P2P: "Pleased to Participate?" Not. Count me out! (October 21, 2014)

Here is my open protest letter to Secretary Burwell (with carbon copies to Dr. Collins and Dr. Frieden) regarding the ME/CFS P2P program:

Dear Secretary Burwell,

AHRQ has asked for public comments on the draft "evidence review" report prepared for the agency as part of the NIH-driven ME/CFS Pathways to Prevention ("P2P") program. I am one of many patients who refuse to participate in the commenting process. Count me out!

In other words, let me stress, for the avoidance of any doubt, that this open letter is in no way to be construed as participation in, or engagement with, the ME/CFS P2P program. Instead, I protest this ludicrous and dangerously unscientific process in the strongest way possible.

As an ME patient and advocate, I will not participate in this kangaroo court the outcome of which is preordained to set back ME/CFS research for decades and which is so unalterably contrived, ill-intentioned and scientifically unsound as to invite only condemnation, not participation or cooperation.

Being a controversial disease, as NIH itself emphasizes, utilizing the P2P program violates NIH's rules for the program.

Moreover, the "evidence review" report prepared for AHRQ by non-ME/CFS experts is only part of this Kafka-esque charade of a process, the ME/CFS P2P, which will conclude with a two-day "workshop" of individuals who are not experts in the field and a "jury" deliberation of those non-ME/CFS experts who will have all of 24 hours to write the final report. You or anybody with a scientific background—or with any common sense, for that matter—cannot, in all honesty, believe that this process will result in any scientifically valid outcome. A jury model is about as incompatible with science as one can imagine. Remember Galileo Galilei and how well a jury of non-experts worked for him? Is that how HHS, NIH and AHRQ see their role: in the same vein as the Roman Catholic Church of the 17th century conducting inquisitions and witchcraft trials?

The insincere call for public comments on a rigged game is a contemptible farce. I will not—by giving substantive comments—provide HHS with the opportunity to claim that patients were heard and that their input was considered when any public comments are guaranteed to be ignored, as they were with respect to the IOM panel where comments were also feigned to be sought.

The final report produced by the non-experts will guide future NIH-funded research, which has been at a paltry \$5 million a year—an inexcusably and unconscionably pitiful amount for a debilitating and complex disease such as ME/CFS, which, of course, has lead to an irremediably flawed "evidence" base. That in turn, makes the P2P process just

about as unfit for this disease as one can imagine. The community is in agreement that a catastrophic result of the P2P process seems to be HHS's intention. Otherwise, HHS would abandon it immediately before the agency causes more harm to patients by forcing them to continue fighting the P2P at tremendous cost to their health and by ensuring a disastrous outcome for patients delivered at the hands of non-experts.

For your information, I am attaching an analysis of the P2P "jury model" that I wrote after this stroke of genius was initially announced to the public during the first ME/CFS IOM meeting in January.

Sincerely, Jeannette K. Burmeister Patient, Patient Advocate and Attorney at Law

P2P: "Patients to Purgatory" or the Jury Model Stood on its Head (February 7, 2014)

"They don't know. They don't know anything."—Susan Maier about the P2P panel members

On January 27, 2014, the Institute of Medicine ("IOM") held its first out of five meetings relating to the development of diagnostic criteria for ME/CFS. It was a two-day meeting, with half of the first day being open to the public. Several government officials gave reports during the open part of the meeting. Susan Maier, Deputy Director of the Office of Women's Health of the Department of Health and Human Services, gave the NIH report on the so-called Pathways to Prevention ("P2P") program currently underway relating to ME/CFS research—parallel to the IOM effort—which will culminate in about 12 months in a workshop in which an appointed panel will (1) receive the report of an evidence-based review/report by the Oregon Health and Science University ("OHSU") (under a task order from NIH), (2) listen to presentations of the government and experts and (3) then deliberate and write a report of recommendations to the NIH within 24 hours of the end of the workshop.

In response to a question from an IOM committee member, Susan Maier described the workshop as based on the "jury model" that requires the exclusion of any clinician or researcher who has any experience with ME/CFS Here is what she said:

"It's a jury model. You have the defense, you have the prosecution; they both know the case really well. They know the details, they know what's going on, they know all the nuance, they know what's going on in media. Your jury is sequestered. **They don't know. They don't know anything.** ... The jury hears the evidence. And they make their decisions based on the evidence. That's essentially the difference between the workshop speakers, the evidence report and the panelists." [emphasis added]

Deep breath! So, NIH really believes that designing the P2P workshop to be analogous to a jury trial is a valid method. Experts and government officials with varying points of view will present their views at the workshop, which Susan Maier likened to the prosecution and defense in a trial. Then the P2P panel, made up—by design—of those with no expertise or prior research or opinions on ME/CFS AT ALL, will take the evidence report of OHSU and the comments of the presenters—the "prosecution" and the "defense"— and deliberate and issue their recommendations in writing within 24 hours(!)

I must say, when I heard Susan Maier give that explanation, with a completely straight face and an obvious expectation of everybody to consider this approach sane, I just about fell off my chair. I found myself shaking my head violently. I even uttered the word "Noooo!" under my breath.

I find it hard to capture in words the absurdity of this approach for what Susan Maier described as "focus[ing on the] improve[ment] of science." Let me add: the improvement of science for an incredibly complex disease, not that I am advocating this model for any other disease. The jury in the American justice system exists in order to assess the facts, not develop or interpret the law. The law is given to the jurors by the judge, who also serves as an impartial screener of the evidence presented by the parties for bias, relevance and many other factors. The outcomes of jury trials do not have any precedential value for future trials or the law.

In the P2P process, the jury model is stood on its head entirely. There is no judge to explain to the P2P panel of non-ME/CFS experts what the "law" is or to screen the evidence presented by the OHSU or the presenters at the workshop. Rather the panel is supposed to determine and confirm what the "law" is from what undoubtedly (or maybe hopefully) will be an abundance of highly technical information presented by OHSU in its evidence review.

This all happens in in an incredibly abbreviated period of time. As Susan Maier said, "We have a enough content for a five-day meeting. We have to cram it into two days." (emphasis added) Even juries in a trial get to deliberate for several days or even weeks and don't have to write a detailed report in that time. The powers that be within NIH dragged their feet for 30 years—ignored us, harmed us, tried to sweep us under the rug and now they can't spare three additional days on a quality workshop? Not that even five days would be sufficient for a complex disease such as ME/CFS.

According to Susan Maier, the "goal of P2P is ... to review the evidence." This evidence will then be applied to all future government-sponsored research of ME/CFS. This is like asking a jury in a murder trial to listen to the evidence as presented by the prosecution and defense, unfiltered and unclarified by rulings or instructions from the judge, and to develop, within 24 hours, a set of definitions and criteria for what constitutes first degree murder, second degree murder, manslaughter and negligent homicide. These will then be applied in all future murder trials.

This is the opposite of the scientific method! And talk about giving the jury model a bad name! Albert Einstein and Clarence Darrow would turn over in their graves.

P2P: Don't Buy the Hype! Protest! (September 24, 2014)

The reason why I will not cooperate with, or participate or engage in, the P2P process is very simple. HHS and NIH have shown time and time again that they do not have ME patients' interest at heart. This disturbing and indisputable fact has been confirmed again very recently in my FOIA lawsuit regarding documents relating to the IOM contract (the clinical equivalent of P2P). HHS's and NIH's conduct in this matter has been dilatory, obstructionist and unlawful. HHS and NIH lost the lawsuit and were ordered by the Court to pay my entire attorneys' fees in the amount of \$139,147.

The Court found: "Ms. Burmeister is clearly the prevailing party in the litigation. Moreover, as outlined in the order granting Ms. Burmeister's motion for summary judgment, **the government's conduct throughout its dispute with Ms. Burmeister was unreasonable**. Ms. Burmeister stood to gain nothing financially from her attempt to obtain documents at issue from the government, and she conferred a benefit on the public through her successful effort to obtain a ruling against the government." [emphasis added]

I initially filed my lawsuit pro se (meaning without engaging lawyers) because I was hoping that, when faced with a lawsuit, the government would finally comply with the law. I wanted to give them a chance to resolve the matter swiftly and without incurring any legal fees. Before filing my complaint, but sadly to no avail, I even gave them a warning that legal action was imminent, unless they complied. Even after filing my complaint, the government did not avail itself of the opportunity to moot the lawsuit (i.e., end it with a relatively small legal bill) by conducting a reasonable document search. Instead, the government filed a frivolous summary-judgment motion five months after I initiated litigation when they could have used all that time to remedy their prior FOIA violations. When faced with my opposition motion that clearly demonstrated that the government was in violation of federal law, they doubled down by filing another brief making frivolous and meritless legal arguments and misstating the law and the facts—the latter, under penalty of perjury. Even as late as in the oral-argument phase did they incorrectly cite the law, as noted by the court.

HHS and NIH have wasted the court's time and energy and worse, they have directly caused my health to dramatically deteriorate as a result of their unreasonable conduct and stonewalling, as the case was factually extremely complex and required my close involvement in discussing strategy with my attorneys, reviewing documents, drafting and revising the motions, etc. This has predictably triggered an intense post-exertional crash, the hallmark symptom of ME. Ironically, HHS and NIH continue to boast of their commitment to our disease. It would follow that they knew about the post-exertional fall-out that their indefensible approach would have on my physical health and yet they passed on every opportunity to right their wrong. Instead, they have done everything to prolong this litigation and drive up my attorneys' fees. Counsel for the government stated during oral arguments that he didn't even understand the case until July of this year, six months into the litigation! Half a year! That is how seriously they take this patient population.

In short, HHS and NIH have acted like bullies vis-à-vis a disabled ME patient whose only "infraction" was to avail herself of her statutory rights. After all that litigating, the court ordered HHS and NIH to do what they should have done more than eight months ago, without a dime spent and without any additional damage to my health: to produce the requested documents. Does anybody honestly believe that the government is somehow— miraculously—going to conduct itself differently in this ludicrous and high-stakes jury-model P2P project when they don't even take a very simple and straightforward FOIA request seriously and instead fight it tooth and nail contrary to explicit instructions by the US Attorney General for clear-cut cases like mine?