

Written Testimony of
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Public Health Committee

Committee Bill No. 5610 -- An Act Concerning the Duties of a Pharmacist When Filling a Prescription for the Treatment of Epilepsy or Prevention of Seizures

Good Morning Senator Gerratana, Representative Ritter, Senator Welch, Representative Perillo and members of the Public Health Committee.

My name is Gyula Acsadi, I'm a Pediatric Neurologist who has been treating patients with epilepsy for more than twenty years.

Epilepsy is a neurological condition characterized by recurrent seizures. It affects adults and children and can be life threatening. If not treated successfully it can lead to cognitive and physical disability and ultimately to significant decline in a person's quality of life. This includes loss of a job and income, loss of a driver's license and strained relationships within a family. Epilepsy affects more than six percent of children and accounts for one of the biggest groups in our own clinic population at CCMC. To treat patients with epilepsy, physicians use various anti-epileptic medications. The ultimate goal of treatment is to keep the patient seizure-free with the least amount of side-effects.

Anti-epileptic medication is effective in general but may have unwanted side effects. "Brand name" medications are supplemented many times by "generic" forms because of lower costs. Generic drugs may work just as well as the brand name drugs but they can be manufactured anywhere in the World with different safety standards and added materials. Most of the generic seizure medications have ten to twenty variants and pharmacies may substitute them at any time.

For approval of "generic medications" by the FDA, the generic drugs should be within an acceptable bioequivalent range to the brand name counterpart with respect to pharmacokinetic and pharmacodynamic properties". This means that taking a generic medicine will result in a comparable blood level and biological effect compared to the brand name medication. The FDA requires the bioequivalence of the generic product to be between 80% and 125% of that of the brand name product and they are always compared to the brand name product not to each other. In a least optimal situation, when a generic drug is switched to another generic drug, the blood level of the medicine may change more than twenty percent.

What does this mean for the patients when they are switched? 1) Blood level and therapeutic efficacy may be lower and can lead to unexplained convulsions. 2) If the patient suddenly has a “break-through” seizure the cause has to be determined. If a medication change was in effect it could be one of the most likely causes but if the patient is not notified about the change and it is also not known for the treating physician, the investigation may include multiple costly tests and various medical interventions some of them maybe painful.

How can we keep track of the adverse effects of medications? FDA has a reporting site for professionals and patients but this will not take place regarding a particular generic medication if the patient or physician has no knowledge about the change.

Is there any scientific data available for the adverse effects during switching brand name medication to generic drugs? Yes, there is a recently published “metaanalysis” looking at only three types of medications by Kasselheim et al. (Drugs March 2010) “indicating no difference in the odds of uncontrolled seizure for patients on generic medications compared with patients on brand-name medications” but there was no comparison between generic drugs. But the study also suggested the following: “The observational study data may be explained by factors such as undue concern from patients or physicians about the effectiveness of generic AEDs after a recent switch. In the absence of better data, physicians may want to consider more intensive monitoring of high-risk patients taking AEDs when any switch occurs.” This can only happen if the pharmacy provides information about the change in the medication

Therefore, I strongly recommend serious consideration and approval of this bill.