Judy Sweets, Lawrence, KS-Wednesday, February 11, 2015

Madame Chair and members of the Public Health and Welfare Committee. Thank you for the opportunity to address you today about Senate Bill 123.

My name is Judy Sweets and I live in Lawrence, Kansas. I have a close relative coping with a severe mental illness and I am strongly opposed to Senate Bill 123.

- In 1993 my wonderful, bright son, just home from college for the summer, was diagnosed with schizophrenia. It was devastating to him and to our family. He was hospitalized for 7 weeks.
- In the hospital and after his release he was prescribed various **1st generation psychotropic** medications including Haldol, Navane, Stelazine, and others. These caused **terrible side effects**--stiffness, flat emotions, no joy, and dystonic reactions. The medications did very little to alleviate his symptoms of depression, anxiety and paranoia.
- For more than a year after his release from the hospital he spent 16 to 18 hours a day at home in bed in a depressed state.
- In the mid-1990s he was prescribed the newer **2nd generation** medications- - **Risperdal** and later the **"drug of last resort"--Clozaril**. That drug was almost miraculous for him. He gradually "came back to life" so to speak. He regained motivation and some cognitive abilities that he had lost. Although he was not cured by any means, his depression and paranoia lessened.
- About 1999 he was put on a trial of the **generic** of Clozaril-[Clozopine] but his symptoms became worse. His psychiatrist then wrote a letter indicating the need for my son to take the **brand** name--Clozaril.
- Since that time Clozaril and several other psychotropic medications have allowed him to lead a fairly normal life and become a contributing member of society--volunteering in various capacities in the community and interacting with friends.
- **I am strongly opposed** to **SB 123** not just because it will adversely affect my son but also because of how it will affect all of the thousands of people having serious mental disorders and those still to be diagnosed.
- Studies have shown that any change in psychiatric medication regimens can cause a **serious relapse** which could result in more hospitalizations, homelessness, incarceration or even suicide. [see appendix] These outcomes would cost the state **much more** than what might be saved by changing our loved one's medications.
- Psychiatric medications **are not** interchangeable and despite what the public is told, **generic** drugs are not always identical to **brand name** drugs. Many generics are made in India or China and have not been tested by the FDA. Though the **active ingredient** is supposed to be the same, the **formulation**, **binding agents** and **delivery system** can be different resulting in the generic

sometimes not working as well as the brand name. [see #3 in Appendix re: the **generic** of Wellbutrin XL 300-- **Budeprion XL 300** being pulled from the market]

- Please do **not** pass **SB 123**. To do so would inevitably lead to changes in medication regimens that would be risky for thousands of Kansans who are coping with a mental illness. Why put the most vulnerable of our citizens in jeopardy?

Thank you for your attention and consideration.

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## Appendix

Comments:

I am coming across many articles that describe various **generic drugs** that **have not been tested by the FDA** and that are **not the same as brand name drugs** despite what some pharmacists and the FDA say. Patients notice the difference between a brand name drug and a generic drug. They report it to their doctors and pharmacists who often tell them that the generic drug is in effect the same as the brand name. But after enough complaints are made some are realizing that often the generic drug is NOT the same.

While the **active ingredient** is supposed to be the same as the **active ingredient** used in the brand name, the **binders** can be different. [i] Also, some of the generics use **a different "delivery system"** than the brand name causing the drug to be expended either too fast or too slow as explained in the excerpt below relating to a **generic** of the brand name **Wellbutrin XL 300**:

Often generic drugs are made in India or China where they are "self-regulated" only. The companies are supposed to do tests and throw out the whole batch if a problem is found in the batch. Instead one company in India "deleted" the results of a bad study and sent the drugs on to the U.S. After complaints from U.S. consumers it was determined through a U.S. investigation that the company had deleted bad results over 5,000 times! [see source #5 below]

The bottom line is that unless the FDA tests **each of these generic drugs**, we can't be assured that what we are taking is equivalent to the brand name drug.—JS

1) "**Understanding Generic Drugs"**

**The FDA** admits on its official website that [when problems occur with a generic drug] it does not have the resources to perform independent clinical studies or the authority to require industry to conduct such studies. See below:

- "FDA is aware that there are reports noting that some people may experience an undesired effect when switching from brand name drug to a generic formulation or from one generic drug to another generic drug. FDA wants to understand what may cause problems with certain formulations if, in fact, they are linked to specific generic products."

- "FDA is encouraging the generic industry to investigate whether, and under what circumstances, such problems occur. **The Agency does not have the resources to perform independent clinical studies and lacks the regulatory authority to require industry to conduct such studies.** FDA will continue to investigate these reports to ensure that it has all the facts about these treatment failures and will make recommendations to healthcare professionals and the public if the need arises".

  Source: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm

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Note: Psychotropic drugs are **not** inter-changeable. They have different effects on different people. And not all brand name and generics are interchangeable. See:

**2) "Questions Raised Over Differences Between Brand Name Rx Drugs vs. Generics"**

http://abcnews.go.com/Health/questions-raised-differences-brand-rx-drugs-generics/story?id=25729595 [ABC news broadcast and article]

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**3**). **"The Budeprion XL 300 Boondoggle"**

"Early in 2007 we detected a problem with the generic version of the antidepressant **Wellbutrin XL 300**. The generic formulation, **Budeprion XL 300**, contained the active drug bupropion. The chemical was the same but the formulation was quite different. Wellbutrin XL 300 used

a **membrane technology** to get the drug into the body. The generic used a **maxtrix technology**, which released the medication substantially faster than the brand name.

Hundreds of visitors to this website reported side effects with the generic that they never had with the brand name. They also noted that the generic did not relieve their depression adequately. We badgered the FDA for years about its approval of the generic formulation. Eventually, the FDA conducted its own tests and agreed that **the generic was not bioequivalent to the brand name** and had Budeprion XL 300 removed from the market in October, 2012."

**Source: The People's Pharmacy [website], "FDA Drops a Bombshell on Slow-Release Generic Drugs." (2014)**

http://www.peoplespharmacy.com/2014/11/17/fda-drops-a-bombshell-on-slow-release-generic-drugs/

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**4) "Clinical effects of a randomized switch of patients from Clozaril to Generic Clozapine"**

http://www.researchgate.net/publication/12028310_Clinical_effects_of_a_randomized_switch_of_patients_from_clozaril_to_generic_clozapine

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**5) "Expose reveals why we no longer trust all generic Drugs"**

http://www.peoplespharmacy.com/2014/12/03/expose-reveals-why-we-no-longer-trust-all-generic-drugs/