

Public Comment
Mary Dimmock

Welcome to all new members. It's wonderful to see you here. And congratulations to Dr. Levine on being named chairwoman.

This is my fourth year here and the thirtieth year since Incline Village and Lyndonville.

The true measure of progress is not the number of activities performed but the bottom-line outcome achieved.

So what outcomes has HHS achieved in the last 30 years?

1. There are no approved treatments and no diagnostics
2. The concept of CFS is a fiasco of disparate definitions sharing nothing more than the ubiquitous symptom of fatigue for which there is no medical explanation.
3. NIH Research funding is dead last in dollars per patient.
4. Medical care is abysmal. Doctors don't think patients are really sick. The most commonly recommended treatments are CBT and GET used to reverse "false illness beliefs" and presumed deconditioning. In spite of the fact that ME patients have adverse responses to exercise. One of our premier medical clinics states that patients have a poorer prognosis if they have an organic illness.
5. Even if doctors do believe patients they have no idea how to help them because the medical education is so bad.
6. Prevalence estimates range from 0.07% to 2.6%. And that's just for Fukuda showing just how sloppy the concept of CFS is.
7. There is little knowledge of ME's natural history. But in 2012, CDC claimed it had been unable to confirm any outbreaks to study that might have helped with that.
8. The experts are reaching retirement but there are virtually none entering the field.
9. Drug companies have virtually ignored the disease.
10. The estimated U.S. economic impact is \$18-23B a year but there is no strategic plan to do anything about it.
11. Recommendations from CFSAC, ME experts and advocates are routinely ignored and there is little transparency with these key stakeholders.
12. There is still a lack of clarity and agreement on what disease is being studied.

The failure to achieve a single one of these outcomes in the last thirty years and the list of the perennial problems that never get resolved is the real measure of what's been achieved, not the endless list of activities that our congressional leaders receive.

HHS' actions have brought us to this moment. It's time that HHS stop the lip service, obfuscation, lack of transparency and meetings to nowhere. Its time that you listen to patients and experts to understand this disease and put in place an aggressive, serious, coordinated, fully funded plan to rescue these patients from their living hell.

Additional material for the binders and the public record

1. Pathways to Prevention Workshop

On May 28, Jennie Spotila and I sent a letter to Dr. Francis Collins, head of NIH, requesting that the Pathways to Prevention Workshop be cancelled. As the letter states, we took this action because of our serious reservations with the appropriateness of this workshop for this disease and its ability to deliver what is critically needed at this time. The main body of the letter is below and included a number of attachments that provided additional detail on each of the key points that we raised. Please read this letter and give our concerns the serious consideration that is warranted by this situation.

More information can be found here: <http://www.occupycfs.com/2014/06/02/collins-please-cancel-p2p/> and here: <http://www.occupycfs.com/2014/06/02/tell-dr-collins-to-stop-p2p/>

2. What disease are we talking about?

At the risk of sounding like a broken record, I think it is essential that HHS be clear on what disease they are actually studying. At the FDA meeting, a patient described a disease that causes neurological, immunological and energy production impairment and is characterized by post-exertional malaise, cognitive dysfunction, unrefreshing sleep.

But the global concept of CFS is based on disparate definitions that share nothing more than medically unexplained chronic fatigue. Allowing one label, “CFS”, to describe such disparate biologically unrelated conditions and definitions as diverse as Oxford, Fukuda, Empirical and Canadian is scientifically sloppy and medically irresponsible.

This is the root cause of why we have such a convoluted evidence base, stalled progress in research and poor clinical care.

HHS must definitively declare that this disease is a biological disease. HHS must declare that PEM is a mandatory, hallmark criterion. And finally, HHS must explicitly state that this disease has nothing to do with the problem of ‘activity avoidance that has resulted in deconditioning’ that PACE and Oxford study and that the NICE Guidelines are treating.

3. Education Workgroup Recommendations

A year ago, HHS informed CFSAC that it would need to develop its recommendations further through workgroups. At the March 2014 CFSAC, the Education Workshop, led by Dr. Sue Levine, advanced a set of recommendations on critical changes for medical education. It is essential that HHS adopt these recommendations.

Further, it is essential that the standardized patient videos currently being developed by CDC include post-exertional malaise as a mandatory symptom. My understanding is that the standardized patient video does not cover PEM and that that is only covered in the supplemental material. If that is correct, that needs to be fixed.

The March 2014 CFSAC recommendations – the following were pulled from the March 2014 CFSAC minutes¹ as they are not yet posted as recommendations. I do not know if there will be any changes in the final version.

1. The Chronic Fatigue Syndrome Advisory Committee (CFSAC) recommends that HHS provide opportunities for dissemination of information through the development of a curriculum at all U.S.-based medical schools providing the tools needed for physicians and other medical professionals to recognize ME/CFS as defined solely by the 2003 Canadian Consensus Criteria and to make appropriate referrals. (references are Experts Letter to Sebelius, Endorsement by IACFS/ME and CCC)
2. CFSAC recommends that funding be allotted to the appropriate agencies that can best develop teaching modules featuring ME/CFS patients with complex presentations as defined by 2003 Canadian Consensus Criteria.
3. CFSAC recommends that HHS provide funding through HRSA and other agencies to support integrative medicine programs featuring learning about ME/CFS patients as defined by the 2003 Canadian Consensus Criteria.
4. CFSAC recommends that HHS fund through appropriate agencies novel programs such as “Project ECHO” comprised of experts and/or multidisciplinary teams with expertise in ME/CFS that reach areas where patients do not have access to adequate clinical care for ME/CFS as defined by the 2003 Canadian Consensus Conference (recommendation references information on ECHO and the Primer]
5. CFSAC recommends that HHS provide funding to gather requisite data (prevalence rate/provider attitudes and knowledge, etc.) regarding ME/CFS patients as defined by the 2003 Canadian Consensus Criteria through established primary care organizations. (references include AAP, AAFP, ACP, ABFP, ACOG)
6. CFSAC recommends that HHS support CFSAC’s efforts to continue to amend CDC website information as has been discussed previously. [references the Canadian Consensus Criteria

Additional Background

As you all know, patients have been subject to abysmal and too often harmful medical care with doctors dismissing that patients are really sick, recommending talk therapy and exercise both of which can be harmful. Even when they want to help, there is little they can do. The root cause of this is what is on the CDC CFS website and other medical information sites. Just a few examples:

- CDC’s CFS Toolkit and other material treat all definitions as the same group of patients and recommends one set of diagnostic and treatment recommendations, largely focused on CBT, GET, sleep hygiene, pacing and sleep and pain medications.
- CDC’s website states that child abuse is a risk factor even though Dr. Jason did a study that found it was not.
- Citing the PACE trial, the Cleveland Clinic Center for Continuing Education recommends CBT to “change the cognitive responses that are thought to perpetuate CFS, such as fears about symptoms or activity” and recommends GET, for which it says the goal is to help “the patient gradually return to their normal physical activities.” It further states that patients have a poorer prognosis if they think they have an organic disease.²
- MedPageToday’s KevinMD, produced in collaboration with the American College of Physicians, states that CBT is used to break “the cycle of effort avoidance [and] decline in physical conditioning and increase in fatigue and can work well in combination with graded exercise.”³

This is what patients contend with every day. To protect patients, this must be fixed.

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Letter to Dr. Collins from Jennie Spotila and Mary Dimmock

May 28, 2014

VIA FACSIMILE AND PRIORITY MAIL

Francis S. Collins, M.D., Ph.D. Director, National Institutes of Health 1 Center Drive, MSC
0148 (Room 126) Bethesda, MD 20892-0148

RE: Pathways to Prevention Workshop on ME/CFS Dear Dr. Collins:

We are writing to request that you cancel the Office of Disease Prevention's Pathways to Prevention Workshop on ME/CFS ("P2P Workshop"). Your immediate action is required to ensure that ME/CFS research and policy is based on the best scientific evidence and processes.

In your April 16, 2014 letter to Representative Zoe Lofgren and colleagues, you said that the P2P Workshop would produce recommendations to move the field forward. We believe that this is not the case, and we offer the following documentation to support our conclusion:

The Workshop is unnecessary and redundant given the recommendations of disease experts and other NIH efforts to advance ME/CFS research and clinical care. See Attachment 1. The Workshop has been structured to address the problem of medically unexplained fatigue, and not the disease(s) known as ME/CFS. See Attachment 2.

NIH has paid lip service to collecting input from stakeholders, but in reality has not involved them in a meaningful way. See Attachment 3. The P2P Workshop process is inappropriate for this disease, particularly because the decision makers will be non-ME/CFS experts. See Attachment 4.

The goal of this Workshop is unclear as a result of numerous contradictory and confusing public statements by HHS about the purpose of the Workshop. See Attachment 5.

Dr. Collins, we are not objecting to the P2P Workshop simply to make a political point or for the sake of criticizing federal efforts to address the challenges of this disease. We are appealing for your help because we know you recognize that ME/CFS is a serious public health issue that needs the best of what science can offer. We sincerely believe that the evidence included with this letter raises genuine concerns that the P2P Workshop does not represent the best of what science can offer, and may very well take us in the opposite direction.

For all of these reasons, we request that you cancel the P2P Workshop. Further, we request that NIH reexamine how to best collaborate with the ME/CFS research and clinical community to achieve the goals of a research definition and strategy. Those who are researching and treating this disease are in the best position to define how to move forward.

We thank you for your consideration of this issue, and we look forward to your reply. Sincerely,

Jennifer M. Spotila, JD jspotila@yahoo.com

Mary E. Dimmock maryedimmock@yahoo.com

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- ¹ CFSAC March 11, 2014 recommendations on medical education. Page 33 - <http://www.hhs.gov/advcomcfs/meetings/minutes/cfsac-minutes-march-11-b.pdf>
 - ² Cleveland Clinic Center for Continuing Education CME - <http://www.clevelandclinicmeded.com/online/casebased/decisionmaking/chronic-fatigue/> Question 9 on CBT. Question 10 on Outcomes
 - ³ American College of Physicians and MedPageToday's KevinMD - <http://www.kevinmd.com/blog/2014/02/mksap-32yearold-woman-chronic-fatigue-syndrome.html> The information on this site is from the American College of Physicians and is part of their Medical Knowledge Skills Assessment Program.