

**Testimony of Patricia Locuratolo, M.D., F.A.A.N.**

**in support of**

**LD 1672, An Act to Require a Pharmacist to Provide Prior Notification to and Obtain Consent from the Prescribing Physician before Changing from One Formulation or Manufacturer of an Antiepileptic Drug to Another**

Joint Standing Committee on Health & Human Services  
Room 209, Cross State Office Building, Augusta, Maine  
Tuesday, February 9, 2010, 1:00 p.m.

Senate Chair Brannigan, House Chair Perry, and members of the Joint Standing Committee on Health and Human Services, Good afternoon.

I am Patricia Locuratolo, a physician and neurologist. I have lived in York, Maine for 26 years and have practiced neurology in the Seacoast area since 1988. I diagnose and treat the breadth of neurological disorders including seizures and epilepsy, both on an in- and out-patient basis. This is a bill born out of deep concern for my patients' safety and well-being. It was several months ago when my 2 partners and I focused in on a pattern of break-through seizures occurring in historically fairly well-controlled patients. Why was this happening? We realized that between the time we had written their yearly prescription and now, the drug had newly become available as a generic and they were switched by the pharmacist to the generic. No one spoke with them about the potential for a change in their blood level of the drug with the switch. No one spoke with them about the potential for a break-through seizure with the switch. No one counseled them to have blood levels drawn before and after the switch, to avoid behaviors that might trigger a seizure, to drive their vehicles less or not at all during the switch. Most importantly, this is not an issue of generic versus name-brand drugs. Generics are, in many cases, much cheaper so patients can afford them and comply with them. This is an issue of communication, risk management, and informed consent.

I called the Pharmacy Board to ask why these conversations had not taken place. I was reminded about the mandatory generic conversion law. Well, this is a mandatory conversation law. In fact, a number of other states have legislation enacted or pending like this one: Iowa, Massachusetts, Minnesota, Wisconsin, Illinois, and Tennessee for example. The American Academy of Neurology and the Epilepsy Foundation have strong position statements supporting the idea of this bill. See the attached documents and the letter in support of LD 1672 from Dr. Robert Griggs, President of the American Academy of Neurology.

What does this legislation do? Here is a scenario: A patient has a prescription for his/her brand-name anti-seizure medication. The prescription says "brand-name only, do not substitute." The patient cannot afford the brand name so the pharmacist calls the doctor and the doctor can have a discussion with the patient about the switch that

goes like this. By law, a generic medication must be absorbed (bioavailable) 80% to 125% as much as the brand-name medication. With the generic you will be purchasing, we don't know if you will absorb it as well so we have to check levels before and after the switch, know you might be at risk for a seizure, et cetera. So, the patient does well with the switch but with the next refill, the pharmacy switches the generic itself to another brand of generic. The prescribing physician who writes "dispense as written" does not prevent this switch from happening. The next generic can have the same 80 to 125% variability in the bioavailability or absorption so we are back to the seizure risk. I spoke with a pharmacist in a Maine big name pharmacy and he said they switch generic manufacturers every 6 months or so. He could try to keep the same generic for the seizure patients but he wasn't sure he could. So, as you can see, the issue demands a conversation and this bill would prompt it to occur.

You might ask, why doesn't the FDA narrow the therapeutic window for anti-seizure medications from 80 to 125% to closer to 100% for anti-seizure medications, knowing that the result of a medication failure is a seizure which could harm the patient, others around him, his employment, his driver's license? We need a good trial to prove the point to the FDA and one is in progress, but the results will not be available for 2 or so years. There are many papers now and plenty of out cry from the Epilepsy Centers of tertiary care hospitals, but they are all anecdotal and the FDA requires a purposely done trial. Being aware of that, in consultation with the Maine Medical Association, I suggest a sunset clause that would sunset LD 1672 in 5 years.

Doesn't this bill cause undue hardship on the pharmacist to obtain consent from the physician? The pharmacist is an integral part of promoting patient safety. Pharmacists contact physicians every day about their patients' prescriptions; they also talk to patients and offer advice. Epilepsy affects at most 1 to 2% of the population so the numbers involved are not large, but the personal and public safety risk of failed anti-epilepsy medications is large.

Doesn't this bill start a "slippery slope" toward non-generic substitution of other drug classes? This is not a bill that promotes brand name drugs over generics. It promotes a conversation that could prevent a seizure and all the harm to the patient and the public that a break-through seizure could cause.

On behalf of Maine citizens with epilepsy and seizures, I urge you to pass LD 1672. I would be pleased to answer any questions you might have.