**P2P Report on Chronic Fatigue Syndrome**

**Comments and Recommendations**

**Cort Johnson (Health Rising - cortjohnson.org)**

I applaud the panel for bringing dignity to the ME/CFS community. It was gratifying, indeed, to see outside experts "get" the ME/CFS community's needs so clearly. Thanks very much for your work!

Most of my recommendations have to do with the need, I believe, to tighten the excellent recommendations of the panel. I believe that the panel underestimates the culture of neglect and dismissal that has characterized the NIH's response to ME/CFS and in doing so has left openings for the NIH to take the least possible action that would appear to comply with them. Historically, this has been the case.

Does the panel, for instance, recognize

- that this million-person disorder has been in the bottom five percent of NIH funding for decades?
- that adjusted for inflation the NIH is spending about what it did on ME/CFS twenty years ago -when it was considered a small, niche disorder? - Unfulfilled Commitments / Broken Promises: The NIH and Chronic Fatigue Syndrome After Twenty Five Years
- that disorders of ME/CFS's prevalence, effects, and economic losses typically receive twenty times as much funding?
- that most major cities in the U.S. do not have **one** expert ME/CFS practitioner?
- that the NIH's response to that dearth of ME/CFS experts has been to turn down requests for Centers of Excellence year after year? That over a decade of requests has not produced one COE?
- That it has responded similarly to both federal advisory panel and Congressional requests for an RFA
- That the last RFA produced for ME/CFS was slated to occur in 2003 but took three years to be produced because the Institutes dragged their feet on providing funding?
- That as the NIH's budget doubled the budget for ME/CFS declined?

- that similar disorders such as fibromyalgia, which also affect large numbers of people (often women) and produce severe economic losses, but do not usually kill, are in a similar situation?

**#202 – Define Disease Parameters :** NIH shall develop a National Research Network consisting of 3-5 centers in the US each with a dedicated research budget of $5 - 10 million and make efforts to enroll other countries in producing similar centers. A funded grant opportunity (Request For Applications (RFA)) should be issued within one year to produce the outcome measures and studies needed create a validated research definition. (See research section for more.)

**#211** – An NIH sponsored conference to examine commonalities and differences among ME/CFS, Gulf War Syndrome, Lyme disease, fibromyalgia, multiple sclerosis, and Parkinson's disease and others should take place within one year. The conference should lay the foundation for an RFA to further explore commonalities and differences in these disorders.

**#213** - Five Centers of Excellence in major metropolitan area should be established within two years, and five more within five years.

**#213-284 Create New Knowledge**

**Recommendations**

- The NIH should bring pathophysiological research funding for ME/CFS into line with that provided for disorders of similar size, economic losses, and disability rates (excluding comorbid disorders such as fibromyalgia, interstitial cystitis, etc. which receive low funding) in the next five years.
- The NIH should produce a series of $5 million RFAs over the next three years to address critical questions regarding the role the immune, autonomic, and central nervous systems and metabolism play in ME/CFS.

**Rationale :** The panel's recommendation that a broad range of pathophysiological targets be explored is very helpful. Their unwillingness, however, to recommend specific federal spending targets, or specific grant programs (RFAs) could allow the federal government to fund one or a couple of studies from each section and say they met the recommendations.

The NIH is currently funding, for instance, at least one neuroimaging study, a gene expression after exercise study, a natural killer cell study and a microbiome study. Funding one or two studies in an area every four to five years means more of the glacial pace of progress that has characterized this field for decades. This is not the rate of progress that patients, the panel earlier noted, want and deserve, and it's not the outcome that the P2P panel, judging from its otherwise very helpful report, wants to see.

The core need is for the NIH to bring pathophysiological research funding for ME/CFS into line with that provided for disorders of similar size, economic losses, and disability rates (excluding comorbid disorders such as fibromyalgia, interstitial cystitis, etc. which receive low funding). Short of a specific recommendation to do this the NIH surely will not.

**#311 – Provide Training and Education**

- Create accredition program to license ME/CFS practitioners.

**#333** – Add working group members

> Recommend that a commission of patient advocates, ME/CFS experts, and federal officials assess the effectiveness of the Working Group in supporting ME/CFS research, identify structural factors that are impeding funding for ME/CFS, and provide recommendations for change.

**Rationale -** This statement, "Opportunities exist within HHS to engage new ME/CFS working group members, to create efficiency, and to co-fund research that will promote diversity in the pipeline, eliminate disparities, and enhance the quality of the science," reflects the panel's understandable ignorance of the structural problems facing ME/CFS at the NIH.

The Working Group is at the top of the list of factors that have stifled – not advanced – opportunities for ME/CFS. If the last fifteen years has shown anything, it has shown that relying on the Institutes to do anything meaningful under the aegis of the Working Group is a pipe dream. Having no set aside budget at the small Office of Womens Research and being forced to rely almost entirely on funds from the Working Group has been a disaster. It was the Working Group's intransigence that resulted in a small RFA

taking three to produce. The WG has to my knowledge not provided funding for single significant ME/CFS project in the almost 15 years it's been in existence.

With the buck not stopping at any of the institutes in the Working group, it's easy to see why all have essentially washed their hands of it. Adding more members (NIMHD or NCI) to the already long list of Working Group members would, unfortunately, change nothing.

What is needed is a reassessment of the funding structure for ME/CFS.

**#340 - Network of Collaborative Centers -** Recommending that the NIH fund five COEs, each with a $5 million budget (?) over the next two years, and five more over the subsequent five years would go a long way toward enhancing research and improving access to medical care in major cities.

- Patients, ME/CFS experts, and federal officials will work together to set a target for the number of investigator-initiated studies needed to bring research funding into line with the disorder's effects and come up with ways to meet that target, including RFAs.
- The NIH will produce a series of $5 million dollar RFAs over the next three years to address critical questions regarding the role the immune, autonomic, and central nervous systems and metabolism play in ME/CFS.
- Smaller grants targeting young investigators should be produced every year for the next five years. At the end of five years the effectiveness of the small grant project should be assessed.

**#328-339**

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- Smaller grants targeting young investigators should be produced every year for the next five years. At the end of five years the effectiveness of the small grant project should be assessed.

**# 363 - Multimodal** - The panel should make explicit its recommendation regarding multimodal trials to ensure such trials involve drugs and other such treatments that affect pathophysiology.

**Rationale:** The panel should take note of the enormous numerical disparity between behaviorally-oriented treatment trials and all other kinds of trials found in ME/CFS. The fact that CBT and GET have been the focus of some thirty clinical trials while no other treatment modality has, to my knowledge, received more than one, indicates the powerful hold that behavioral studies, many of them UK and European government funded, have had in the clinical trial arena.

While the panel stated that neither CBT nor GET should be considered a primary treatment, it might reflect that, given the history of bias in this disorder, that recommending multimodal clinical trials could be interpreted as recommending a biopsychosocial approach to treatment - an approach that has failed, after many efforts, to get at the cause of ME/CFS. With so many other compelling research needs present, putting more money into that approach would be counterproductive.

**#365 – FDA -** New pathways for drug development need to be developed that take into account the barriers found in large, poorly studied heterogeneous disorders that get little interest from drug companies such as ME/CFS.. A panel of patient advocates, ME/CFS physicians and experts, federal officials, and drug company officials should identify those barriers and provide recommendations to surmount them.