Kim Witczak
Oral Presentation to FDA Advisory Committee
on Pfizer COVID-19 Vaccine
December 10, 2020

Good afternoon.

My name is Kim Witczak and I am speaking on behalf of Woodymatters, a drug safety organization started after the death of my husband due to an undisclosed side effect of antidepressants. We represent the voice of families who live every day with the consequences of the current drug safety system. I am also on the board of directors for USA Patient Network, an independent patient voice advocating for safe, effective and accessible medical treatments.

Right now, the world is looking for HOPE so we can get back to normal. Too many lives and livelihoods have been lost.

Like many of us, we put blind faith and HOPE in the system that ultimately failed us.

I have several concerns about rushing novel vaccines to market.

The public needs assurances that FDA's review was thorough and independent, given the process for reviewing new products usually takes 6-10 months. How could the FDA be as rigorous in weeks, this time?

Is there a process built-in if there are dissenting scientific reviews within the agency? This needs to be available and FDA scientists need to be protected for whatever their judgment is and not be political like many of the past controversies such as antidepressants/suicide have been handled within the agency.

Transparency is everything. Assuming FDA approval, then ALL data must be released and made public. This also includes process information like Pfizer's "Data Monitoring Committee" who determined it was safe…is it public? If not, it should be.

We also need a transparent process for catching safety signals and communicating with the public. It needs to be real time like we saw in the UK yesterday with the allergic reactions reported after taking Pfizer's vaccine, and NOT in weeks/months/years later like history has shown with other products with serious harms.

Post market safety monitoring will be more important than ever. We really don't know what the short- and long-term harms are given the short duration of these trials. Will the FDA be staffed up to handle the large task of closely monitoring that will be needed? Like MAUDE, the medical device reporting system which includes the patient narratives in the public reporting, the FDA needs to do the same for VAERS. Narratives can help tell a more complete story that just data without giving away important patient details.

Finally, I have huge concerns with possible unblinding of placebo participants and giving them the actual vaccine as Pfizer CEO alluded to be willing to do. If this happens, we will lose our control group.

In closing, I am directing this comment to the News Media. You have a HUGE responsibility to dig deeper, ask critical questions and not just be an extension of the manufacturers' PR department and accept press releases like the Wall Street Journal article earlier this week that included a Pfizer suppled chart showing efficacy by subgroups where Blacks had 100% efficacy. This should have sounded alarms and begged additional questions about 100%, and if they dug deeper, they would find there weren't many blacks in the trial.

Please seek out independent researchers, scientists and others without political or financial agendas.

Ultimately, the public is the real-world clinical trial. **It's one big human experiment.**

The only ones that have 100% immunity in this will be the pharmaceutical companies. They get all the benefits of sales, without any of the legal liability should something go wrong.

I'd like to thank you for your careful consideration of my comments. I know firsthand the importance of your advisory committee work.