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Oral Testimony to FDA Vaccines and Related Biological Products Advisory Committee On Pediatric COVID-19 Vaccine June 10, 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. I have no financial conflicts of interest.

There are over 74 million children between 0-17 years old in United States and close to 2 billion globally.

While I don't personally have kids, I care deeply about them. They are our future and will be here after you and I leave this world.

And that's why I am here today.

I have great concerns over the authorization or worse yet, fear a premature full BLA approval of COVID vaccines for children.

For starters,

Is there <u>really</u> an emergency with children and COVID?
The data show kids are neither in danger nor are they dangerous. They are small percent of total cases with an even smaller # who experience serious illness or die. I must question the timing of last Friday's CDC's announcement of the rise in children being hospitalized with COVID. Of course, the media ran with it and more fear was stirred up. All perfectly timed in advance of this meeting.

Does the public truly understand how pediatric trials work? Like how few children are actually in these clinical trials? Like how efficacy/protection in pediatric trials is often determined by immunobridging (based on an assumption using adults' experience)? Or how safety is considered adequately characterized with only several hundred trial participants? Assumption on top of assumption. This hardly makes me feel confident in how these investigational "one size fits all" shots are being evaluated especially when there's the potential to be used in millions and millions of healthy children around the world. Trust me, the average person doesn't understand this. All they are being told is they are "safe and effective." These are just empty buzz words if the supporting data isn't meaningful.

The truth is we don't really know much about these novel vaccines. The "safe and effective" messaging is being thrown around by everyone from government officials to the media, community and religious leaders to Hollywood celebrities. Then mix in all the promotions like "multi-million lottery, free donuts for year, free baseball ticket when get shot at stadium, free shots for a shot at the local bar" and so on. This subconsciously creates the illusion of there being no downsides whatsoever, nothing to weigh or consider.

Right now, the discussion around vaccines seems to be less and less about the science and becoming more and more driven by political motivations and agendas. With all the talks about mandates and having kids vaccinated in time for start of the school year, there is certainly political pressure to fully approve and license these vaccines. However, this is completely outside of the FDA's purview and opens pandora box for compulsion. Like mandates, approving these vaccines to help bolster public confidence and convert the vaccine hesitant is backwards and is again outside the FDA's legal purview.

Last week, I along with a group of 26 researchers and clinicians from around the world filed a Citizen Petition. (I believe you received a copy in your meeting documents and trust you have read it.) We outlined several efficacy and safety measures that must be met before serious consideration is given to granting full approval of any COVID-19 vaccine. Including:

1) completing at least 2 years follow up of participants in pivotal clinical trials, even if they were unblinded and lack a placebo control group;
2) ensuring that there is substantial evidence of effectiveness that outweighs harms in special populations including babies, children and adolescents;
3) and a thorough investigation of all severe adverse reactions, including deaths.

We, simply, cannot ignore the growing evidence of harm being reported to VAERS and just accept the narrative that it is a good thing because it means the shot is working. It reminds me of the attitude that the drug companies and the medical establishment

had back when we were trying to get black box suicide warnings added to antidepressants and were quickly dismissed as "suicide is inherent in the disease of depression." We need to dig deeper and find out if there is a causal link. Norway's government did this for 100 nursing home deaths following vaccination and found the link was "likely" causal for 10 and "possibly" causal for another 26. And in the US we have found nothing?

As you are debating the merits of approving the vaccines for children, including babies, please look inward and honestly ask yourself if this is truly the right thing for humanity. What if, years down the road, you found out the decision you made today, negatively impacted your children and grandchildren's health? Do you want this on your watch?

I often think back to the 1991 FDA Advisory Committee meeting debating whether there was a link between Prozac and suicide/violence. At the time, every one of the Advisory Committee members with financial ties to industry voted NO. It wasn't until 2004 - 13 years later, with even more antidepressants on the market as well as now approved for children, that black box warnings were finally added – using some of the same data from 1991. How many lives were destroyed, including my husband's, because of the decision made in 1991?

My closing message to you…

Go Slow. There's no rush.

Our children and grandchildren's lives are depending on you.

Thank you for your consideration of my comments.