

My name is Kim Witczak and I came here on my own dime.

Thank you for allowing me to address the committee. As you heard earlier this morning I was recused from serving on today's advisory committee as Consumer Rep. because of my lawsuit against Pfizer for an unrelated drug that was resolved over 10 years ago.

Since I had spent time preparing and studying the briefing documents, I wanted to be present for this very important debate.

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There is no doubt that cigarette smoking is a huge contributing factor to premature deaths in our country, in fact, globally.

And I fully support the need for having treatment options including the drugs we are discussing today available to smokers to aid in their quitting.

With this being said, there were a couple things that caught my eye about this large safety study that we should consider before removing the black box warning:

The FDA found all kinds of problems with the study accurately identifying the psychiatric events. For example - I am personally concerned about agitation/anger cases being coded as irritability which can be a result of quitting smoking.

I also wanted to know more about the two intentional overdose cases that were not coded as a suicide attempt.

There was a case where a patient died in a car accident and they didn't know whether he was driving and it might have been a suicide.

These are just three examples of issues with coding after reviewing only a small group of individual cases, I believe about 100.

With these many problems shouldn't we have an independent review of all the cases?

I would also ask whether we should exclude the 12 sites and the investigators who were paid more than \$25,000 to promote Chantix? Did this play any role in the results?

There's seems to be too much room for subjectivity or incomplete information around the narrative of the event.

Here is the current medication guide for Chantix (which I think is quite good!):

What's the most **important information**

I should know about Chantix?

Some people have had serious side effects while using CHANTIX to help them quit smoking, including:

New or worse mental health problems, such as changes in behavior, hostility, agitation, depressed mood, and suicidal thoughts or actions. **Some people had these symptoms when they began taking CHANTIX, and others developed them after several weeks of treatment, or after stopping CHANTIX.**

Stop taking CHANTIX and call your doctor right away if you, your family, or caregiver notice agitation, hostility, depression or changes in your behavior or thinking that are not typical for you, or you develop any of the following symptoms:

- **thoughts about suicide** or dying, or attempts to commit suicide
- new or worse **depression, anxiety, or panic attacks**
- feeling very **agitated or restless**
- acting **aggressive, being angry, or violent**
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- abnormal thoughts or sensations
- seeing or hearing things that are not there (hallucinations)
- feeling people are against you (**paranoia**)
- feeling **confused**
- other unusual changes in behavior or mood

Now here's Pfizer's proposal for changes to the medication guide.

(PAUSE):

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But at the end of day, the real question in my mind given my earlier comments about this study as well as ALL the anecdotal reports the FDA has received over the years is....

Can we sleep comfortably tonight KNOWING that its TRULY safe to eliminate and delete an important patient protection?

Thank you for being willing to consider my comments.