Response to P2P Draft

from Cecy Nielsen

Here are my comments in regards to the P2P report about ME/CFS. I'm referring to the 389 version of the report.

I want to mainly address the following lines 10 - 11:

"Unfortunately, ME/CFS is an area where the research and medical community has frustrated its constituents, by failing to assess and treat the disease and by allowing patients to be stigmatized."

While it is correct that ME/CFS patients have been hugely underserved, misrepresented and stigmatized, which has led to understandable frustration, it is not primarily the research community that has failed them, it is the federal agencies.

The responsibility for the current situation lies with NIH, CDC and DHHS. I feel it is absolutely vital that this is clarified in the final report.

DHHS, NIH and CDC have over the past three decades had many chances to further the ME/CFS field; intiate and foster research which would have led us to understanding of disease mechanisms, biomarkers and treatments; start and maintain a constructive stakeholder dialogue with both patients and expert clinicans and researchers; communicate correct information about the disease and raise proper awareness. They have chosen to do none of these things.

Instead, they have kept funding levels for ME/CFS research in the bottom 5% amongst the approximately 230 diseases and conditions the NIH funds, in spite of ME/CFS being a rather common disorder (estimated to affect 1 million Americans) and one with a massive disease burden, leaving the sufferers very incapacitated, often house bound or bed bound. The ME/CFS patients suffer greatly, they live in a state of eternal severe flu. The need is dire.

Yet the funding has been kept at miniscule levels, preventing any significant progress in research.

NIH has not taken any action to change this. In 30 years, there has only been one major grant opportunity for ME/CFS. In 2011, NIH organized a very good State of the Knowledge Workshop on ME/CFS (the one positive action taken by the agency in all these years), and it

was generally expected that an RFA would follow. But it never did.

Researchers commonly report on how difficult it is to get ME/CFS projects funded. This cannot be due to low quality applications, since the same researchers do not find it hard to be awarded funding for similar projects aimed at other disorders. Several researchers are known to have left the ME/CFS field for this reason. Others are very loyal to the ME/CFS patients, since they know how much they suffer and how real and severe this organic disease is, but they are rejected funding again and again.

A case in point is Professor Ian Lipkin of Center for Infection and Immunity at Columbia. When the controversy about whether a retrovirus, XMRV, could be causing ME/CFS was at its height, NIH called in Dr Lipkin to conduct a study to once and for all establish whether the retrovirus was present in this patient population. NIH at that point lauded Dr Lipkin, presenting him (and justifiably so) as one of the world's leading virologists. They wanted the ME/CFS community to trust him and his findings, since Dr Lipkin is such a top-notch scientist. This was all well and good, and the community did trust and accept Dr Lipkin's important findings.

However, when Dr Lipkin then took an interest in the ME/CFS enigma, became engaged in ME/CFS research and after some initial studies made plans for a large study exploring what he believes is one of the most important areas of ME/CFS research–the gut microbiome–his grant applications have been repeatedly rejected by the NIH. The same researcher which the agency proclaimed world-leading is denied funding when he applies for funds to study ME/CFS.

(Dr Lipkin has had to turn to the patients, who are now trying to crowdfund this study, see www.microbediscovery.org)

This is just one example. It is clear that the low levels of funding for ME/CFS research cannot be explained away by "few applications" or "low-quality applications". There are structural barriers impeding ME/CFS research at the NIH. Before these are changed, no progress will take place.

It has not been productive to have ME/CFS belong to the NIH ORWH (Office for Research on Women's Health). The decision to move the ME/CFS research program from the NIAID to the ORWH has proven to be a disaster for the disorder. Three CFS Research Centers have been shut down and research funding has declined. Adjusted for inflation,

NIH is spending as little on ME/CFS today as it did twenty years ago when ME/CFS was considered a small niche condition.

Likewise, it is clear that Trans-NIH Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome Research Working Group is not an organizational construction which can take the ME/CFS field forward.

These institutional barriers urgently need to be resolved, preferably by moving ME/CFS to an Institute which can meaningfully engage in and foster ME/CFS research. Otherwise, research will continue at its current glacial level.

Since the CFS Research Centers were shut down, expert researchers and clinicians–as well as patients–have called for new Centers of Excellence conducting bench-to-bedside research, but this has been repeatedly dismissed. DHHS' own advisory committee on ME/CFS, CFSAC (CFS Advisory Committee) has in the past decade made 9 or 10 recommendations for Centres of Excellence. Still this has not come to fruition.

Similarly, there have been repeated calls for Requests for Applications (RFAs) for ME/CFS. Only in the past four years, the CFS Advisory Committee has made three recommendations stating that NIH should issue Requests for Applications for biomedical research on etiology, biomarkers and clinical trials. The International Association for CFS/ME (IACFS/ME) have written to the Director of NIH requesting RFAs. Members of Congress have done the same.
Still, no RFAs have been issued.

In fact, multiple RFAs over several years are needed, since funding levels for ME/CFS need to be multiplied by 20x or even 60x to reach levels proportionate with prevalence, disease burden and societal cost and on par with comparable diseases.

Summary:

I request that lines 10-11 be changed so that this sentence reflects the fact that NIH, CDC and DHHS have failed to take relevant measures to ensure progress in the ME/CFS research field or enable adequate health care for ME/CFS patients.

I also request that the final report include precise recommendations, with time and numerical targets, on the following:

- that the institutional barriers at the NIH preventing progress in the ME/CFS research field urgently be resolved
- that NIH shall issue multiple RFAs for biomedical ME/CFS research over the coming years, bringing ME/CFS up to funding levels matching the funding levels for MS, a similar disease
- that NIH fund several biomedical Centres of Excellence (preferably starting with the clinics involved in the current CDC multi-site study, all run by well-established ME/CFS experts)

I thank you for your consideration of my comment. You have the chance to bring about much-needed change in the ME/CFS field and, ultimately, bring urgently needed help to this patient community, which has been underserved and neglected for so many years.

Cecy Nielsen