Testimony of Kim Witczak
before the
FDA Hearing on PDUFA IV
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My name is Kim Witczak and I am from Minneapolis, Minnesota.

I am here today to represent the voice of families who live every day with the consequences of the current drug safety system. Unfortunately, I know first hand what it feels like to lose someone. On August 6th, 2003, my life changed forever. I became a widow.

My husband of almost 10 years died of Zoloft-induced suicide at age 37. Woody was not depressed nor did he have a history of depression or any other so-called mental illness. Woody was given Zoloft from his General Physician for an insomnia diagnosis and took his own life 5 weeks later. Woody had just started his dream job as Vice President of Sales with a start up energy efficient lighting company and was having difficulty sleeping as entrepreneurs often do. I was out of the country on business for the first three weeks he was on Zoloft. When I returned, I found Woody one night in fetal position on our kitchen floor crying with his hands wrapped around his head like a vise, telling me he felt like his head was outside his body looking in. Never once did we question the drug. Why would we? It was FDA approved, heavily advertised as safe and effective, AND it was given by Woody's doctor that he has seen for years and trusted.

From the beginning, something didn't add up about Woody's death. So my brother-in-law and I started researching the only thing that made Woody change during this extremely short period of time. Zoloft.

Our journey for the truth has led us to the FDA, HHS, Congress and the Courts. In fact, this is our 23rd trip out here since Woody died.

In our battle for Woody, we were able to get confidential internal Pfizer and other drug company and FDA documents made public that showed the suicide risk was known since 1980s and kept from the public.

I used to think that when the FDA gave its stamp of approval it was under the highest standards. I quickly realized that this is not always the case. I was also shocked to learn that the drug industry through PDUFA paid a large portion of the FDA budget to approve their drugs. The very nature of

the industry paying fees to the regulator in which it's supposed to regulate is riddled with conflicts of interest from the get-go. In some countries, its called bribery -- in ours it's called PDUFA. With PDUFA, we lost the idea that the FDA had a watchdog role. Instead PDUFA created new marching orders.

Ideally, this system wouldn't exist at all. However, it seems to be a reality given the current state of the federal budget. If this is something we have to live with, why not take the user fees collected under PDUFA IV and put into a general treasury kitty in which Congress appropriates like other budgets, as Representative Hinchey has proposed. This would help keep drug company influence out of the picture.

With that being said, I would like to offer input from my perspective on changes you proposed and some you didn't.

While I am happy to see post market safety as part of PDUFA IV, it seems to be lip service. No meat on the bone. On the drug approval side, there are tangible, measurable requirements and a much larger budget to do their job. But what about the post market side? We need to know specifics to ensure that the drug safety staff has the ability to do their job, and not trumped by politics, conflicting interests, or senior staff who want to avoid the embarrassment because they approved the drug in the first place.

I fully support the Dodd-Grassley proposal that separates the post market safety office from the office of new drug approvals. There has to be more money appropriated to post market safety. We need to increase the staff that not only reviews post market studies and adverse reports, but also train some to act more like true investigators and proactively look for potential problems before they kill.

In the case of the antidepressants, it's literally the same people who approved the drugs back in the late 80's/early 90's who are now overseeing the safety reviews. They continue to defend their decisions for approval despite mounting evidence over the years. Most people don't realize that David Graham was one of the first within the FDA that didn't think Eli Lilly addressed the suicide concern he saw in 1990!!!!

As part of this post market safety emphasis, consumers need to be a part of the equation. Since most drugs get approved after being tested on a small number of people in clinical trials, the true clinical study happens in the real world when millions get put on the drugs. More money needs to be

allocated to revamp the Med Watch program. It has a lot of potential, but most Americans don't even know it exists. One idea is to include in all direct-to-consumer ads and communications a tag that directs the public to report side effects to the FDA through the Medwatch program. Another possibility is to allocate some of the PDUFA funds to create a public awareness campaign that promotes the FDA Medwatch program. This would be a separate FDA initiative from the DTC tag. The FDA could set up a specific call center that takes these calls and is trained on asking information seeking questions. Think of it like a claims center within an insurance company.

But in order to do this successfully, you need to have the technology and systems in place. More money needs to be allocated to improve technology NOW and not in creating a 5-year plan. The technology exists today, so let's use it. The drug companies do. The days of faxes, scans, and manually having to review boxes upon boxes of files are over. The fees from PDUFA IV should pay for this technology. Don't let the industry use your lack of technology to their advantage. These systems ultimately will simplify and expedite the approval process, help in post market safety analysis and aid you in the ability to search key words in MedWatch and other data bases which ultimately leads to a stronger FDA.

As we all know, DTC advertising is, unfortunately, here to stay. I truly believe DTC has greatly influenced the large numbers of people taking drugs that they don't need and unnecessarily throwing them into potential risk. From the outside, it looks like you are being proactive and getting additional funds above and beyond PDUFA for reviewing DTC ads. However, the amount you plan to collect is a drop in the bucket for the drug companies. That's barely the cost of a small national TV/print media buy for one drug. It's still voluntary much like the voluntary posting of clinical trails by the drug companies. There is no guarantee it will happen. The review of all ads or at least the key messaging should be mandatory.

I had the opportunity to speak before the FDA's hearing on DTC in November 2005. At a minimum, DTC advertising must be held to a higher standard. There needs to be guidelines that are written and followed by the industry with monetary penalties if not followed. This is a serious business that can have serious or sometimes fatal side effects. Prescription drugs are not like other consumer products. They should not be treated in same manner as cars, soap, or fast food. DTC ads must be grounded in truth. Safety has to be #1 concern.

I have spent my entire career working for various advertising agencies, I can tell you the fact that it can take 30-45 days to review ads is unrealistic given production schedules and the client's own internal routing needs. A process needs to be put in place that allows for ads to be reviewed on a timelier basis. Maybe there's an advisory panel made up of consumers, communication specialists, FTC, and FDA officials that can brainstorm reasonable guidelines.

I have a few more comments about PDUFA IV in regards to drug safety. The first is on conflicts of interests on advisory boards. We need to reduce, if not eliminate them. Maybe PDUFA funds could pay advisors without conflicts for their time vs. having ones with ties to the industry. It's hard to believe you can't find potential panel members without drug company ties. At the December FDA hearing on antidepressants, the consumer rep on the panel held one of the highest amount of affected company stock. Can the public really trust that this person is going to look out for the interests of the consumer when she has a lot of money tied up in stock that could be affected by FDA action?

I would also like to address off-label use. As I mentioned Woody was given Zoloft for an off-label use for insomnia. Obviously you can't do anything about physicians promoting or using drugs for off-label uses. However, I am sure you are aware of the widely known off-label uses for certain drugs. Here's a perfect opportunity for the FDA to be proactive. You should demand that further safety studies be done on known off-label use. If you don't have authority to demand follow up studies on off-label or any other post market safety study, then ask for it. In the case of antidepressants, after the 1991 FDA public hearing on Prozac and adult suicide, the FDA determined that based on the evidence the suicidality issue needed to be further studied. Guess what, the drug companies didn't design new studies to look at the agitation, activation phenmonen relating to suicides and the FDA never followed up. That's a disgrace.

It is clear that the FDA needs more money to adequately do their job. Ideally, this money would have no ties to the industry. Earlier this week at the oversight hearing on Ketek, I heard an outside the box idea on how to help bring in additional funds for the FDA -- an additional 1-cent added to every prescription sold in America that would to help fund the post market safety system of drugs currently on the market. I know I wouldn't personally have an issue paying 1 penny more to make sure the drug I am

about to take is truly safe. I am sure most Americans wouldn't have an issue either.

In conclusion, I came here today in the hope that Woody's story, and the lessons it holds will be helpful in reaching meaningful change.

As you debate over the merits of PDUFA IV, I want you to remember Woody for his story represents countless of Americans who personally paid the price for past FDA failures. This has real life consequences. Our lives, not statistics, are at stake. Someone once said that statistics are human stories without the tears. Please don't forget the horror, grief, and ocean of tears.

We have a historic opportunity to work together to restore the FDA back to the gold standard it once was.

Thank you for your consideration.