

Kim Witczak
Oral Presentation to FDA Advisory Committee
On J&J COVID-19 Vaccine
February 26, 2021

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.

Yesterday's Washington Post headline says it all... "The joy of the vax: The People giving the shot are seeing hope, and it's contagious."

You can feel the energy of excitement growing – Clearly, people are looking for hope and these vaccines give the illusion that there is light at the end of the tunnel. Too many lives and livelihoods have been lost.

Hope is a powerful motivator. But, what is the hope based on?

On the surface ... the efficacy may not be as high as the other two investigational vaccines on the market. But it is one shot and doesn't need the extreme refrigeration like the others.

Since it is all but assumed that J&J will receive emergency authorization this weekend, I am going to use my time to address some general concerns I have.

- 1) I am concerned that the public does not fully understand what Emergency Use Authorization means. Most seem to assume it means full FDA approval. We may never have FDA approval on any of these vaccines, especially if we lose the placebo control group of the ongoing phase 3 clinical trials. These vaccines need to be continually framed as investigational and we are learning as we go in the real world.

- 2) It seems EUA is the new standard during this time. With new variants popping up, there could be an endless market for potential booster shots. Test, deploy, find out – seems to be the new acceptable strategy.
- 3) Is the public being given true informed consent and made aware that these vaccines are still investigational and don't stop transmission? There is a general belief that the shots will help in stopping the transmission of the virus. The powerful messaging by media, the companies, and public health entities is that we need to get everyone vaccinated. The narrative seems to have a growing element of shaming and coercion. You don't want to be the reason we can't society back to life or worse yet, get grandma sick. There are people who feel they need to get the shot in order to keep their jobs, see family, go to sporting events, concerts, travel again. Basically, get back to life.
- 4) And now, we see celebrities, politicians, influencers joining in on this mass vaccination effort while telling the public the shots are safe.
- 5) Speaking of safe, how can the public be assured that harms/adverse events are being taken serious? The adverse events that we have seen occur in the short term are being quickly dismissed and accepted as the vaccine is working....it's priming our immune systems.

It is critical that those getting vaccines know to report their harms and that they are followed up? I was personally contacted 3 different young healthcare workers that experienced horrific side effects after their first shot. They took the proper reporting measure to FDA, CDC, and the companies. To this day, none of them have been contacted or followed up by the companies. Given this is an EUA, must be made that it is critical and there is follow up by the companies.

Given the Reuters story from earlier this week with the headline – First month of shots find no safety issues with Pfizer/BioNTech, Moderna vaccines:

- 6) Of course, we still know nothing about long term impact on our immune systems, fertility, and other health related issues.

7) Finally, who determines when this state of emergency is lifted? it is hard to put the cat back in the bag. We need to always keep this at the back of our mind as we move forward. Ultimately, in this current pandemic environment, the public is the real-world clinical trial. It's one big human experiment.

Thank you for the opportunity to address the committee.