

# Massachusetts CFIDS/ME & FM Association

*Education, Support and Advocacy since 1985*

April 3, 2015

## Office of Disease Prevention

National Institutes of Health  
6100 Executive Blvd., Room 2B03, MSC 7523  
Bethesda, MD 20892-7523

Re: Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, missing public comments

I am President of the Massachusetts CFIDS/ME & FM Association, and I am writing this letter on behalf of our Board of Directors. I also speak on behalf of the Connecticut CFIDS & FM Association, whose Board endorsed and co-signed these Comments.

Our Association's Board, after many hours of study and work, submitted public comments on the draft report for 2014 Pathways to Prevention Workshop: Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. Our comments were submitted by email on time, on January 16, 2015, at 10:51 a.m. to prevention@mail.nih.gov. I have a copy of this email.

It has come to my attention that our Comments were not returned in the FOIA request submitted by Jennie Spotila, and that NIH has now acknowledged that "one set" of public comments were not given to the panel for consideration. I conclude that our comments are among those missing (along with others, including those from the Chronic Fatigue Syndrome Advisory Committee which surely deserved most a careful reading).

**To say that I am outraged would be an understatement.** Although the initiation of the P2P process was a surprise, we took it at face value as a sincere effort to help patients who are living with this terrible illness. Our response to the findings presented in the draft report was reasonable, cooperative, thoughtful and constructive, and by submitting our comprehensive and carefully documented comments we worked within the rules to make the P2P as successful and useful as it can be. For the ODP not have followed a process to ensure that **all comments received by the deadline** were passed on to the panel is, to my mind, a **gross dereliction of duty to the public trust**, and feeds the suspicions of some advocates that there is a conspiracy against patients with this illness, or, at minimum, an incredible disrespect.

Our careful reading of the draft report, creating our comments, then discussing each point with the 15 members of our Board in a lengthy telephone conference, followed by assembling the documentation for each point, and putting the document into final form and circulating it for approval in MA and CT, required perhaps 100 person-hours. **We would like to be assured that**

**the product of this joint effort receives more than a cursory review at the last minute to ensure there is nothing there that might change the final report as it has already been written.**

I acknowledge the honesty of the Office of Disease Prevention in admitting that some comments were not given to the panel, and in trying to rectify this gross error. **I would like to be informed of what actions will be taken to give the panel adequate time to review and discuss the missing comments, and how these will be incorporated into their revision of the report.**

The missing comments, at least ours, those from the Chronic Fatigue Syndrome Advisory Committee, and those from advocate Mary Dimmock, of which I have personal knowledge, addressed not only errors, but many important issues throughout the entire report, in detail, with carefully constructed rationales for each point and many references. They represent many hours of careful reading, thought and discussion among groups of knowledgeable stakeholders. They surely deserve equally careful review by the panel, **as a group and in person**, which would provide an opportunity for equally careful consideration and response to these points by the panel. **The recently released report from the Institute of Medicine should also be reviewed and considered by the panel.**

The final version of the Pathways to Prevention report on ME/CFS is a document that will stand for many years. It should guide NIH's future response to research on this illness, which as the IOM report implied, has been grossly inadequate to date. The first draft, which was written very quickly after the public workshop, essentially reiterated points that were made by the experts at the workshop, and the recommendations, while not incorrect, were relatively weak and gave lip service to the need for more research in many areas. Our comments suggested making the recommendations much stronger, and in particular, suggesting a dollar figure to concretely represent the relative scope of the research needed for this disease.

Unfortunately the ARHQ evidence review, because it did not discount the evidence for treatment recommendations which were based on the Oxford definition, specifically results from the PACE trial, was contradictory to the panel's draft report which recommended "retiring" the Oxford definition. This was a point mentioned in many of the submitted comments, including ours, and a crucial issue which we very much would like to see resolved/corrected in the final report. Any "evidence" which suggests the efficacy of Graded Exercise Therapy as a treatment for this illness, especially a paper based on a faulty selection of study subjects and documented issues with interpretation of the data, does a great disservice to patients, for whom this treatment can be harmful (also well documented). The IOM report makes this point as well. **Now is the time, and your report is the place, to bury this treatment recommendation once and for all**, a strong point made by all 3 sets of omitted Comments.

All stakeholders, especially patients, deserve a voice in this process. Although we have documented that at least 3 Comments of which I have personal knowledge, those of our (and the

CT) Association, those of the CFSAC, and those of advocate Mary Dimmock, were apparently not provided to the panel, we have no way of knowing what other comments from the public/patients were also not given to the Panel. EVERY patient (and member of the public) deserves to have their point of view represented. **If it were not for the careful attention and follow up (in the form of a FOIA request) by patient/advocate Jennie Spotila, this situation would never have come to light.** To ensure that our federal agencies follow their own procedures should not require this degree of skepticism and diligence by the public.

In closing, we would like answers to the following questions:

- 1. How will the missing comments be retrieved? Can they even be found? (I would be happy to re-submit our comments if you cannot find them.) How many comments were not passed on, and from whom were they? (Would obtaining this information require another FOIA request?)**
- 2. Exactly what process will be used by the panel to reconsider their revision in light of these comments?**
- 3. What actions will be taken to prevent any future occurrences of an error like this? How can the public be assured that their input will be received and carefully considered?**

We thank the ODP for undertaking this important study, and appreciate the work of those who served on the panel, as well as the many experts and other stakeholders who attended the Workshop and shared their knowledge and perspective on this disease. We very much hope that the final report, which will have considered ALL public input, will build on the draft and be as strong as the IOM report in outlining the past failures with regard to this disease and calling for rectification of these weaknesses in the future. Specifically, the patients need solid treatment recommendations (to the extent they exist), access to specialized care and benefits of translational research through Centers of Excellence, and well-funded and directed future research in the many areas pertaining to the illness which are mentioned in the report. The millions of patients whose lives have been taken away by this disease deserve this much.

Very sincerely,



Charmian Proskauer, President  
On behalf of the Board of Directors  
Massachusetts CFIDS/ME & FM Association  
[www.masscfids.org](http://www.masscfids.org)