

Statement Before:

The Public Health Committee
Friday, March 11, 2011

Re: Committee Bill 5610: An Act Concerning the Duties of a Pharmacist When Filling a Prescription Used for the Treatment of Epilepsy or Prevention of Seizures

Good morning Representative Ritter, Senator Gerratana and members of the committee. My name is Marghie Giuliano. I am a pharmacist and the Executive Vice President of the Connecticut Pharmacists Association, a professional organization representing 1000 pharmacists in the state of Connecticut. I am here today to speak in strong opposition to **Committee Bill 5610: An Act Concerning the Duties of a Pharmacist When Filling a Prescription Used for the Treatment of Epilepsy or Prevention of Seizures**

Committee Bill 5610 amends current legislation mandating that a pharmacist cannot substitute an antiepileptic drug for another upon initial filling or refilling without obtaining written permission from the prescriber. It actually creates a separate dispensing process for these medications. There is no clinical evidence that supports the reasoning behind this bill—that changing manufacturers for antiepileptic drugs causes seizures. Carving out this therapeutic class of drugs from the generic substitution laws sets a precedent for other groups to seek similar legislation for other therapeutic classes of drugs and creates unnecessary and costly processes that pharmacists, patients, taxpayers and insurance companies absorb.

As you know, our association has opposed this legislation for the last few years. Prescribers currently have the authority to determine what brand or what generic medication a patient should receive by writing “no substitution” or “brand medically necessary” on the prescription. In years past, we have offered to create a directive in legislation for the prescriber to indicate “no substitution” for generics as well as brand although we believe current legislation allows for this. For example, if a prescriber would like the pharmacist to dispense Teva’s brand of Gabapentin then he/she only needs to indicate that on the prescription. And, as many of you are aware, we have in the past agreed to compromise language which was rejected by the Epilepsy Foundation.

As medication experts, pharmacists clearly understand the concerns surrounding substituting medications with a narrow therapeutic index. We weigh all the clinical considerations when making a generic determination. Additionally, the language in the bill that includes ICD-diagnoses codes on the prescriptions is helpful in making any generic decisions. However, as we have stated before, there is no scientific evidence to date that demonstrates this therapeutic class of drugs needs to be handled differently than any other medication in the dispensing process.

Moreover, the Agency for Healthcare Research and Quality (AHRQ) recently conducted an evidence-based assessment of antiepileptic drugs. The purpose of this study was to specifically investigate whether or not there was statistically significant clinical evidence to support allegations that changing manufacturers for antiepileptic drugs causes seizures. Results of the study showed no statistically significant evidence of an increased risk of seizures or adverse events when switching antiepileptic drugs (brand to generic; generic to generic).

There are two other areas of concern with this legislation; the additional costs to the healthcare system, and more importantly, the impact on the patient. With some of the antiepileptic medications coming off patent, it will be more cost effective for both the patient and the payer to move to generic medications. Setting up barriers to this process is counterproductive. Additionally, the language in this legislation does not clearly define how long patients will have to wait for their medications before the prescriber determines if the pharmacist can substitute or change manufacturers of their drug. This too could become a barrier to access and adherence. If the prescriber does not give consent, and the pharmacy is unable to supply the specific product, the patient will have to find another pharmacy that has their medication.

Recent reports of drug shortages could also impact this legislation. It is becoming increasingly difficult to obtain some medications due to the shortage of raw materials. There are many things to consider. Our primary concern should be to ensure that the patient gets their medication in a timely manner.

Last year we saw the introduction of similar legislation for medications that treat blood disorders. We know that if the proposed legislation passes other brand manufacturers will introduce legislation to “carve out” entire therapeutic classes of drugs from generic substitution laws as well. If a precedent is set, we will see immunosuppressant drugs and drugs for Fibromyalgia looking for the same treatment. Tennessee and Illinois have both seen this progression. Most other states have halted this legislation. This type of legislation is appearing in other states. **In reality, it is just a way to protect brand name products from being substituted.**

CPA is certainly sympathetic to the challenges that patients with epilepsy face. Implementing a protocol-based collaborative practice agreement is the best solution in addressing the needs of this population without disrupting the current dispensing process for everyone.

We will continue to work with the committee to find a solution. However, we strongly urge the committee to oppose this legislation as written.