Kim Witczak
Oral Testimony to FDA PDUFA VII Hearing
September 28, 2021

Good afternoon.

My name is Kim Witczak and I am speaking on behalf of Woodymatters, a drug safety organization started in 2003 after the death of my husband due to an undisclosed side effect of antidepressants. Woodymatters represents the voice of thousands of families who live every day with the consequences of the current drug safety system. We make sure the real world patient perspective is represented in healthcare conversations, such as the one we are having today. 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.

Over the past year and half, the pandemic has highlighted the need for having a strong regulatory agency that can respond quickly. It has also shined a light on other things such as issues with conflict of interest, political interference and the importance of a strong safety system when it comes to our medical products.

This is my 3rd PDUFA authorizations that I have participated in. In reviewing the draft materials for today's meeting, I would like to make the following comments.

1. The priority once again seems to focus on expedited and speedy approvals. With the public being the ultimate end customers of FDA approved products, performance goals should be based on safety and efficacy- not just speed. It shouldn't be an either or proposition. I get it, the industry expectation of FDA is to approve products quickly so they can get on the market faster - but this sometimes at the expense of safety. Obviously Covid has highlighted the pressure and public's desire for speed.

As the consumer rep on the FDA Psychopharmacologic Drugs Ad Com, almost every drug that we have reviewed has used some fast tracking pathway like Breakthrough Therapy, Accelerated Approval, Priority Review for unmet need and

have used REMS program as a catch all for safety. In my opinion, we need to stop relying so much on voluntary REMS strategies to flag safety issues instead of focusing on premarket resolution of safety concerns. Everyone knows that voluntary REMS are rarely effective.

We also need better, quicker response and communication of adverse events and harms. I still support a previous idea of separating staff responsible for premarket approval from postmarket safety. We need proactive surveillance from variety of sources – unlike what we are witnessing playing out in real-time with the COVID vaccines. There needs to be an attitude of safety first and desire to actively investigate reports of harms vs quickly dismissing or disregarding as "not related to product."

2. We need leverage resources to fund outside, non-conflicted experts, consultants, and make investments in upgraded technology that is designed to detect and aid in proactive surveillance.

We need to redesign the FAERS/Medwatch system. This important post market safety tool needs a big data solution that can be customized to capture many fields of information. It also needs to allow someone to view and search all reports by any key word in the report. IT can then build an algorithm connecting a string of words together so other searchers will benefit from a previous user's search.
The other thing that is desperately needed in FAERS is to improve the public facing system so the data tool is available to anyone. It needs to be intuitive and user friendly. We need to be able to see who reported an event. Was it patient reported, physician, hospital, manufacturer reported, etc. It also needs to include the narratives in reports. The only thing you can see in the drug reports are the codes…not the story of what happened to patient.

The technology and solutions are out there and doesn't need to take $60m and years to build. It all comes down to motivation. As I always say when it comes to safety – Its only as good as the motivation and intention behind it.

3. FDA staff/retention – The FDA needs staff to do this important work. They needs to have a space for free thinking and debate over ever changing science. Unfortunately right now with the COVID vaccines, it has become political and we are not able to have conversation. Politics should NOT be driving decisions.

4. I appreciate FDA's ability to pivot during the pandemic, but now we need to get back to in-person inspections and Ad Com meeting with remote options.

5. Finally, there has to be a culture of openness and transparency within the FDA. There should be no closed door meetings when it comes to PDUFA. The public should be included in these initial negotiation meetings.
6.
7. I'd also like to see a concerted effort in involving different types of patient/consumer voices – It is important to get the real world, middle of America harmed patient, who has no agenda or financial interest. Their voices are often drowned out by patient and consumer groups supported by industry interests.

Lastly, we need annual performance reports of FDA's ongoing work…

Specifically, it would be good to know the # or % of previously approved NDA/BLA that were subject of subsequent warnings or withdrawals

or

% of drugs approved using gold standard of having at least 2 phase 3 placebo controlled trials demonstrating consistent and robust evidence of safety and efficacy.

Or

An update on drugs with REMs at time of approval. I know as consumer rep, I would be interested in hearing what status is on our committee previous drug reviews.

At the end of the day, we all need a strong FDA, - one that is based in science and not politics and ultimately sees its customers as the public and not a partner just servicing the industry. We need a watchdog.

I appreciate your time and being open minded when considering my comments and others during this process.

Thank you!