

To the NIH Pathways to Prevention on Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome Panel;

It was a tough decision for me to make regarding whether to respond to the P2P draft report, or boycott and just send a letter of protest, as so many are doing. Patient advocate Gabby Klein presents a poignant argument for not responding to the report in a Phoenix Rising article that you can read by following the attached link: <http://phoenixrising.me/archives/26387>. But after much consideration I've decided that I have a lot of specific comments related to the report so I am submitting my comments below.

Overall I would say that the P2P Draft report and the AHRQ evidence review reveals little that patients, advocates and the handful of expert physicians that care for us, haven't already communicated to the HHS, NIH, CDC, FDA, DSS over and over again for 30 years now. We really didn't need a "non-biased" review of the evidence by a "jury" of non-experts to tell us what we already know—the research is scanty because of poor funding and general lack of interest and bias by the research community, health care providers, academia, the biotech industry and charitable foundations. As a result patients suffer day in and day out because there is no treatment for this disease—or worse, the only recommended treatment offered to some, CBT/GET, causes significantly more harm than good.

Much of the report appears to be filled with comments that the panel probably believes patients and advocates what to hear, but then tries to camouflage recommendations you know we are against by using different terminology such as "multimodal treatment" and "spectrum disorder". When looking at it (the report) as a whole, it is full of contradictions and superficial recommendations—how can you recommend "retiring" the Oxford definition then still give credit to studies that used that definition? And recommendations for "patient education" and "self-management" are always just "fluff" no matter what disease you are talking about. Unless the report comes with a full fledge promise by the NIH to increase funding to levels commensurate with AIDs or MS, I'm afraid it is worthless to patients with ME (PWME).

In regards to my comments, please note that I refer to the illness as ME for Myalgic Encephalomyelitis. This is in response to a national advocacy effort to reflect the reality that the disease we suffer from is not Chronic Fatigue Syndrome but rather a neuro-immune disorder that is characterized by PEM/PENE and other devastating symptoms and that we are not simply people who are tired.

Also please note that I am using the 403 line version of the published reports.

Comments on the P2P Draft Report:

Line Number	Report statement	Comments
5	An estimated one million people, mostly women, are affected.	There are various estimates on the prevalence of ME in the population. This quote should provide reference as to what estimate you are using and for what country (e.g. US, worldwide?).

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		<p>While there probably are <b>more</b> women who have the disease than men or children, I think it is misleading to say it affects <b>mostly</b> women. Through my personal acquaintances, I know of 4 men with the disease- if I include myself (I am female) that's 80% male vs. 20% female with the disorder. Personally, I think the number of men, and children/adolescents are largely underestimated due to reasons stated further in your report.</p>
6	<p>ME/CFS is an unmet public health need with an economic burden estimated to be greater than \$1 billion.</p>	<p>It is really unclear where the panel got 1 billion dollars.</p> <p>Research published in 2008 by Dr. Leonard Jason estimates direct and indirect costs at between 18.8 to 23.9 billion dollars annually in the US based on data from the late 1990s and on an estimated 800,000 with the illness.  <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2324078/">(http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2324078/)</a></p> <p>A later study published by Lin et al in 2011 commissioned by the CDC estimated direct and indirect costs for a ME/CFS population <b>in Georgia</b> to be 452 million in healthcare expenditures and 1.2 billion in lost productivity. While they caution extrapolating this to the full US population, they do note that if that was to be done the total economic impact could be as high as 51 billion dollars annually.  <a href="http://www.resource-allocation.com/content/9/1/1">http://www.resource-allocation.com/content/9/1/1</a></p>
7-9	<p>ME/CFS results in major disability for a large proportion of the people affected. Limited knowledge and research funding creates an additional burden for patients and health care providers.</p>	<p>I agree with these statements</p>
33-34	<p>..., and it overlaps with many other diseases (e.g., fibromyalgia, major depressive disorder, chronic pain).</p>	<p>I don't believe the research indicates that there is a lot of "overlap" with ME and major depressive disorder. In fact I believe Dr. Natelson showed in his presentation to the panel that he was able to distinguish ME from Major Depressive disorder and Fibromyalgia. So please correct this statement.</p>
36	<p>no primary prevention strategies.</p>	<p>How can you have a primary prevention strategy when you don't know what causes ME?</p>

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36-38	The lack of a universally accepted case definition for ME/CFS has led to difficulty in determining its prevalence and incidence, and has contributed to variability in the estimates reported.	I agree with this statement
38-43	The Oxford criteria (published in the Journal of the Royal Society of Medicine in February 1991) are flawed and include people with other conditions, confounding the ability to interpret the science. The lack of a consistent, specific, sensitive diagnostic test and set of criteria has hampered all downstream research on pathogenesis and treatment, causing harm and preventing ME/CFS from being considered as a distinct pathologic entity.	I agree with this statement
49	...there are no agreed-upon parameters for defining ME/CFS,	<p>This statement is not true. In the fall of 2013, in response to the notice that HHS was commission IOM to come up with a new case definition of ME, over 50 ME experts and over 160 ME advocates signed letters to the HHS Secretary Sibelius asking that HHS and its departments adopt the Canadian Consensus Criteria.</p> <p><a href="https://dl.dropboxusercontent.com/u/89158245/Case%20Definition%20Letter%20final%2010-25-13.pdf">https://dl.dropboxusercontent.com/u/89158245/Case%20Definition%20Letter%20final%2010-25-13.pdf</a></p> <p><a href="http://thoughtsaboutme.files.wordpress.com/2013/10/sibelius_letter_advocates2.pdf">http://thoughtsaboutme.files.wordpress.com/2013/10/sibelius_letter_advocates2.pdf</a></p>
50	and 163 symptoms have been associated with ME/CFS.	I do not believe this is correct--did you mean to say there are 163 symptom combinations using the Fukuda criteria, of which only about 35 include PEM? To me this should raise red flags as to the use of the (Fukuda) criteria similar to concerns for the Oxford criteria.
76-78	Over the last 20 years, minimal progress has been made to improve the state of the science for patients with ME/CFS, and the public and provider community is frustrated.. Patients want their concerns to be heard, a	I agree with this statement except you might want to make that 30 years instead of 20.

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	meaningful recovery (not just incremental improvement), and a cure.	
79-80	Educational efforts are needed to help patients and their health care providers better understand this disease and scientific processes	So you understand this disease process? How can one educate on something one doesn't understand? Quite honestly the only ones who understand ME are the patients and the handful of experts that treat us.
80-81	The scientific community also has a responsibility to address issues that are meaningful to patients.	<p>Unfortunately the "scientific community" that has latched onto ME is psychiatry/psychology which has a financial interest in trying to prove that CBT/GET and other "multimodal" treatments are effective because their livelihoods depend on getting PAID to administer these treatments. Way too much money has been spent on these trials which are not meaningful to patients.</p> <p>For the biomedical scientific community to latch onto ME, they need reassurance that their grant requests will be funded. Until there is more money committed to biomedical ME research, the incentives will continue to be misaligned and will result in little progress in advancing the understanding and treatment of ME.</p>
82-86	There is reproducible evidence of neurocognitive dysfunction with abnormalities in functional magnetic resonance imaging (fMRI) and positron emission tomography (PET) studies. Strong evidence indicates immunologic and inflammatory pathologies, neurotransmitter signaling disruption, microbiome perturbation, and metabolic or mitochondrial abnormalities in ME/CFS, potentially important for defining and treating ME/CFS.	Agree, now where's the money coming from to do replication studies and to find treatments for these issues? This goes back to the basic need for more funding from NIH to a level similar to MS and HIV and then hopefully other funding avenues will follow.
87	Overall, limited patient and professional education has impaired progress in managing ME/CFS.	I completely disagree with this statement as it implies that there are ways to "manage" ME. I can assure you that patients find out soon enough how to "manage" their ME symptoms. We don't need "professionals" to tell us how to "manage" our disease. Also, "managing" ME does not enable us to return to full function--for that

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		we need treatments—and those treatments don't currently exist.
93-95	A multitude of symptoms are associated with ME/CFS, with substantial overlap with other pathologic diseases (e.g., fibromyalgia, major depressive disorder, and a variety of chronic pain or inflammatory conditions).	<p>This statement is confusing and could be misleading as noted above regarding the statement lines 33-34. Yes, ME patients do have symptoms that are similar with other conditions but as most <b>ME experts</b> will tell you it is easy to distinguish an ME patient from a MDD patient or a fibromyalgia patient.</p> <p>This is major reason why we need to include PEM/PENE in the definition of ME. The CCC, as agreed upon by a panel of experts and advocates, would be the best option for the time being.</p>
105-106	A clear case definition with validated diagnostic tools is required before studies can be conducted.	We have a clear case definition that our experts and advocates have endorsed (see line 49 above). I would hate to hold up research due to further disagreement on definition and diagnostic tools. The ME experts and advocates endorsing the CCC acknowledge that it isn't perfect, but also that there is no likelihood of a perfect case definition until further research that leads to a clearer understanding of the etiology of ME happens. So you have a chicken and an egg situation. If 50 of the world's leading experts on ME have agreed that the CCC is the best we have, why not listen to them?
113-116	Existing treatment studies (cognitive behavioral therapy [CBT] and graded exercise therapy [GET] demonstrate measurable improvement, but this has not translated to improvements in quality of life (QOL). Thus, they are not a primary treatment strategy and should be used as a component of multimodal therapy.	<p>This statement should be deleted from the report. It contradicts previous statements and is a contradiction within itself. Patients with ME should not be recommended to undergo CBT/GET or multimodal treatment anymore than someone with MS, heart failure or cancer.</p> <p>I think there is enough evidence regarding the flaws in the patient populations and mythologies used in the CBT/GET studies to raise serious concerns regarding the published results and how they would apply to a true ME population using the CCC or ICC criteria. So therefore they should not form the basis for any recommendations in the P2P report.</p> <p>If people want counseling or help with concrete services (such as home attendants, home delivered meals, assistance with applying for SSI/SSD etc.) then they should be provided those services but counseling, CBT/GET or "multimodal therapy" should not be "recommended" as a primary or secondary or tertiary treatment.</p>

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130-134	<p>In general, little attention was given to how self-management may empower and improve health and QOL for patients with ME/CFS. Physicians are inadequately trained to instruct patients in self-management skills (e.g., pacing, realistic goals, physical self-awareness, basic rights, understanding emotions, exercise, relaxation), and there is a lack of data demonstrating the efficacy of self-management on health outcomes.</p>	<p>Patients have nothing else but self-management options. We all learn to self-manage and don't need doctors or other health care professionals to advise on this, in fact, I would argue that health care professionals advisement on self-management is likely to be very poorly done and possibly result in worse outcomes.</p> <p>The only thing regarding physician and health care provider education I would emphasize would be to educate providers about PEM/PENE, how to assess for it and how to advise patients that have PEM/PENE. To me this is a critical component of ME that most doctors have no clue about. Patients with PEM/PENE should be advised to scale back on activity and "pace" to avoid repeatedly "crashing" and getting worse. Doctors should also be made aware that patients presenting with PEM/PENE will likely not be able to continue working or educational efforts and they should be ready to provide support in completing paperwork etc. required for disability benefits, alternate school arrangements etc.</p> <p>I've submitted this comment to the CDC website as a professional nurse several times and so far no changes have been to the information on the CDC website. To me this is significant dangerous oversight that I hope will get rectified as soon as possible.</p>
135-138	<p>In many cases, lack of instructions or guidance for including graded exercise therapy often causes additional suffering, creating fear of harm from a comprehensive self-management program that may include some physical activity (e.g., mild stretching).</p>	<p>The theory behind graded exercise is that by slowly increasing activity you can eventually increase tolerance and get stronger—I counter that is a complete and total misnomer for patients with ME. As someone who was extremely active and fit when I was suddenly struck with the onset of ME I continued to lose my ability to do physical or mental activity slowly, day by day. I do try to remain as active as possible, but whatever this disease does to one's body, it makes the natural ability to build endurance through regular activity completely non-existent. This is one of the reasons why I believe focusing on studying PEM/PENE is critical to this disease, it truly is a disorder where living makes you sick. And it has nothing to do with depression or lack of motivation. I am highly motivated to get back to doing everything I love; I just am not able to do it because it makes me ill. And no, I'm not "afraid" of physical activity, I do what I can and stop when I start getting symptoms in order to ensure that I don't over extend my "envelop" and set myself up for serious PEM/PENE that can last for days,</p>

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		<p>significantly compromising my ability to function.</p> <p>It would be much more helpful if you deleted this statement and instead recommended further studies into understanding PEM/PENE, the mechanisms behind it and possible treatment. I personally believe that if you could stop PEM/PENE, many of us would be able to return to a much higher degree of functioning.</p>
142-143	<p>Many patients with ME/CFS are misdiagnosed and treated erroneously with potentially toxic therapies that may cause harm and diminish hope.</p>	<p>It is not clear where you get the data behind this statement, from what I've seen in the research and on patient forums so far I think that most toxic therapies for ME as reported by patients include CBT/GET and possibly antidepressants while many of us seem to improve on antivirals, amplitgen and rituximab.</p>
163-167	<p>To advance the field, retrospective, prospective, and longitudinal studies that are practical and reproducible are needed. Longer follow-up and a lifespan perspective are needed to understand ME/CFS effects on the whole individual (e.g., patient decision-making, patient expectations, sexual health and childbearing). The symptoms patients consider clinically meaningful are not in the scientific literature; this discordance must be rectified.</p>	<p>I agree with this statement noting that the symptoms patients consider most clinically meaningful are PEM/PENE.</p> <p>Also, can you please back up the statement with assurances on where the funding will come from to do these studies?</p>
168-177	<p>Current research has neglected many of the biological factors underlying ME/CFS onset and progression. Research priorities should be shifted to include basic science and mechanistic work that will contribute to the development of tools and measures such as biomarker or therapeutics discovery. The following questions need to be answered:</p> <ul style="list-style-type: none"> <li>• What is the pathogenesis of ME/CFS? What is the role of virologic mechanisms, especially herpes viruses? Does</li> </ul>	<p>I agree with this statement except for the question about it being a "spectrum disorder" which should be deleted. I would also like to know how do you propose funding this research?</p>

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	<p>mononucleosis lead to ME/CFS in adolescents?</p> <ul style="list-style-type: none"> <li>• What is the role of other pathogenic agents?</li> <li>• Is this a genetic disease? Is there a gene-environment interaction?</li> <li>• Is ME/CFS a spectrum disease?</li> <li>• Are different pathways responsible for different symptoms?</li> </ul>	
179-180	<p>ME/CFS is a chronic, complex condition of unknown cause and with no cure. We have learned some about the mechanisms of the disease, but nothing has improved the lives of the patients.</p>	<p>Agree</p>
181-185	<p>Overall, there has been a failure to implement what we already know for patients with ME/CFS while it steals their health and well-being has stifled progress. Patients must be at the center of the research efforts, and their engagement is critical, as is outreach to underserved and vulnerable populations.</p>	<p>This implies that we know things that help improve lives and function—I don't think that true, in fact it is very misleading. Except for therapies such as amplitgen (which is not available to most of us), antivirals, and possibly rituximab (also not available to most of us) we really don't have treatments that work. Patients do the best they can by "self-managing" but pacing is NOT LIVING. And CBT/GET which has been recommended for decades has not helped. So, I think this statement needs to be revised to say that we need further replication studies of biologically based treatments that appear to help, including amplitgen, antivirals and rituximab.</p> <p>I do agree that patients need to be at the center of research efforts. I also agree that outreach to "underserved" and "vulnerable" populations like those that are house/bed bound and just disengaged for the medical system are needed.</p> <p>I further assure you that patients have been totally turned off by psychologically based approaches and will likely not be willing participants in any "multimodal" based recommendations.</p>
191-192	<p>The dissemination of diagnostic and therapeutic recommendations should focus on primary care providers.</p>	<p>The dissemination of what diagnostic and therapeutic recommendations? Do we have those? The best we have right now is the IACFS /ME Primer, which can be found through this web link:  <a href="http://www.iacfsme.org/Home/Primer.aspx">http://www.iacfsme.org/Home/Primer.aspx</a></p> <p>But I think we are very far away from getting primary</p>

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		<p>care providers competent in diagnosis and “treatment” of ME. Until we know the underlying etiology and actually HAVE treatments, it is dangerous to make this statement. I think the best we could hope for in the immediate future is for PCPs to be educated on PEM/PENE, to advise patients as I indicated previously, and then to be aware of the nearest ME expert to refer their patients to.</p> <p>I also think we need to worry about continuing to grow the field of ME experts until this disease is fully understood, easily diagnosed and treated, at which time, depending on the complexity, maybe it could be managed by PCPs. I doubt this will happen in my lifetime.</p> <p>As it stands now, I’ve been ill just under 3 years. I’ve so far fired 4 PCPs and 4 integrative medicine doctors and currently do not have a PCP nor do I wish to try to find another one. If I do ever go to another PCP I have no intentions of telling him/her that I have ME. I thank god that I have a terrific ME expert who is board certified in infectious diseases, who has been able to help me tremendously in more ways that I can count.</p>
192-194	Potential conflicts of interest among investigators need to be properly vetted, discussed, and addressed by all stakeholders.	It should be noted that the largest area of conflict of interest by investigators is those studies done by psychologists whose livelihood depends on providing those services. Studies done by pharmaceutical companies could also be biased, but we have very little of those in ME. Otherwise, most of the studies into the biological cause of ME are performed by investigators who have no conflicts and who only stand to lose money and their reputations by studying this “taboo” illness.
200-205	To accelerate the progress of ME/CFS treatment, we recommend the following overarching research strategies: <b>1. Define disease parameters. Assemble a team of stakeholders (e.g., patients, clinicians, researchers, federal agencies) to reach consensus on the definition and parameters of ME/CFS.</b> A national and international research network should be developed to clarify the case	<p>I truly hope you are not recommending yet another NIH sponsored project. It seems HHS/NIH is good at recommending those—why? To give yourselves the business?</p> <p>My I remind you of my comment above regarding the fact that 50 of the US and international ME experts all agreed on adopting the Canadian Conesus Criteria.</p> <p>Also, may I point out that the whole P2P process seems to have ignored discussion of that fact that the NIH commissioned the IOM project on re-definition of ME/CFS which has been taking place at the same time</p>

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	definition and to advance the field.	that the P2P was happening. Your absence of comment about this just makes it seem like there has been absolutely no coordination of the two projects. In my professional experience, this would be looked upon as poor management at the top of the organization, where the right hand doesn't know what the left hand is doing.
205-212	There are tremendous opportunities on which we have not yet capitalized to learn across disciplines and from other diseases such as Gulf War Syndrome, Lyme disease, fibromyalgia, multiple sclerosis, and Parkinson's disease, to determine commonalities and differences. Additional NIH Institutes and Centers not presently represented in the Trans-NIH ME/CFS Working Group should be included in the effort. Thus, we encourage the convening of a conference of scientific leaders that is open, inclusive, and transparent.	<p>Unfortunately the areas you mention, Gulf War Syndrome, Lyme Disease (ie chronic lyme), fibromyalgia and Parkinson's are also diseases where the etiology is poorly understood and/or there are no good treatments. The only exception is MS where they do seem to be making advances. I would definitely add other auto-immune disease to the list of opportunities.</p> <p>And once again, I disagree with your recommendations more conferences and costly meetings. There are existing avenues that should be used instead of using our tax dollars and precious ME research dollars for meetings.</p>
215-219	The NIH Institutes and Centers (e.g., the National Center for Advancing Translational Sciences [NCATS], the <b>National Center for Complementary and Alternative Medicine [NCCAM]</b> ) and other U.S. Department of Health and Human Services (HHS) agencies should coordinate research efforts to promote efficiency and effectiveness,	<p>Mentioning anything about Complementary and Alternative Medicine should be totally stricken from this report and cautionary notes should be added regarding the fact that ME patients are prime candidates for CAM SCAM providers/physicians.</p> <p>Do you send your cancer patients or diabetes patients to CAM providers?</p> <p>None of this has any research backing behind it, and it just leads to patients spending thousands of dollars, not covered by insurance, on wasteful and in my case, harmful therapies. There should be all kind of warnings regarding these therapies. In fact, I find it unsettling that NIH has an institute on this, unless its purpose is to provide proof to regulate CAM providers out of business, I would prefer my tax dollars and any dollars related to ME research not go to studying CAM.</p> <p>Regarding the coordination of HHS agencies to promote efficiency and effectiveness, see my comment above regarding the apparent lack of coordination between the</p>

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		P2P and IOM initiatives.
221-280	See document	<p>I agree with these statements, but again I ask who is going to fund this and I would like to point out that CFSAC recommendations for data registries have been turned down by HHS and Dr. Lipkin’s research on the microbiome has been declined NIH funding twice—resulting in a crowd-funding initiative that so far has not produced the money needed. Others are doing high-throughput sequencing but have been limited by research dollars, same thing for neurocognitive and neuro-imaging studies.</p> <p>Regarding the fibromyalgia statement on line 251. First of all, I don’t think many fibromyalgia patients would say that the current “approved” medications for fibromyalgia are very effective. Secondly, I think many of these treatments have been tried for ME and are probably first line treatments recommended by PCPs, but they have not been shown to be effective and should probably meet your categorization of “toxic” treatments given to PWME, just like CBT/GET.</p> <p>Finally, I can go on about each of these recommendations which are just empty statements without some promise from NIH to increase funding.</p>
281-284	Studies investigating homeopathy, non-pharmacologic, complementary, and alternative medicine treatments are needed. Studies addressing biopsychosocial parameters (including the mind-body connection), function, and QOL should be encouraged.	<p>As a patient who has wasted thousands of dollars on CAM, I do not want any of my tax dollars and precious ME research dollars wasted on CAM SCAM research.</p> <p>Please delete these recommendations so we can focus on understanding the biological etiology of ME and try to find real cures.</p>
289-290	The NIH should develop an ME/CFS methodological workgroup.	<p>Once again you mention another NIH workgroup, are you trying to find projects for yourself? I am against any more of our ME research dollars being spent on NIH working groups, especially any that do not include appropriate ME specialists.</p> <p>What about just using CFSAC?</p>
311-315	Provide training and education. Although many health care providers do not fully understand ME/CFS, primary care clinicians	Does anyone fully understand ME/CFS? I think the closest we come to that is our experts. So yes to PCP referring to ME experts and no to the rest including your recommendations for a treatment team. What we need

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	<p>will be instrumental in ensuring that patients are treated or referred to appropriate specialists. We believe ME/CFS is a distinct disease that requires a multidisciplinary care team (e.g., physicians, nurses, case managers, social workers, psychologists) to optimize care.</p>	<p>is a team of multi-specialist to treat us and to further the research including:</p> <ul style="list-style-type: none"> <li>• Cardiology/neurology ( why is there no mention of autonomic dysfunction and POTS, NMH in this report?)</li> <li>• Neurology for cognitive dysfunction and things like sensory gaiting abnormalities, actual balance issues, and sleep disturbances etc.</li> <li>• Endocrinology—how many of us are hypothyroid or have history of thyroid cancer? According to my ME expert the prevalence is higher in ME— and thankfully once my doctor found I was hypothyroid and had anti-bodies for Hashimotos she ordered a thyroid US which unveiled a cancerous nodule. This is after I couldn't get into see an endocrinologist without a referral and <b>NO PCP</b> would test me or refer me.</li> <li>• Rheumatology, again, how many of us have auto-immune thyroid disease, RA, Sjogrens?</li> <li>• Exercise physiologist to perform the 2 day CPET tests (again, another important recommendation missing from this report).</li> </ul> <p>I have no need for nurses, case managers (I run case management programs) social workers or psychologists to treat me. And as noted before, except for people in need of concrete services (home attendants, meal delivery, applications for SSI/SSD, Medicare/Medicaid) due to their <b>disability</b>, I don't see these as needed recommendations for the majority of PWME.</p>
315-316	<p>Thus, properly training that workforce is critical, and we strongly encourage engaging with:</p> <ul style="list-style-type: none"> <li>• Health professional licensing and accreditation agencies to ensure a curriculum that facilitates ME/CFS knowledge acquisition</li> </ul>	<p>You could start but updating the CDC website as has been recommended so many times by so many people including CFSAC, and circulating the IACFS Primer more widely. Other than that I would just recommend training around understanding PEM/PENE and how to advise patients as well as knowing where the nearest ME specialist to refer patients.</p> <p>But in reality, until we have more research into understanding etiology and we have REAL TREATMENTS I think this is largely a wasted effort and should be a low priority recommendation.</p>
326-327	<ul style="list-style-type: none"> <li>• Patients—in addition to the medical therapies they are receiving, patients must become</li> </ul>	<p>PWME are probably some of the most active participants in their overall treatment that you will find. In fact, patient directed care is probably the norm here. Please</p>

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	active participants in their overall treatment.	remove this suggestion from the report.
328-339	<p>5. Finding new funding resources. With a relatively small number of researchers in the field and finite resources, there is a need for partnerships across institutions to advance the research and develop new scientists. New collaborative models, investigator-initiated studies, career development, and small grant mechanisms with specific attention to developing a cadre of junior investigators, including women and minorities who may offer innovative new approaches, are needed.</p> <p><b>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</b> disparities, and enhance the quality of the science (e.g., the National Institute on Minority Health and Health Disparities [NIMHD], the National Cancer Institute [NCI], the Department of Education’s National Center for Medical Rehabilitation Research, [NCMRR], the Department of Defense [DoD]).</p>	<p>Another good recommendation on paper but it lacks substance behind how you envision it getting done. Just what are the--“<b>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,..</b>”? Can you please elaborate?</p>
340-	<ul style="list-style-type: none"> <li>• Create a network of collaborative centers working across institutions and disciplines, including clinical, biological, and social sciences. These centers will be charged with determining the biomarkers associated with diagnosis and prognosis, epidemiology (e.g., health care utilization), functional status and disability, patient-centered QOL outcomes, cost-effectiveness of treatment studies, and the role of</li> </ul>	<p>CFSAC is currently working on a recommendation for Centers of Excellence for ME. I recommend that the P2P report endorse those recommendations here and strongly urge HHS/NIH to help fund them.</p>

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	<p>comorbidities in clinical and real-life settings. The centers should provide a complete characterization of control populations, as well as those who recover from ME/CFS. Ideally, these collaborative studies will recruit from the broad spectrum of Americans and will use measures that are reproducible.</p>	
357-	<p>7. Improve treatment. Patients should be active participants in care and decision-making. Lessons can be learned from palliative care, such as compassion, communication, and symptom management to improve the quality of care. Studies examining the role of self-management techniques as part of a comprehensive treatment plan for patients with ME/CFS during and after clinical interventions should be explored. The modest benefit from CBT should be studied as adjunct to other modalities of treatment such as self-management. Future treatment studies should evaluate multimodal therapies. Comparative effectiveness research is also needed. We recommend that the NIH and the FDA convene a meeting on the state of ME/CFS treatment.</p>	<p>I don't think ME patients are complaining that they are not active participants in their care and decision making. We have repeatedly voiced our concerns and recommendations through CFSAC and other venues for 10 years or more. What we need is for HHS/NIH/CDC to listen to us.</p> <p>The comment here regarding palliative care is out of place, except for those who are dying as a result of ME and in need of end of life care, all we have is symptom mismanagement and our choices for that are pretty non-existent and best done in the hands of ME experts. So until we know the etiology, and have real treatments this is just another empty statement that should be deleted.</p> <p>Regarding self-management, I will reiterate--we all learn how to "self-manage" through pacing, but PACING IS NO WAY TO LIVE and we really don't need any research dollars going to studies on pacing. There is an abundance of information and programs PWME can access on the internet if they need help with self-management.</p> <p>Patients are totally turned off by CBT and your new disguise for it ("multi-modal therapy"), so the uptake will be minimal and is best left out of your recommendations. Remember, that's all that's really been offered for decades and you don't see us all jumping up and returning to work or running marathons, do you?</p> <p>Finally, you are recommending yet another meeting, this time with the NIH (instead of meetings, can you just increase our research dollars?) and FDA. Are you not</p>

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		<p>aware that FDA just completed a series of meetings that covered the state of ME treatment, or lack thereof, and provided approval to fast track new therapy development. Maybe you should ask, why has no one jumped on the opportunity presented by the FDA? Or would pharmacological studies fit into your “bias” category? How about revisiting amplitgen again?</p>
379-382	<p>Thus, for needed progress to occur we recommend (1) that the Oxford definition be retired, (2) that the ME/CFS community agree on a single case definition (even if it is not perfect), and (3) that patients, clinicians, and researchers agree on a definition for meaningful recovery.</p>	<p>I agree with retiring Oxford definition, and suggest you recommend retiring all the rest of the definitions that don’t require PEM/PENE and also consider supporting the 50 experts and 160+ advocates that have endorsed the CCC.</p> <p>Regarding a definition of meaningful recovery, while I agree that it is important to do, without any current promising treatment options, I’m not sure you will find anyone who has had “meaningful recovery” so it may be more difficult to define than you think.</p>
383-386	<p>Attention should be focused on providing access to high-quality, multidisciplinary care; refining assessment; and clarifying endpoints that suggest improvement and quality care. We believe there is a specific role for multimodal therapy. Although no data on primary prevention were presented, this does not prohibit secondary and tertiary prevention efforts</p>	<p>This whole statement is wrong and should be deleted.</p> <p>First, multidisciplinary care is needed, but the disciplines needed include: immunology, neurology, cardiology, endocrinology, rheumatology and exercise physiology.</p> <p>What we don’t need or want is “multimodal therapy”. By recommending “multimodal therapy”, you have completely lost the trust of patients reading this report. Patients will not be fooled by the new terminology which only serves to continue to feed into the general belief by the healthcare community that this disorder is psychogenic in nature, the exact thing you point out in the beginning of the report as being problematic.</p> <p>Also, what do you mean by secondary and tertiary prevention in regards to ME? There is no preventing ME, no one knows how to do that and so far there is no treatment that provides significant symptom relief or return to functioning so please remove this statement.</p>
386-389	<p>Once a cause is determined, primary prevention efforts should begin. The NIH should incorporate concepts from public health prevention and HHS efforts to decrease disability and promote health and well-being for the</p>	<p>I think we are very far away from finding a “cause” for ME, and even if it was found tomorrow, there’s little expectation that a way of preventing it will quickly follow suit. How many of the 7000 or so diseases recognized have real prevention possibilities? Can we prevent, MS, Parkinson’s, Alzheimer’s, or RA? Once again, this statement should be deleted or at minimum edited to</p>

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	ME/CFS population.	indicate that is a far reaching goal.
390-391	There is a role for new and ongoing policies to spark innovation and fund new research. For instance, new avenues are needed to fund research, such as the Prescription Drug User Fee Act.	<p>Yes we need funding for more research. Perhaps you could elaborate on how you see securing significant funding under the Prescription Drug User Fee Act?</p> <p>So far, there has been very little interest by the biotech and pharmacology industry on funding research on ME.</p> <p>As far as I know, there has been no uptake by these industries since the FDA report on ME almost a year ago. Maybe you could do a little research for the final report as to why that is?</p>
392-397	The NIH should work with the Centers for Medicare & Medicaid Services (CMS) and the Patient-Centered Outcomes Research Institute (PCORI) to develop demonstration projects of patient-centered medical homes for people with ME/CFS. This should be done using a comparative effectiveness research framework with clear endpoints and continuous evaluations to improve health care and to determine best practices that are evidence-based. Best practices should then be translated to primary care clinicians.	<p>Once again, I completely disagree with these statements and think they should be stricken from the report and replaced with that recommendation that HHS/NIH/CCD/FDA should be encouraged to work with CFSAC to assist with and follow through on their recommendations, currently being formulated, to fund ME Centers of Excellence.</p> <p>We are far away from primary care (which is the basis of medical homes) being capable of providing care to ME patients. First we need to understand etiology and develop treatments that work, then possibly, depending what is discovered in this basic research, bring primary care into the picture.</p> <p>Until that time, as I've indicated before, I will only get my care through an ME expert, and if for some reason I need to find another primary care provider (the batting record on that is pretty bad) I will NOT reveal that I have ME to him or her as it totally biases their ability to provide good care and treatment for anything non-ME related.</p>
397-399	Federal agencies (e.g., AHRQ, the U.S. Department of Veterans Affairs [VA]) and professional societies should work together to create quality metrics and a standard of care.	Yet another meaningless premature recommendation that should be stricken from the report.
399-403	We also recommend that federal departments, advocacy groups, and industry work together in public-private partnerships to help	Once again you are recommending more meetings and panels that are a waste of time, money and effort. We already have CFSAC, why not recommend that HHS, NIH, CDC just follow-through on CFSAC recommendations?

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	<p>advance research for ME/CFS. Lastly, we recommend that the ODP convene another ME/CFS Expert Panel in the future to monitor progress. We hope our work has dignified ME/CFS and those affected, while providing expert guidance to the NIH and the broader research community.</p>	<p>Perhaps we need stronger HHS leadership helping to run CFSAC that will increase the likelihood of recommendations getting funded and implemented?</p> <p>Also, in regards to recommendations for an “Expert Panel” in the future I do hope you mean a real “Expert Panel” since the panel for this review was deliberately filled with “non-experts” which is of no service to us.</p>

Thank you for reading through these 17 pages of comments.

CL, BSN, CPHQ

Patient with ME since 2012