila, J.D.
Cort Johnson	Nancy Visocki
Patricia LaRosa, R.N., MSN	Toby Vokal
Denise Lopez-Majano	Charlotte von Salis, J.D.

Robert Miller	
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## Appendix 1 - Details on Priorities

These four priorities are not new. They have been stated repeatedly in CFSAC deliberations, CFSAC recommendations and public testimony. However, in spite of bright spots, the overall government response to these priorities has been uncoordinated, underfunded, not sustained and too often misdirected.

- 1. Resolve the definition, name and classification confusion.** With the focus on fatigue, the 1994 Fukuda definition and the 2005 Empirical definition have hopelessly blurred the distinctions between ME/CFS, depression and generalized chronic fatigue. (6,7). They are out of date and lack the requirement for the one symptom considered to be the hallmark of the disease: post-exertional malaise. Use of these definitions has contributed to research results that cannot be effectively compared across studies (6) and has contributed to inappropriate diagnosis and treatment.

In October 2009, the CFS Advisory Committee (CFSAC) recommended that “DHHS recognize a need for and support a national effort to arrive at a consensus definition of CFS that is accurate, standardized and reflective of the true disease.” (7) We support that recommendation. It is long past time to subset Fukuda-defined patients and actively consider the existing 2003 Canadian Consensus Criteria (CCC) or 2011 International Consensus Criteria (ICC) for those patients who suffer from the hallmark post-exertional malaise.

Beyond the definition, the name *CFS* has been confused with everyday tiredness and “chronic fatigue” ever since the CDC created it in 1988. Yet, many experienced clinicians and researchers recognize the equivalency or close similarity of ME and CFS based on the growth in scientific understanding and have adopted the term *ME/CFS*. All of DHHS should follow the NIH’s lead and adopt the term *ME/CFS* as recommended by the CFSAC in October 2010. (8)

Finally, the current version of the ICD-10-CM classifies CFS as a symptom under “chronic fatigue” even though WHO defines CFS to be a neurological disease, and the CFSAC has been recommending the same since 2004. The Coalition 4 ME/CFS submitted a proposal to NCHS in July 2011 to request CFS be reclassified. To date, NCHS has not made the change, communicated their decision or responded to queries on the status. It is crucial that NCHS ensures that the ICD-10-CM classification of CFS is aligned with WHO’s neurological classification before ICD-10-CM rolls out. (9)

- 2. Provide a fair share of research funding, focused on biological pathologies, biomarkers and treatment.** In 2012, ME/CFS NIH funding at \$6M is ranked 220 out of 232 diseases, far below that of other diseases, such as MS (\$121M) or lupus (\$105M) with a similar level of disability and lower prevalence. Even hay fever gets more at \$7M. (10) Worse, some of the limited NIH funding available has instead been spent on grants that ultimately were unrelated to the study of ME/CFS or focused on psychological and other tangential issues. (11)

In May 2011, the CFSAC recommended “ME/CFS research receive funding commensurate with the magnitude of the problem.”(12) We similarly are asking the NIH to provide a fair share of funding commensurate with the devastating personal and economic impact of this disease and direct it specifically toward investigation of the underlying biological pathologies

of ME/CFS and to identify the desperately needed biomarkers and treatments that will address those pathologies.

Beyond the level of funding, researchers have stated that the available NIH funding options are too restrictive to fund the needed innovative studies. In addition, the SEP lacks the continuity provided by a standing chairperson and resubmitted proposals can end up with new reviewers who lack context. (13,14) The NIH has stated that not enough proposals are submitted. (14) The lack of new researchers entering the field is a concern. Dr. Nancy Klimas suggested that the NIH could make a substantial leap forward by doing what has been done successfully in other disease areas, that is make “a full-court press effort to draw in people from other fields, encourage K awards, encourage training grants and encourage centers and programs.” (14) We ask the NIH to make such a “full-court press effort” for ME/CFS to address these challenges so the needed funding can get to researchers.

Finally, we are concerned that where ME/CFS is housed may affect the amount of funding, coordination and how the disease is perceived. Given what research is now showing about the disease, the NIAID or the NINDS may prove to be a more appropriate agency, in time. Regardless of where it is housed, we ask for a commitment to appropriate funding, cross-division coordination and an effort to decrease the stigma currently experienced.

3. **Educate the medical community.** With the exception of a handful of ME/CFS experts across the country, most doctors do not understand ME/CFS or even believe it is a physical condition. Some recommend treatments, such as aerobic physical activity that can cause not only temporary exacerbation of symptoms but prolonged disability. Lacking support from doctors, patients are left to search the Internet.

While the CDC has begun to modify their website and provide updated educational material, it is still based on the outdated Fukuda definition. Much more encouraging is the recently released IACFS/ME ME/CFS Primer for Clinical Practitioners, based on the Canadian Consensus Criteria (15). This primer far surpasses anything available for clinical use. We recommend that the CDC adopt the IACFS/ME primer as its new baseline and collaborate with international ME/CFS experts and patient organizations to refine it where needed and to proactively educate the medical community.

4. **Accelerate the FDA pipeline for ME/CFS.** ME/CFS applications have been shuffled across six different divisions in the FDA (16) and the only drug in the pipeline for ME/CFS has been effectively buried since 1997. Today, patients only have inadequate symptomatic relief. No treatments or biomarkers have come out of the process. A separate letter to Secretary Sebelius and Drs. Hamburg and Woodcock has requested an FDA stakeholder meeting to start to understand the challenges related to drug review and approval and to identify opportunities to accelerate approval. The FDA and ME/CFS stakeholders, including patients, need to work together to find ways to ensure that the process delivers the full complement of drugs and biomarkers needed to effectively diagnosis and treat patients.

## Appendix 2 - References

1. CDC Web Site <http://www.cdc.gov/cfs/symptoms/index.html>
2. Jason et al, Causes of Death Among Patients With Chronic Fatigue Syndrome. *Health Care for Women International*, 27; 615-626, 2006  
[http://www.theoneclickgroup.co.uk/documents/ME-CFS\\_docs/Causes%20of%20Death%20-%20CFS%20Patients.pdf](http://www.theoneclickgroup.co.uk/documents/ME-CFS_docs/Causes%20of%20Death%20-%20CFS%20Patients.pdf)
3. Klimas, Dr. Nancy in the New York Times Health Blog <http://consults.blogs.nytimes.com/2009/10/15/readers-ask-a-virus-linked-to-chronic-fatigue-syndrome/>
4. Jason et al, "The Economic Impact of ME/CFS: Individual and societal costs", *Dynamic Medicine* 2008, 7:6 <http://archive.biomedcentral.com/1476-5918/7/6/>
5. Ranciello, Vincent, "A tale of Two Viruses: Why AIDS was Pinned to HIV, but Chronic Fatigue Remains a Mystery. *Discover Magazine*, January 2012 <http://blogs.discovermagazine.com/crux/2012/01/12/hiv-in-xmrv-out-how-scientists-deduce-what-does-and-doesnt-cause-a-disease/>
6. Multiple references have examined the issues with the definitions. Examples include:
  - a. Jason et al, "Comparing the Fukuda et al. Criteria and the Canadian Case Definition for Chronic Fatigue Syndrome, *Journal of Chronic Fatigue Syndrome*, Vol 12, 2004 <http://www.cfids-cab.org/cfs-inform/CFS.case.def/jason.etal04.pdf>
7. CFSAC October 2009 recommendation to address definition issue <http://www.hhs.gov/advcomcfs/recommendations/10302009.html>
8. CFSAC October 2010 recommendation to adopt ME/CFS across HHS <http://www.hhs.gov/advcomcfs/recommendations/1012-142010.html>
9. CFSAC November 2011 discussion on ICD-10-CM [http://www.hhs.gov/advcomcfs/meetings/minutes/cfsac\\_min-11082011.pdf](http://www.hhs.gov/advcomcfs/meetings/minutes/cfsac_min-11082011.pdf) and [http://www.hhs.gov/advcomcfs/meetings/minutes/cfsac\\_min-11092011.pdf](http://www.hhs.gov/advcomcfs/meetings/minutes/cfsac_min-11092011.pdf)
10. 2012 NIH funding, [http://report.nih.gov/categorical\\_spending.aspx](http://report.nih.gov/categorical_spending.aspx)
11. Pat Fero and Charlotte von Salis, Analysis of use of NIH funding from 2000-2010
  - a. Pat Fero's testimony to the CFSAC on this analysis is at hour 1.31 on video. <http://www.youtube.com/watch?v=uB8xnB69KaE&feature=youtu.be>
12. CFSAC May 2010 recommendations to provide ME/CFS funding commensurate with the problem. <http://www.hhs.gov/advcomcfs/recommendations/05112011.html>
13. May 2011 CFSAC testimony by Lily Chu on need for flexible funding approaches [http://www.hhs.gov/advcomcfs/meetings/presentations/publictestimony\\_201105\\_chu.pdf](http://www.hhs.gov/advcomcfs/meetings/presentations/publictestimony_201105_chu.pdf).
14. CFSAC NIH discussion on challenges with getting grants - lack of applications, need for other approaches to funding – see page 29-32  
[http://www.hhs.gov/advcomcfs/meetings/minutes/cfsac\\_min-11092011.pdf](http://www.hhs.gov/advcomcfs/meetings/minutes/cfsac_min-11092011.pdf)
15. ME/CFS Primer for Clinical Practitioners, IACFSME, published May, 2011 <http://www.iacfsme.org/Portals/0/PDF/PrimerFinal3.pdf>
16. Assignment of Drugs Developed to Treat CFS [http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm241014.htm?utm\\_campaign=Google2&utm\\_source=fdaSearch&utm\\_medium=website&utm\\_term=cfs&utm\\_content=2](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm241014.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=cfs&utm_content=2)