Public Comment

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My name is Jeannette Burmeister. I have been sick with ME for more than seven years. I appreciate the opportunity to address the committee today.

I attended the FDA's Drug Development Workshop in Bethesda, MD at the end of last month. If I had to use one word to describe that meeting it would probably be "surprise."

Surprise at the fact that most of the few ME clinician experts were not invited to the meeting. Dr. Dan Peterson, arguably, THE most experienced and successful in treating ME patients, was not invited despite many patients' desperate and repeated pleas to include him. Dr. Enlander—not invited. Dr. Kogelnik—not invited. Dr. Lapp—not invited. …

Ampligen, the only drug in advanced clinical trials for ME and the only ME drug on the horizon for years, probably decades—not on the agenda. A real head scratcher and another indication for what this meeting was not going to yield: tangible results or even just concrete next steps.

Going into the meeting knowing this, many patients who attended in person or via the live webcast were surprised at how well the meeting was organized and how respectfully patients were treated. I personally expected one and a half days of the same old ineffective and disingenuous we-feel-your-pain appeasement. There was definitely some of that; hard to switch gears after years of neglect and denial. Whether anything concrete will happen as a result of the meeting remains to be seen, but I got an ever-so-slight sense of something finally "clicking." One thing I noticed, and it may or may not mean anything, after declaring ME a serious and life-threatening disease in September of last year, the term "life-threatening" was not used once during the April meeting. One can only hope that this is not back-paddling on the agency's part.

The biggest surprise of them all though was the palpable eye-opening that occurred among the FDA officials. There were some genuine epiphany moments being had by the officials while hearing from patients. It was astonishing to hear so many of them express that they had been unaware of the extent of the patients' suffering and symptoms. One has to ask what that says about the effectiveness of this committee, CFSAC, and the self-proclaimed advocacy group for this illness, the CFIDS Association of America. How is it possible that the FDA just now started to understand what patients and their doctors have been telling them for decades? One thing is for sure though: There is definitely no more deniability on the part of the agency and that alone is a big step forward.

However, as an Ampligen patient with amazing results on the drug, it is quite bittersweet to hear the clinical team leader of the FDA division responsible for not approving Ampligen in February of this year, Dr. Theresa Michele, admit, and stress, that, despite listening to many CFSAC meetings, she has not been aware of the symptoms of ME as

clearly as she was as a result of listening to patients' testimony at the April meeting. I cannot help but wonder if the decision not to approve Ampligen might have differed had there been a clearer understanding of the seriousness of the disease by the FDA before the decision was made. Given that Ampligen is in grave danger of disappearing in light of the denied FDA approval and the resulting very real risk of the sponsor's bankruptcy, a predicament the FDA is well aware of, it's almost intolerable to think that thousands or maybe hundreds of thousands of patients could be helped by a safe and effective drug had there just been more understanding of the disease. Tragic.

Given the many Aha! moments on the part of the FDA at the April meeting, it became undeniably obvious that it is crucial and exceedingly urgent that the FDA and other government agencies meet with the ME expert clinicians who have successfully been treating ME patients. Otherwise, it is fair to ask what the government is afraid of and whether it is really interested in making progress with regard to treatment options. It is also imperative that the government agencies finally acknowledge that there are many biomarkers for ME—biomarkers that are well established for other diseases—especially given the difficulty of getting drugs approved in their absence. I cannot tell you how frustrating it is to keep hearing that there are no biomarkers. Talk to Dr. Peterson, Dr. Klimas, Dr. Enlander and all the other experienced ME clinicians. They will gladly tell you about low NK cell function and other various immune abnormalities, like elevated cytokines; high viral titers; abnormal VOs max and tilt table tests, etc. It's long past due that the government learns about and tells insurance companies and pharma about them. Hearing from the FDA at the April meeting that the official establishment of biomarkers for ME will take at least a year is really unacceptable. Some of us don't have another year to wait for something that has been available for a very long time. 30 years were wasted. Wouldn't it be appropriate to try and make up for some of that time, finally?

The FDA meeting was a huge step in the right direction and I would like to take the opportunity to express my sincere thanks to Rear admiral Kweder and her team for an impressive and much appreciated meeting. Now, we just need some concrete results and some real progress.

Thank you!