COMMONWEALTH OF PENNSYLVANIA
HOUSE OF REPRESENTATIVES

HEALTH AND HUMAN SERVICES
COMMITTEE HEARING

STATE CAPITOL
RYAN OFFICE BUILDING
ROOM 205
HARRISBURG, PENNSYLVANIA

MONDAY, MAY 19, 2008
11:00 A.M.

PRESENTATION ON HOUSE BILL 98
ANTIEPILEPSY MEDICINE

BEFORE:
HONORABLE FRANK L. OLIVER, MAJORITY CHAIRMAN
HONORABLE GEORGE T. KENNEY, JR., MINORITY CHAIRMAN
HONORABLE LOUISE WILLIAMS BISHOP
HONORABLE LAWRENCE H. CURRY
HONORABLE BRYAN CUTLER
HONORABLE ROB KAUFFMAN
HONORABLE KATHY M. MANDERINO
HONORABLE FRED McILHATTAN
HONORABLE EDDIE DAY PASHINSKI
HONORABLE DOUGLAS G. REICHLEY
HONORABLE TIM SEIP
HONORABLE KEN SMITH
HONORABLE JOHN J. TAYLOR
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REPORTER

I N D E X

TESTIFIERS

CHAIRMAN OLIVER: This meeting will now come to order.

Good morning.

The members will introduce themselves, starting from my far right.

REPRESENTATIVE MANDERINO: Good morning. Kathy Manderino, representing parts of Philadelphia and Montgomery Counties.

REPRESENTATIVE TAYLOR: Representative John Taylor, from Philadelphia.

MS. BAROWSKI: Valerie Barowski, analyst, House Health and Human Services Committee.

REPRESENTATIVE KENNEY: George Kenney, Republican Chairman, representing different parts of Philadelphia and Montgomery Counties.

CHAIRMAN OLIVER: Frank Oliver, majority Chairman, Representative from Philadelphia, 195th District.

MR. MITCHELL: Stan Mitchell, staff.

REPRESENTATIVE BISHOP: Louise Bishop, representing Philadelphia, the 192, Wynnefield and Overbrook.

CHAIRMAN OLIVER: Thank you very much.

Today's public hearing will be pertaining to House Bill 98. We do have the prime sponsor of the

legislation here, Representative William Adolph, who will certainly appear before this committee at this time. Thank you very much.

Representative, you may proceed.

REPRESENTATIVE ADOLPH: Thank you, Mr. Chairman.

Good morning.

Chairman Oliver, Chairman Kenney, members of the Health and Human Services Committee, I want to thank you, number one, for this opportunity to testify today and for giving us an opportunity to have a public hearing on House Bill 98. I really appreciate that.

Epilepsy, for those members that may or may not know, is the most common neurological condition in children. In fact, it is the third leading condition just behind Alzheimer's and stroke. There are over 3 million people in the United States that have some form of epilepsy, and over 30 percent of those folks are under the age of 18.

House Bill 98 would simply amend Section 3 of the Generic Equivalent Drug Law by adding that a pharmacist may not interchange an antiepileptic drug without prior notification of and the signed, informed consent of such interchange from the

prescribing physician and patient or legal guardian.

What this really means is that a pharmacist may not change one brand name with another brand name, a brand name for another generic drug, or for that matter, a generic drug with another generic drug without prior notification and consent from both the prescribing doctor and the patient.

It seems like a very simple law, okay? And I think the folks that are going to follow me testifying will go into more detail regarding some of the consequences and some of the results that they see out there when a pharmacist changes the prescription from a generic to a generic without first notifying the neurologist.

I feel that with the passage of House Bill 98, it will affect actually thousands of people in the Commonwealth and improve their quality of life.

So without further ado, I would like to let the experts of this legislation testify in front of this committee. Thank you for this opportunity.

CHAIRMAN OLIVER: Thank you very much.

REPRESENTATIVE ADOLPH: Thank you, Mr. Chairman.

CHAIRMAN OLIVER: Any questions?

Representative Manderino.

REPRESENTATIVE MANDERINO: Thank you.

Bill, I just want to, because I do not want to presume that the experts will know the current status of the law; they know their issue.

REPRESENTATIVE ADOLPH: Yes.

REPRESENTATIVE MANDERINO: Under the current law, if a doctor fills out a prescription and they put a brand name down and they check on the bottom of the form "no substitution" -- or I don't know what it says, "brand name necessary" or "no substitution" -- I am assuming that the only difference between the current status of the law and what your bill is asking us to do is that you are adding not just physician consent, which I believe exists now, but patient consent as well.

Am I correct that the only change to the current status of law that you are asking for is patient written consent as well, or is there more to your change to current law language than I'm understanding?

REPRESENTATIVE ADOLPH: You are correct. Adding the patient would be new, okay? However, I believe that there also would be a change regarding the generic to generic, okay?

And for some reason -- and there are going

to be patients testifying, I understand, later, who will tell you what is going on out there. I know that there's a check mark that the doctors are supposed to be signing as they are prescribing the medicine, and for whatever the reason is, and I have been told that there is a little flaw in the law and there has been some serious consequences as a result of this breakdown in the current law, and this would tighten it up and prevent these types of seizures from taking place.

REPRESENTATIVE MANDERINO: Okay. So if I may, just one follow-up.

The tightening up of the law that you are suggesting is for all substitutions or just substitutions for antiepilepsy drugs?

REPRESENTATIVE ADOLPH: Just antiepileptic drugs.

REPRESENTATIVE MANDERINO: Okay. So someone else may say that the flaw in the current law exists for more than just antiepilepsy drugs. It is just that your bill is trying to cure it for only antiepilepsy drugs.

REPRESENTATIVE ADOLPH: That is correct.

REPRESENTATIVE MANDERINO: Thank you, Mr. Chairman.

REPRESENTATIVE ADOLPH: Any other questions?

CHAIRMAN OLIVER: Thank you very much, Representative Adolph.

The Chair also recognizes the appearance of Representative Smith.

The next scheduled person to testify will be Judy Painter, who is the Executive Director of the Epilepsy Foundation for Western/Central Pennsylvania. You may proceed.

MS. PAINTER: Thank you.

Good morning. My name is Judy Painter, and I am here this morning representing the Epilepsy Foundation organizations in Pennsylvania.

Our organizations provide support, education, and services to the more than 120,000 Pennsylvanians and families who live with seizures every day.

The Epilepsy Foundation Western/Central Pennsylvania and the Epilepsy Foundation Eastern Pennsylvania -- Jeanette Chelius, representing the Eastern Pennsylvania -- are the only two agencies in our State solely dedicated to protecting and advancing the interests of people with epilepsy.

We are here this morning to ask for your careful consideration of an issue that affects

virtually all seizure patients, children and adults alike.

I want to begin by thanking the members of the House Health and Human Services Committee for taking the time to learn more about epilepsy, about how medications affect those coping with seizures, and about how seizure patients are affected by the way in which various medications are dispensed by local pharmacies.

We owe a special debt of gratitude to Representative Bill Adolph, who is the prime sponsor of House Bill 98. This pharmacy issue is critically important to people who take anticonvulsant drugs, but it can be a complex problem, and we thank Representative Adolph for taking a leadership role in addressing this issue.

You will hear a lot today about breakthrough seizures and epilepsy drugs. You are likely to hear some technical discussion about regulations and clinical issues as well. I am certain you will hear that generic drugs are "the same" as the branded product.

I want to talk to you about the very personal, very human aspects of this issue, and most importantly, I want to drive home the point that in

the case of medications used to control seizures, generic does not mean "the same."

Like many Americans, perhaps you have never seen a seizure. I want to be sure that each of us has a clear idea in our mind of what it means to have a seizure, and I also want to encourage you to keep in mind what happens to a person who is having a seizure.

I have a very brief video I would like to share with you, but first to the parent and the person who definitely asked to be excused while we show this video.

(A video presentation was given):

MS. McVEY: This man is currently having a complex partial seizure. Right now he is not aware of his actions or movement or responding to people. The seizure is starting at the face and shoulder and it will spread throughout the rest of his body momentarily.

He is now convulsing in his entire body. Anyone that has this type of seizure, they can lose bladder and bowel control; they can bite their tongue. They usually last about 1 to 2 minutes. It becomes an emergency at 20 minutes when breakdowns can occur.

This little boy is having an absence seizure. If you watch the face, he is in and out of consciousness. These seizures only last about 5 to 10 seconds, but they can affect his alertness and his ability to concentrate for the rest of the day. He is not aware he is having seizures, but he is.

This little boy has myoclonic jerk seizures. You will see that his arms jerk forward during the seizure. It usually happens in the form of clusters. He is aware that it is happening, so it is very frightening to him. He may lose whatever he may have been holding, but he won't lose consciousness during this seizure. He can also jerk in the legs as well.

And finally, this man has atonic or drop-attack seizures. You will see him drop forward, head first. Obviously, the emergency here is the head injury that can occur.

Thank you.

MS. PAINTER: Thank you, Patti.

Those are just some types of seizures. As you hear testimony today, I would ask that you keep these images in mind.

What you have just seen is the undisputable truth about what happens when a person has a seizure. Anytime a person has a seizure, that person is in

jeopardy of injury, and in some cases, even death.

Those at greatest risk are patients whose seizures are currently controlled. There are approximately 120,000 Pennsylvanians with epilepsy. Of those 120,000, 70 percent have control because of medication.

Can you imagine being a patient or the parent of a child who thinks this condition is controlled by medication? Imagine you or your child has been seizure free for many years, and then one day you are blindsided by a breakthrough seizure.

If you are an adult in Pennsylvania, you immediately lose your driver's license and possibly your job. Your independence is gone, and you are no longer able to provide for your family the way you were the day before. As a child, there are constant struggles with school, friends, and confidence.

Now imagine finding that the reason you or your child had a breakthrough seizure is because your pharmacy changes your medication.

The problem, as we now understand it in layman's terms, is that the Food and Drug Administration's rules allow for differences in the formulation of all medicines that are labeled as generic equivalents. I will defer to our medical

experts to explain this issue later.

I want to make it very, very clear that what we are seeking as a remedy to this problem is not a mandate for the use of brand-name drugs.

The Epilepsy Foundation, both nationally and locally, has always recognized the benefits of using generic drugs. Our organization has never advocated for a mandate on the use of brand-name epilepsy drugs, and we have always encouraged patients to take advantage of generic medications whenever possible. Again, our position is that epilepsy patients deserve initial and continued access to all potential treatments for seizures.

The problems related to this issue occur when a pharmacy substitutes a generic medication for a brand-name drug. It also occurs when a pharmacy interchanges one generic medication for another from a different supplier.

There are many men and women who will be coming back from Iraq with Traumatic Brain Injury who will develop seizures in the next 4 or 5 years. Studies show us that 50 percent of veterans returning from Vietnam with TBI experience a seizure within the first 5 years. Our veterans don't deserve to fight another war against the pharmacy and the insurance

company to remain seizure free.

Another study suggests that children who have seizures as infants are 15 percent more likely to develop autism later in life. Any parent of a child with autism will tell you that the last issue they need to worry about is a breakthrough seizure due to medication.

Epilepsy patients in Pennsylvania must be protected. Our primary position on this issue is very simple: We believe that once a patient achieves seizure control, nothing should interfere with, change, or limit the patient's access to that treatment. And if there is anything that could change or affect the treatment, then the patient and the physician should be notified and given the opportunity to carefully consider the potential impact of that change.

The other thing I wanted to note was that Senator Kennedy had a seizure over the weekend. The whole family came to see him. He was life-flighted to a hospital. I think he had two seizures.

I well remember when Chief Justice Roberts had his seizure. You know, the press constantly talked about the fact, is he still going to be able to be Chief Justice? There is still so much stigma

attached to people having seizures that a lot of people do not talk about it.

You probably are wondering, you know, why there isn't more militancy about this happening and people talking about it, and the reason is, most people won't talk about themselves having epilepsy. And the other thing is, most doctors will tell them that they have a seizure disorder. So now what they are doing with the children who are autistic is saying that they have a seizure disorder. But what we are really trying to talk about is the antiepileptic drugs that are used to treat seizures.

And I want to thank you so much for taking the time to listen to what we had to say this morning.

CHAIRMAN OLIVER: Thank you very much.

Any questions from any of the members?

If not, thank you so much for appearing today before this committee.

MS. PAINTER: Thank you.

CHAIRMAN OLIVER: The next scheduled persons to testify will be Diane Smith, who is a parent, and Laura Little, also a parent.

And who might you be?

MRS. SMITH: I'm Diane Smith. Good morning.

CHAIRMAN OLIVER: Good morning.

MRS. SMITH: Well, good morning. I am Diane Smith, and I have had epilepsy for 40 years.

I stand before you in prayer to represent my brothers and sisters who may not be as blessed as I am this morning, who may not be able to speak the way I can, so I thank you for this moment.

I come here today to share my story and my strong support for House Bill 98. My story begins as I had my prescription refilled at our local pharmacy in October of '07. My seizure medication allowed me to be seizure free for several years.

Picking up my prescription order at our local pharmacy, my husband believed he was given my brand prescription, as usual. Instead, he was given the generic Oxcarbazepine. We remained ignorant to the fact that that generic had now been dispensed because we recently changed our prescription plans due to increased health costs in the same year.

This purchase showed no difference in copay, and no discussion of a drug substitution took place. No special label was on the bottle saying a change was made, and the pills even looked the same. They were oval and they were yellow.

Of course, my illness took some time for me

to notice. It began with increased petite mal seizures. My diet and the time I took the medication never changed. I began to search for anything that might be a further reason why.

A few weeks later, at work, I had a grand mal seizure, in front of customers at my job. I was rushed to the hospital in an ambulance. You can imagine I was shocked when the nurse pulled the bottle from my purse and we found that, yes, indeed, I was on a generic drug. We were so upset, I reported CVS on the Internet, and I even placed complaints to them.

Every disability may impose a life of challenge. Those without one may never truly appreciate what others go through just to accomplish normal activities. Forty years of epilepsy, with the right seizure medicine, has allowed me to make a choice, a choice to not be disabled.

I am a mother of three, I have been a financial manager for 20 years, but I am humbled to this disease.

I will conclude this morning by mentioning that some savings are not what they may seem. CVS was approached weeks later and told that we needed brand specific. That same pharmacy argued with my

husband that we should select a generic.

When my husband shared our story, he didn't hear from the pharmacist that they were sorry that those things had happened to us; we were told that it was legal and that the State of Pennsylvania would never allow such an incident to occur. Looking back, I'm still wondering what that statement meant.

I think I have the right to be informed as a patient, especially with something that directly affects my life, my family, and others that surround me. I hated those seizures, but I believe I hated more that I frightened those that surrounded me. I'm still affected by the financial burden and the emotional burden that surrounded that event, but I will recover.

I'm 46 years old, and yes, I made a choice. I made a choice to not be disabled. There may be cost savings for some by switching medications, but it should never come at the risk of the patient. I hope you feel the same, and I thank you for your consideration.

Thank you.

CHAIRMAN OLIVER: Thank you very much.

Any questions from any of the members?

If not, thank you very much for testifying

this morning.

You may proceed, Mrs. Little.

MRS. LITTLE: Good morning. Thank you, Mr. Chairman.

My name is Laura Little, and my daughter, Alexandra, has had epilepsy since she was 3 years old. She is now 10.

Alexandra has tonic-clonic seizures. Some people call them grand mal seizures. When she seizes, she has massive convulsions where she literally bounces off the floor. She foams at the mouth; her arms and her legs stiffen; she gets an irregular heartbeat and shallow breath. Alexandra is unresponsive to my touch or to my voice. This is then followed by Alexandra turning white, she stares at the ceiling, and then becomes limp like a rag doll.

In 2004, while she was foaming at the mouth, her airway was blocked and she almost died going into respiratory arrest. Alexandra suffered through seizures over 75 times within the first 60 days of onset. I can't even begin to guess how many she has suffered through in the last 7 years, as we have stopped counting. Her seizures can last several minutes or they can go on as long as an hour.

Alexandra is very unique in that she only seizes when she sleeps. As a result, my husband and I take shifts when she sleeps at night. I take the first shift from 7 to 11 p.m.; my husband takes the longer shift from 11 to 5:30 a.m., and then I resume at 5:30 to 8 a.m. My husband does better without sleep, so he takes the longer shift. We have been doing this every single night for the last 6 years.

We have had Alexandra evaluated by seven different neurologists at five different institutions, including Penn State, Children's Hospital of Philadelphia, the Cleveland Clinic, the Miami Institute for Children, and currently, the most successful of the group, Wellspan Neurology of York. No one can tell us what has caused this disorder, and the doctors have no idea if she will ever recover.

The seizures affect every aspect of Alexandra's life. She has extreme speech and language difficulties, and her motor skills are very awkward and clumsy. She could read and write when she was 4 years old, but she no longer has these abilities due to the seizures. And I will tell you she's probably the only 10-year-old out there who has never seen fireworks or never played a video game.

This is what we deal with on a routine

basis, but you need to understand that it gets worse with medication changes.

Every time Alexandra has a medication change, we can expect a seizure. When the doctor gets frustrated with the lack of efficacy of one drug, they switch her to another. We pay extra close attention all night to catch a seizure as soon as possible.

The doctor has given us prescriptions for Diastat, which is what this us. This is basically a rectal injection of Valium, and it is to stop the seizure. When I'm home alone by myself, this is a nightmare. You need to imagine a girl flopping up and down. I have to literally lie down on top of her. I have to insert this tip into her rectum without perforating her rectum to give her the medication. It is very, very difficult to do.

You need to understand that seizures induce more seizures, so it is extremely, extremely important to stop them as quickly as possible. We know to pay extra attention when we know about medication changes, but if we don't know about a change or if my doctor has not informed me of a change, we could be caught off guard.

From what I understand, the pharmacist is

supposed to notify the patient if a branded medication has been changed to a generic or from one form of drug to another. This may be what the rules are on paper, but I can tell you firsthand that is not what happens.

I should tell you that I have an excellent rapport with my pharmacist. They know all about Alexandra, and with that said, I will tell you that when I went to go pick up my daughter's prescription, had noticed that her Lamictal had changed shape. Now she takes a tubal Lamictal, which is now in generic form. It went from a square shape to an elliptical shape. I thought we were given someone else's medication in error. I was then told that the Lamictal was now generic. I called my doctor, and he was not informed. If I wouldn't have noticed that this was changed on my own, I would have never been notified. Somebody needs to tell us when these kinds of changes take place.

We are fully aware that generic medications are less costly to us and to our insurance company and that they are more profitable for a pharmacy to dispense versus a brand drug, but the costs in the long run are more in that I am spending more money on these syringes, more money on ER department visits,

doctor visits, and lab visits to get my daughter's blood level drawn. The costs outweigh the savings, and of course the unnecessary trauma to my daughter, in my opinion, is unconscionable.

Antiseizure medications are extremely sensitive and have different affects on different types of people. Antiseizure meds are not like prescribing a cholesterol reducer. A branded drug and a generic drug might reduce a cholesterol level a few points, but antiseizure medications are not like that. One antiseizure drug will not necessarily prevent a seizure and have the same affect as another.

In addition, Alexandra is on multiple medications. My doctor and I need to know about the medication changes, as the new drug may interact with the other medications that she's already on.

Furthermore, as you know, every medication has a different side-effect profile. How am I supposed to help her if I don't know what's going on?

In conclusion, if you remember nothing else today, please remember this: 1 child in every 100 suffers from epilepsy. This is the most prevalent pediatric neurological disorder in our country, even more prevalent than autism, which occurs in 1 out of

every 150.

With respect to our State, there are more Pennsylvanians, young and old alike, that suffer from epilepsy or seizure disorders than State residents with Parkinson's, Cerebral Palsy, Multiple Sclerosis, and Muscular Dystrophy combined -- combined.

This law will have an impact on the quality of life of tens of thousands of people, so for that reason I am asking you to do the right thing and put House Bill 98 into law.

Thank you for your attention.

Thank you, Mr. Speaker.

CHAIRMAN OLIVER: Thank you very much.

Any questions from any of the members? Representative Reichley.

REPRESENTATIVE REICHLEY: Thank you, Mr. Chairman.

Thank you, Mrs. Little, for your testimony.

I'm coming at this from a lot of ignorance, so if you'll please accept my apologies in advance for some of the questions.

Was your daughter born with the epileptic condition? Did you know about it right from the very beginning of her life?

MRS. LITTLE: No. She actually had onset

when she was 3 years old. And like I said, we've had her to five different institutions, well-known institutions, seven different neurologists, and nobody can tell us what the situation is, you know, why she has it.

I mean, our gut tells us we know what it is, but Alexandra was the only person in Dauphin County several years ago to be attacked by a rabid groundhog and, unfortunately, had to go through the entire rabies vaccine regiment. That is done over a 5-week period of time, and right after that, she started having seizures.

REPRESENTATIVE REICHLEY: All right.

The medication which you have described using, are there other means of administration of similar kinds of drugs, or is this the best one for her and therefore that's why you use it? Do you know?

MRS. LITTLE: I'm not an M.D. or a Pharm.D.; I'm just a mom with a sick little girl, although I do have a degree from Penn State from many decades ago. But this is what I have been told to give her. If there is something else I can give her, I don't know about it.

But for her, I need to lay her on the floor,

pull her knee up to open up her anus a bit, and then give her the injection, keep it there for 3 seconds, and then pull it out, and then pray that it will stop. Sometimes it stops in a minute or two, and the longest one lasted an hour after we gave her the injection.

REPRESENTATIVE REICHLEY: Okay. I didn't know if this means of administration was exclusive to this particular drug or if that is true for all epileptic medications?

MRS. LITTLE: This is what I call the bailout drug. She takes Depakote and Lamictal every day. So she takes her medications three times a day. This is only when she has a grand mal. I need to stop it as quickly as possible, because seizures induce more seizures.

REPRESENTATIVE REICHLEY: Okay.

MRS. LITTLE: And this is what the emergency departments in the hospital give out. Because she has so many, I have my own supply. I have these in every car, on every floor of my house, and we have nine of these at all times. I mean, these are very, very expensive.

REPRESENTATIVE REICHLEY: Okay.

MRS. LITTLE: So this is just in case she

has a grand mal and I need to end it as quickly as possible.

REPRESENTATIVE REICHLEY: Okay.

And if you are not able to get the drug administered in a timely fashion, what can happen with your daughter then?

MRS. LITTLE: Well, in 2004, she almost died.

REPRESENTATIVE REICHLEY: Okay.

MRS. LITTLE: With the foaming of the mouth, what happened is, it blocked her airway and she went into respiratory arrest. And fortunately, before it was too late, the paramedics, they got here in time and they were able to drain it out, and they took her to the emergency room.

REPRESENTATIVE REICHLEY: And with the incident that you related about you noticed the change in the shape of the pill---

MRS. LITTLE: Right.

REPRESENTATIVE REICHLEY: ---had there been anything accompanying that? Was there like a little slip of paper or anything like that from the pharmacist saying this has been switched?

MRS. LITTLE: There possibly could have been; I do not recall anymore. But I do not remember

it saying anything was switched. I just remember, when we get our prescriptions filled, it kind of gives you a generic, this is what the adverse events are, this is what the drug name is, that type of thing. But nothing that this has been switched, no.

REPRESENTATIVE REICHLEY: All right. Thank you, Mr. Chairman.

MRS. LITTLE: Is that all?

REPRESENTATIVE REICHLEY: Thank you.

MRS. LITTLE: Anyone else?

CHAIRMAN OLIVER: I want to thank you very much for appearing and rendering your testimony today. Thank you so much.

MRS. LITTLE: And I truly do appreciate everyone's attention. Thank you very, very much.

CHAIRMAN OLIVER: The next two persons to testify will be Dr. Laura Hershkowitz, the Northshore Clinical Associates, and Dr. Paul McCabe of Pinnacle Health Systems in central Pennsylvania.

DR. HERSHKOWITZ: Good morning.

Thank you so much for my opportunity to support House Bill 98. I mean, when I listened to those poignant stories, this is my every day. I want you to know this. I'm an epileptologist. I'm a seizure specialist. This is all I do all day, is

work with children and adults who have seizure disorders.

I work in Erie, Pennsylvania. I'm the Director of Neurophysiology at Hamot Neuroscience Institute, and each year I treat thousands of patients, both young and old, who have epilepsy and seizure disorders, and all too often I see patients who are having problems that are related to the inconsistencies in the medications that they receive.

In the case of drugs used to treat seizures, I want you to understand that this is a completely different medical disorder. This is not like having, you know, a headache or a stomachache; you know, if your pillow is changed, you just get another headache or another stomachache. Seizure disorder is a life-threatening disorder, and even the slightest variation in the formulation of drugs can reduce the effectiveness of the medication and can lead to loss of seizure control. So just something very small can cause something very big.

So there are problems when patients are changed from branded drugs to generic and from different generic suppliers. Everything has to be the same.

Unfortunately, there are multiple suppliers

of different generic drugs. There is a generic drug called Zonisamide that the last time we looked had 15 different suppliers. I have five written in my statement, but it is now up to 15 different suppliers of the same generic drug.

At the pharmacy level, patients are routinely told that these generic drugs are the same, but in fact they can differ significantly. Let me tell you about one of my patient's stories. You heard Laura's and Diane's stories.

I have been T's neurologist for 10 years now in Erie. He's a 14-year-old boy who has a malformed left ventricle in his heart, and I included a picture of him. He suffered numerous strokes as a baby, which left him in a wheelchair with difficult-to-control seizures.

He has an incredible spirit. He is obsessed with sports and determined to be a sportscaster when he grows up.

Finally, things were going well for him. He was seizure free on a delicate combination of three drugs that I had for him. It was 2 years of pure bliss for him and his family. They went to the Erie SeaWolves games, and he even got to be guest announcer.

However, recently, two of T's seizure medications became available in generic formulation, and they were substituted by the pharmacy without my permission, despite me signing "brand necessary" on the prescription and without his mother's knowledge.

His first breakthrough seizure occurred at school. He seized for almost 45 minutes and was life-flighted -- so imagine the cost of this. It was not only an emotional and a medical issue, but he was life-flighted, because it was that serious, to Pittsburgh Children's Hospital from Erie where he stayed for 6 days.

Since this time he has regressed terribly, and as Diane pointed out, seizures beget more seizures. The prolonged seizure hurt his speech. He has been in intensive therapy to try to regain his skills, and he has also suffered five more seizures. And I have been unable to regulate his blood levels of seizure medication back to their original therapeutic levels.

Every month, he is given different generic medications with no continuity, and despite my protest and petition, Tanner's Access card refuses now to pay for brand seizure medication now that there are generics. And his mother has recently gone

to the church to try to raise money for T to get consistent branded seizure medication if his Access card will not pay.

So what I want to leave you with today is that generic substitution of seizure medication is fraught with danger and uncertainty, any substitution of seizure medication.

Epilepsy is a unique disorder. Breakthrough seizures can caucus brain damage, injury, and even death. Persons with epilepsy need complete continuity with their medications, and even small changes can precipitate a seizure.

The FDA does allow variation in the bioequivalents of these drugs, and they can vary significantly. But the FDA never says that generics are equal to each other. They say they are equal to brand in bioequivalents. Unfortunately, the practice of pharmacy is that they are all, quote, "equivalent," so they exchange them regularly -- so generic A for generic B for generic C, whatever is cheaper that month.

And the big issue with seizures that I want you to understand is that we can't measure them, okay? So there is no measurement to warn of an upcoming seizure. I can't tell you that there is

going to be one until it happens.

So to fail a generic medication -- I want you to understand this, because it is incredible -- to fail a generic medication, which is the requirement to get brand again from most insurance companies, you literally have to have a seizure with all of its devastating and costly consequences. So that's incredible.

The potential savings of generic seizure medications, or switching them to generic, are ruined by the cost of the single breakthrough seizure. That Diastat that Diane showed you is $200 for a packet of two of those. It is $200. So that's a rescue medication for a prolonged seizure. So the ER, the ride alone in the ambulance to the ER is incredibly expensive, and that doesn't even include if you are life-flighted like my patient and have to go stay in the ICU.

In the State of Pennsylvania, patients will lose their license for 6 months or longer if they have a breakthrough seizure and most of them can't continue to go to work, and the economic consequences of this are huge.

And the other thing I want you to remember is that I have many, many patients who are on the

road right now driving who have been seizure free for years and years. They are driving. So a substituted medication puts all of us at harm should they have a breakthrough seizure while driving, okay?

So in the next year, there are three more seizure medications that are going generic, and the problem is going to multiply. It is going to continue without your intervention.

So I stand before you and I humbly thank you for allowing me to speak in favor of this bill. Please help us to help our patients have continued continuity of their seizure medications. Thank you.

CHAIRMAN OLIVER: Thank you very much.

Questions? Representative Pashinski.

REPRESENTATIVE PASHINSKI: Thank you, Mr. Chairman, and thank you, Doctor, very much for your testimony.

I came in a little late, so I apologize and may have missed some of this information.

How many patent drugs are available that you would say you would prefer over the generics?

DR. HERSHKOWITZ: Well, until recently, our newer medications did not go generic. So in the last -- the older medications were generic, and in fact we had such poor success with them that those were

switched back most often. People are on the brand of those as well.

So in the last -- well, I will tell you, right now the concern is that in the next few months, there will be five or six of them now that will go generic that are very important medications to us.

If you could just get the same generic again and again, that wouldn't be an issue, but you can't do that. It's always switched. That's the whole problem. We're not against generics. I'm not against a generic stomach pill or a generic headache pill, nothing, but for people with epilepsy, it is a unique disorder. That is why we are here.

REPRESENTATIVE PASHINSKI: How about with the new patent drugs, though, how would you implement them? If you have patients that are satisfied at this point with the medication that you have been using, whether it is patent or generic, how would you decide to use some of the new patent drugs?

DR. HERSHKOWITZ: Well, we don't fix things that aren't broken, okay? So if you are seizure free on any medication, I don't care what it is, if it is generic A, I want generic A every time. If it is brand X, I want brand X and I only want brand X. You don't mess with success. So I would never change a

patient -- never -- as a physician. It would be malpractice to change a patient who is seizure free.

Okay; now, we do this only under financial constraints, that now the insurance company says, "Hey, we are not going to pay anymore." Then the patient goes, "I can't afford $400 a month." And I always shudder if I ever have to make a change, because again, you have seen the consequences.

REPRESENTATIVE PASHINSKI: Okay. Thank you.

DR. HERSHKOWITZ: Thank you.

CHAIRMAN OLIVER: Representative Manderino.

REPRESENTATIVE MANDERINO: Good morning. Thanks for your testimony.

If I'm understanding your dialogue just prior with Representative Pashinski, new generics coming on the market would only get tried or tested if the current medicine that someone is on starts to fail for some other reason.

DR. HERSHKOWITZ: In the ideal world, but that's not what happens. In the ideal world, as soon as it goes generic, that's what gets substituted. So you are on brand for 5 years---

REPRESENTATIVE MANDERINO: Okay; I understood that point, but what I'm saying is, under the language of this bill---

DR. HERSHKOWITZ: Right.

REPRESENTATIVE MANDERINO: ---the way it is drafted, you said, as a physician, I do not mess with success, and I absolutely understand that. So therefore, if brand X is working for me, I would never switch a patient to generic Y until brand X fails for some other reason.

DR. HERSHKOWITZ: Correct.

REPRESENTATIVE MANDERINO: Okay.

DR. HERSHKOWITZ: Or if I did, if there were financial constraints, I would want to make sure I got generic Y every single time. And generic Y that came from Switzerland, not generic Y they got cheaper from China that month, or, you know, generic Z that was cheaper. That's the whole issue.

REPRESENTATIVE MANDERINO: Right. I am understanding this generic to generic issue that you are bringing up.

With regard to the patient that is on the Access card, I thought that we had an appeal process---

DR. HERSHKOWITZ: You do, and it's a very long, hard one. And sometimes they just, especially, you know, it's a whole different ball game here, but especially the Access -- what am I trying to say --

the companies like MedPlus and those, you know, they are tough. They are brutal.

REPRESENTATIVE MANDERINO: Okay. So if you---

DR. HERSHKOWITZ: Actually, we have been turned down numerous times.

REPRESENTATIVE MANDERINO: From the appeal.

DR. HERSHKOWITZ: From the appeal, yeah.

I appeal all day. I literally pay people. Do you understand? I'm in private practice epilepsy. I pay people every day to do this, to appeal drugs all day long.

REPRESENTATIVE MANDERINO: Okay.

DR. HERSHKOWITZ: It is incredible.

REPRESENTATIVE MANDERINO: Okay.

Is your practice, I take it from your testimony that your practice is exclusive to patients with epilepsy.

DR. HERSHKOWITZ: Yes. I'm a neurologist, and I'm trained as an epileptologist. So I have a 2-year fellowship after neurology in seizure disorders.

REPRESENTATIVE MANDERINO: One of the questions that I asked Representative Adolph at the beginning was, and the reason I asked it is because

the story that we are hearing this morning with regard to patients with epilepsy is not the first time we have heard this story. We have heard this story with regard to hemophiliacs. We have heard this story with regard to folks who take psychotropic drugs that are trying to balance very sensitive mental illness treatment, et cetera, et cetera.

So I guess going back to my original question, if there is something that needs to be fixed, why are we fixing it only for epilepsy? Is there something especially more unique to epileptics than there would be to hemophiliacs than there would be to somebody who is manic depressive who can have a very severe neurological reaction to a medicine switch? Or is it all, that this is an emerging problem in all of these areas?

DR. HERSHKOWITZ: You know, I can't speak on all those areas. This is my everyday life, you know, in taking care of people with seizures and this is what I know, and it is just an incredible problem. So we are here for them.

REPRESENTATIVE MANDERINO: Okay. But as---

DR. HERSHKOWITZ: I'm sure -- I can't imagine being the mother of a hemophiliac. I'm sure that is also very important, but I do not know the

issues with that.

REPRESENTATIVE MANDERINO: Okay. But in terms of the action or interaction of the medicine when you are dealing with somebody with some neurological disorder, the change could be, the change in and of itself could be a trigger and the results could be just as dramatic with some other conditions.

DR. HERSHKOWITZ: Yes.

REPRESENTATIVE MANDERINO: This is just the condition I know. That is what you are saying.

DR. HERSHKOWITZ: Well, again, I think it is a fairly unique condition from many other conditions, because you cannot measure. There's nothing to measure. You can't measure -- it's not blood pressure pills. You can't measure it. You know, you can't take their blood pressure and say, oh gee, the generic blood pressure is not working and, you know, we need to bring it down or add more. You can't. You don't know until it's too late. I think that is the point we are trying to bring out.

REPRESENTATIVE MANDERINO: And it could be the same for some psychotropic drugs, depending on what you are controlling as well?

DR. HERSHKOWITZ: Again, I'm not an expert

in that.

REPRESENTATIVE MANDERINO: Okay. Thank you. Thank you, Mr. Chairman.

DR. HERSHKOWITZ: Thank you.

CHAIRMAN OLIVER: Representative Taylor.

REPRESENTATIVE TAYLOR: Thank you, Mr. Chairman.

Dr. Hershkowitz, I think you will get a few more questions since you are the first physician.

DR. HERSHKOWITZ: Sure.

REPRESENTATIVE TAYLOR: But it seems like what we have established is that this is a terrible condition, not only for the patient but for the families, and that in many cases, when there's a change in a drug, there are catastrophic consequences.

From a scientific or a chemical point of view, why is that? Because nobody has said why that is; just because there's a change. Why?

DR. HERSHKOWITZ: Well, epilepsy is an electrical disorder in the brain, so it is electrical short-circuiting in the brain, okay? And everybody has epilepsy for a different reason, okay? Sometimes we don't know; sometimes we know why. And people have a very narrow therapeutic -- so it is a very

delicate balance.

Everybody has what we call a narrow therapeutic index in themselves, so what it takes to get somebody seizure free is unique for everybody. And it's a balance, and anything throws that off. So for some patients it is flashing lights. You heard a mom who said my kid has never seen fireworks and never played a video game, okay? For some people, it could be alcohol or change in diet, those kinds of things.

So everything has to be as relatively the same as possible. And the biggest issue for people is their medications. Their medications have to stay the same, because we are trying to either increase the inhibition of this electrical short-circuitry in their brain or decrease the spread of the excitation.

It is like having a little match in the forest. You know, you don't know it's there, but it is always burning, and when the leaves fall on it, the whole forest goes up in flames. That's a seizure, okay? And what we are trying to do with these medications, it is like literally putting a glass over this flame in the forest, okay? We can't put it out; we don't know how to cure it, but we know

how to contain it, and we are doing everything we can to contain it.

And it's a very, very delicate balance. If you put a glass that has got a crack in it over it instead of the good one, you know, then the flame can move, okay? That is kind of the imagery I try to use to explain this to people.

REPRESENTATIVE TAYLOR: Yeah; and I guess the question I'm trying to get at, and it may go back to something that Kathy was talking about, where maybe it's an issue of generic versus brand name across the board.

But let's say your patient that you said was seizure free and may be driving right now and suddenly switches medication and has seizures that they didn't have for years, is there then an analysis of the new drug that was prescribed and whether or not that was not exactly the same as the brand name that they had?

DR. HERSHKOWITZ: In an ideal world, there would be, but, you know, there are tons and tons and tons of these patients, so nobody -- you know, you look at it and you go, oh, God, it's the generic, but I don't have any lab that will tell me, gee, you know, it's a 10-percent difference. I do have a

blood level. I go, wow, the level has really dropped; look at that; it is clearly not the same drug, or it is not the same amount. And the excipients in it are different, you know, so.

REPRESENTATIVE TAYLOR: So from the results, we are concluding that something must have gone wrong.

DR. HERSHKOWITZ: Something must have changed, yes.

REPRESENTATIVE TAYLOR: But we don't really know.

DR. HERSHKOWITZ: Well, again, we know if the bottle all of a sudden was different if for 10 years you got the same exact drug and now you got a different one. That's the whole point.

And you didn't know. If you know, you can prepare. When I'm changing people's drugs, usually they are not driving. So if I'm going to make a major change in somebody, I'm going to tell them, you can't drive for 6 months or 3 months or whatever it is and we work it out. But if you don't know, you are going to pick up your pills and you get something different, that is where the trouble is.

REPRESENTATIVE TAYLOR: So I think that would be a pretty serious reason to take that

particular drug and analyze it and take it off the market as an equivalent if it is in fact not an equivalent.

DR. HERSHKOWITZ: Again, the FDA allows a range of equivalency, which, again, it depends on your disease state. If it's a headache pill, it doesn't matter. In our case, with our seizure patients, it matters. The consequence matters.

But they do allow a range, because that is, you know, under -- I mean, you can get a range of drugs. You know, they are not all exactly the same. But what we are trying to say is that in this case, the disease state is very different.

REPRESENTATIVE TAYLOR: Thank you, Mr. Chairman.

CHAIRMAN OLIVER: Representative Reichley.

REPRESENTATIVE REICHLEY: Mr. Chairman, I will wait until the next witness just to help move things along. I'll wait until the next witness to ask questions.

CHAIRMAN OLIVER: Okay.

Representative Bishop.

REPRESENTATIVE BISHOP: Thank you very much.

Dr. Hershkowitz, as a doctor, do you have time or is there time for the patient, when you have

already prescribed a medication that is working and that patient is taken off that medication, is there time or is it too life threatening to find another medication that might possibly be able to control the seizures?

DR. HERSHKOWITZ: Well---

REPRESENTATIVE BISHOP: In other words, do you lose patients when they are taken off the medication you have prescribed, put on a lesser medication, when perhaps it is not strong enough, not enough to medicate to keep them where they should be?

DR. HERSHKOWITZ: Right.

REPRESENTATIVE BISHOP: Is it life threatening?

DR. HERSHKOWITZ: Absolutely. Epilepsy is a life-threatening condition, so I lose in my practice probably three patients a year from things like sudden death in epilepsy, which is a very bizarre condition. People die from seizures. They can choke; they can suffocate.

And then accidents. Even a small seizure, you know, where you are stopped and staring like some of those videos, you can veer off on I-90 into oncoming traffic.

REPRESENTATIVE BISHOP: So in order to keep

them alive, you are under obligation to find the right medication through your experience that will maintain the seizures.

DR. HERSHKOWITZ: Correct. And again, if we don't have good success, people have seizure safety issues. If we know that we are changing medications, we know that we haven't come up with the right formulation yet, then we use safety issues.

But it is when everything is great and, you know, we are blindsided by a change in medication. That's the issue that we are here for today.

REPRESENTATIVE BISHOP: Thank you.

DR. HERSHKOWITZ: Thank you.

CHAIRMAN OLIVER: Representative Kenney.

REPRESENTATIVE KENNEY: Thank you, Mr. Chairman.

Doctor, in your testimony you spoke about Tanner, one of your patients, and it was that two generics became available and "They were substituted by the pharmacy without my permission, and without his mother's knowledge."

DR. HERSHKOWITZ: Right, and I have had this with several of my patients. He's just one example.

REPRESENTATIVE KENNEY: Okay. But what did you write on the prescription?

DR. HERSHKOWITZ: Always, I always write "brand necessary" -- "brand necessary," "brand medically necessary." BMN is the State of Pennsylvania, "brand medically necessary." You write it on the bottom of the prescription.

The problem is in the refills, so it is the refills that get substituted. And I don't know why that is. I can't speak to that. I don't understand why that is.

REPRESENTATIVE KENNEY: Was this a refill?

DR. HERSHKOWITZ: I'm sure it was. I mean, it's not a new prescription.

REPRESENTATIVE KENNEY: Okay. So hopefully in the pharmacist's system it said "brand name necessary."

DR. HERSHKOWITZ: Again, I can't speak to their system; I can only speak to my side of the issue where I write these on these prescriptions and these substitutions happen. Why they happen, I do not understand.

So I think that is why we are here today, to tighten the law to make sure that these things don't happen, and if they are going to happen, if there's going to be a substitution from one generic to another, from a brand to another, I'm informed, the

patient is informed, or the patient's caregiver is informed. That's the whole point of us being together here.

REPRESENTATIVE KENNEY: Okay. So with the legislation, it would be the pharmacist would see this---

DR. HERSHKOWITZ: Would say, hey, I can't do this automatically. The kid has been getting brand, and I can't just write for this without calling the doctor and telling the mother and getting permission.

Or if he has been getting a certain generic from a certain generic supplier and that supplier has either been changed or is no longer available, then that would be something that would be reported as well -- hey, the supplier has changed -- so everybody signs off on it and says, okay, we understand now; the drug is now different.

REPRESENTATIVE KENNEY: Do you have patients on generic that you prescribe generic?

DR. HERSHKOWITZ: I have patients that have been on generic that I have prescribed because of financial issues, that we have sat down, we have understood what we are doing, and I'm always worried because they cannot get the same supplier every time. So I have had them try to get as best relationships

with their pharmacies as possible so they can get the same drug every time.

But again, it is based on the economics of this switch. This switch occurs on an economic issue.

REPRESENTATIVE KENNEY: In other words, once you stabilize someone on a medication you are comfortable with, you would never move them.

DR. HERSHKOWITZ: I would never move them, exactly. It would be too risky.

REPRESENTATIVE KENNEY: Thank you.

Thank you, Mr. Chairman.

DR. HERSHKOWITZ: Thank you.

CHAIRMAN OLIVER: Representative Pashinski.

REPRESENTATIVE PASHINSKI: Thank you, Mr. Chairman.

Doctor, could we pursue this for just a minute? I'm sorry.

DR. HERSHKOWITZ: Okay.

REPRESENTATIVE PASHINSKI: It was my understanding that a pharmacist could never change the prescription if a doctor writes that it is brand medically necessary. It is my understanding that a pharmacist---

DR. HERSHKOWITZ: It was my understanding,

too. My life has turned out differently. It happens on a regular basis. It was my understanding, too. That is the way I was taught to write it.

REPRESENTATIVE PASHINSKI: Is it with this particular pharmacist or is it many pharmacists?

DR. HERSHKOWITZ: It is many, many pharmacists. And it is Medco. You send it away to Medco, and now the 3-month supplier that, you know, your drug in now on 3 months, and it goes away and it comes back not what I wrote for. That was my understanding, too. That was why---

REPRESENTATIVE PASHINSKI: Did you challenge that?

DR. HERSHKOWITZ: I challenged it all day long, but I got, you know -- we get nowhere.

REPRESENTATIVE PASHINSKI: Do you have written proof that you have done this and that they have declined?

DR. HERSHKOWITZ: Well, I write appeals for medications on a regular basis that are turned down, because the patient hasn't, quote, "failed" the generic substitution yet. And what it means to fail, I'm here to tell you, what it means to fail is to have a seizure. How can I allow that to happen? This is my daily life.

REPRESENTATIVE PASHINSKI: Right; I agree.

DR. HERSHKOWITZ: It makes no sense.

REPRESENTATIVE PASHINSKI: I agree completely.

DR. HERSHKOWITZ: And you guys are catching on now, because it makes no sense.

REPRESENTATIVE PASHINSKI: Well, we are just trying to sift through it all.

DR. HERSHKOWITZ: Yeah. This is welcome to my life. Yeah; exactly.

REPRESENTATIVE PASHINSKI: Okay.

Let me ask you two more questions.

DR. HERSHKOWITZ: Okay.

REPRESENTATIVE PASHINSKI: You of course have Tanner's example, you know, which is certainly a tragedy. Now, do you have other failures that are going on at this time?

DR. HERSHKOWITZ: Yeah, I have had many other failures, and to report them, first of all, I'm never sure where to report them to. The FDA has a MedWatch Web site, if you have ever gone on it, that is incredibly complex to try to get through it, volumes and volumes. I can barely, you know, conclude a day before 10 p.m. trying to take care of all my patients, to be filling out, you know, the

volumes of paperwork for everything.

But yes. So all doctors, when you poll neurologists -- and my colleagues, if they should ever get a chance to speak, have all this data. But if you poll neurologists, we all say we have had all of these, so it is a problem. It is our problem. But, you know, as far as making it public knowledge in published studies, I mean, there is some of it, and my colleagues will be happy to tell you that, if you will let me off the hot seat.

REPRESENTATIVE PASHINSKI: Well, just one more question, because you are doing real well.

DR. HERSHKOWITZ: Okay; let's do it.

REPRESENTATIVE PASHINSKI: You are talking faster, too.

DR. HERSHKOWITZ: Yeah.

REPRESENTATIVE PASHINSKI: What is the difference, how much difference is there between one generic and another generic?

DR. HERSHKOWITZ: Well, again, my understanding is that the difference -- first of all, these drugs, the generic drugs, are tested on healthy volunteers. So they are not tested on people with epilepsy. They don't need to be tested on people with epilepsy, which is very interesting, and they

don't need to be tested at the levels that we use in people with epilepsy. So that is also very interesting. That is my understanding, again. My colleagues have the data.

So there is an allowable variation. It has to be kind of technical between 80 percent and 125 percent, and then it has to do with confidence intervals and some stuff I don't understand.

But again, the FDA does allow that something is bioequivalent if there's a certain amount of variability. So generic A is bioequivalent to brand if it falls between 80 and 125 percent and then 90 percent confidence intervals and stuff, and the same with generic B. However, they never say A and B are equivalent, because they are not. One could be on one half of the spectrum and one could be on the other half of the spectrum. So they never say that, but in practice they are exchanged as if they are.

REPRESENTATIVE PASHINSKI: Okay. And could you give me an example of the difference in the prices?

DR. HERSHKOWITZ: You know, I don't know. I have called, my nurse practitioner and I have called ourselves and said, hey, we are patients; we want brand Zonegran; what is the difference between that

and Zonisamide? And we were told 30 or 40 bucks. So they are still expensive. The seizure medicines are very expensive, the newer ones.

But, however, what we are dealing with is insurance companies and other things, and they always give you a much bigger, if your patient wants this, you know, they will have to pay some huge costs. They always say a bigger cost. So I don't know if they are getting them bundled or if they have, you know, a different price that is given to them, so I don't know.

But that's a whole different issue than we are here today. We are here today about, you know, being informed about changes. We can't, you know, change the whole system, but we can change being informed at a level on the pharmacy, which is what we are trying to do today.

REPRESENTATIVE PASHINSKI: And I appreciate that, and I'm looking forward to the statistics that are going to be coming before us. But I do think it is important for us to know all the pitfalls---

DR. HERSHKOWITZ: Absolutely.

REPRESENTATIVE PASHINSKI: ---so that when we make our choices and decisions, it is completely informed.

DR. HERSHKOWITZ: Yeah, and I appreciate your good questions.

REPRESENTATIVE PASHINSKI: Thank you very much.

DR. HERSHKOWITZ: Thank you. I thank all of you.

CHAIRMAN OLIVER: All right. Thank you very much.

Dr. Paul McCabe -- briefly. Thank you very much.

DR. McCABE: I would also like to thank the Pennsylvania House of Representatives Health and Human Services Committee for allowing me to speak in favor of House Bill 98.

Like my associate, I also am a specialist in the treatment of patients with epilepsy. I have been located in central Pennsylvania, and I have been responsible for well over 2,000 different patients with seizure disorders.

I am here to speak on their behalf, on behalf of all other neurologists and physicians, and also on the Epilepsy Foundations of Pennsylvania. But as you heard, we are not here to talk against generics per se but to bring to the attention some of the problems that can occur with them.

Generic substitution isn't the same in every disease state, as you have heard. Some disease states you can monitor changes; others you cannot. And there can be variation from individual to individual, which is probably the biggest issue we deal with in epilepsy.

As you heard, the testing for generic drugs many times is a small group of patients, 15 or 20. They are given a single dose of the drug. There is a washout period, they are given a single dose of the generic equivalent, blood levels are measured, and that is how they determine their equivalent. They do not have to prove they are effective. That is based on the data that was provided by the drug companies that made the brand name.

So you have heard many different individual accounts of problems that have occurred. What I want to review are some of the published studies that show how widespread of a problem this can be, and I'm going to bring four different articles and case issues up to express that.

So the first was a survey sent out to almost 300 neurologists asking them about issues that occurred when generic drugs were substituted for brand-name seizure drugs -- specifically, how many

times did they have problems with breakthrough seizures; how many times have they had problems with adverse events, because that can also be a problem.

Out of this group, 67.8 percent of the doctors reported an increase in seizures when this occurred, and 56 percent reported an increase in side effects when this change occurred.

Even more impressively was they looked at the same thing if a change was made from one generic to another generic, and again, they saw an increase -- 32.5 percent reported an increase in seizures, and 26 percent reported an increase in side effects.

Ultimately, it added to the cost, and this was seen because 63.4 percent of the neurologists surveyed reported patients needed extra visits; 48 percent reported that patients required emergency room visits; and 17.6 percent reported their patients had to be hospitalized, and you heard one of the more severe cases that that happened.

Canada is very familiar with generic drugs. They are very proactive with epilepsy. They are required to keep track of these changes more so than we are. So they looked at a comparison between epilepsy and seizure drugs to other disease states, in particular, high cholesterol and depression. They

compared three brand-name seizure medicines -- Depakote, Frisium, and Lamictal -- to brand name versus generic -- Zocor, which is used for high cholesterol, and Prozac and Celexa, which is used for depression.

What they reported was switchbacks were related to either increased seizures or side effects. For the seizure medicines, 20.9 percent of people on Depakote required switching back to the brand name, 20.7 percent on the drug Frisium required switching back to brand name, and 12.9 percent on Lamictal required switching back to the brand name.

Of patients that were able to stay on generics, a significant increase in dose was noted in most patients to be able to keep their disease state under control, as much as 6.2 percent of a higher dose, which ranges to an extra pill in many of these medications.

The other thing notable here is you have heard the tediousness that we have to go through with paperwork. Well, in Canada, they have to go through several documents that they have to fill out in order to have their patients go back to brand name, and their doctors were willing to do this to get these patients back on to a brand-name drug.

In another small recent study, one of the newer drugs, Lamictal, which is due to go generic -- it is one of the most widely prescribed drugs for epilepsy -- Denmark did a study, a small study, of nine patients that were switched from brand to generic. In Denmark, their guidelines are much tighter. Rather than allowing an 80 to 125 percent variation of the confidence interval, theirs only ranges from 90 to 111 percent.

They followed drug levels much more closely. They did blood levels every 3 to every 4 hours as opposed to just a single drug level, and what they found was out of the nine people, five of them fell out of the expected or required range that was predicted based on these generics.

In terms of clinical outcome, one patient that was seizure free had a recurrence of seizures; one patient went into status epilepticus -- what you heard earlier, the continuous seizure that is life threatening; one patient became so dizzy that they fell and developed a blood clot on their brain and had to go to emergency surgery.

In the U.S., again, we have an even wider variation. And also, since these drugs have been tested and passed the strict codes that were

required, the conclusion came about that this had to be variations due to each individual patient, since these drugs had passed the test to get them approved.

What this also shows is that even if we do blood levels before and after a change, a single blood level still may not be enough for us to predict which of our patients may develop seizures.

The final case I am going to bring was a single case that occurred here in Pennsylvania back in the 1980s. A neurologist who is now retired -- I know him well -- his patient was given generic Tegretol. She went into status epilepticus and died. It was later found that the generic formulation she was receiving did not meet the standards of the generic, yet still was released on the market. And the company had even had reports already of problems with their generic, and they continued to make them available.

Therefore, even though generic medications must test within a tight range and that confidence interval I mentioned of 85 to 120 percent in layman's terms equals about only a 5- to 10-percent variation, that still does not meet the standards for many individual patients. And although some disease

states allow you to monitor what happens when you switch to a generic, we don't have that advantage with epilepsy. As you heard, it's an all-or-none phenomena.

So in conclusion, I just want to say we are not objecting to the use of generic medications. However, generic medications carry many features that in the condition of epilepsy you need to be aware of, and if changes are made in these medications, the physician and the patient themselves have to be made aware of these.

I myself, like Dr. Hershkowitz, have had many times generics substituted, despite my writing "brand medically necessary."

And the price difference does become an issue, because it depends on the contract made between the individual insurers, and I have seen differences of only $15 but differences of $400 that a patient would have to pay out of pocket.

So again, I would like to thank you for your time, and I would like you to keep in mind that with Senator Kennedy and his recent seizures, I find it unlikely that they are going to find it suitable to start him off on a generic medication for seizures, if they decide to treat him.

Thank you.

CHAIRMAN OLIVER: Representative Pashinski.

REPRESENTATIVE PASHINSKI: Thank you, Mr. Chairman.

Thank you, Doctor.

Could you tell me, how many epilepsy drugs are generally used in treating your patients?

DR. McCABE: I would say between the older drugs that have been out for years and the newer ones, there are about 10 of them. Seven to eight are the major players that we use.

REPRESENTATIVE PASHINSKI: That is it?

DR. McCABE: That's it.

REPRESENTATIVE PASHINSKI: Is the testing process sufficient to determine the expected outcome? You indicated that there might be some improprieties in the way it is tested.

DR. McCABE: Well, in the eyes of the FDA, they feel it is. In the eyes of physicians that treat chronic unpredictable diseases, we find it very difficult to understand why a single test done on healthy subjects somehow mimics what we see in chronic, everyday disease states.

REPRESENTATIVE PASHINSKI: So that might be something that has to be also reviewed.

And the FDA is the one then, the only one, that will approve or disapprove the drug?

DR. McCABE: That is correct.

REPRESENTATIVE PASHINSKI: So therefore, they have accepted whatever testing is being done.

DR. McCABE: Correct.

REPRESENTATIVE PASHINSKI: Okay.

And you said that there was a difference sometimes between $15 and $400 between these generic drugs, or was it the high patent drug?

DR. McCABE: No -- well, that's the difference that the patient may have to pay between the generic versus the brand name. So it really depends on the insurance carrier, in part how much of the medicine they need.

But I have had one patient come in and tell me that the difference month to month was $15, another patient that it was going to be close to $400 out of their pocket to have to take the brand name versus generic.

REPRESENTATIVE PASHINSKI: Okay.

If a new high-patent drug comes onto the market for epilepsy, how would you be informed about this drug and how would you decide to use this drug on your patient?

DR. McCABE: Well, for most of the drugs, we are aware years in advance that they are in the testing phase, and many of us participate in the testing phase that is required through the FDA.

Currently, the cost of getting a drug approved, a brand-name drug, is about $100 million. And like anything else, there are so many years of patent to recoup that cost. With generics, none of that cost is incurred, which is why they are so much cheaper. They are able to follow the study results of the brand name and only prove through this one single test that they are equivalent.

So most of the time we know when drugs are coming out. Why we may choose to use them varies. We have patients that have failed everything else, so they will be the first in line.

There may be specific instances or issues with that drug that makes it different enough from other existing drugs that favor, you know, side effects, for example, interactions with other medications that could be severe if you are unaware of them.

So those are the types of things we are usually looking at when we are deciding that.

REPRESENTATIVE PASHINSKI: And the last

question.

Once a patent has expired, what do you call that drug then? Is that a generic drug?

DR. McCABE: No, the company that makes it still makes a brand-name drug, and they are still responsible for it meeting all the requirements of a brand-name drug. However, studies out there show that once one of these drugs loses their patent, almost 80 percent of the drug under that name is going to be dispensed as the generic.

So it is a huge changeover in a very short period of time. But those companies still continue to make the drugs under the same circumstances, and the only difference may be whether or not they decide to change their pricing.

REPRESENTATIVE PASHINSKI: I see. Thank you very much. I appreciate it.

DR. McCABE: Thank you.

CHAIRMAN OLIVER: Representative Reichley.

REPRESENTATIVE REICHLEY: Thank you, Mr. Chairman.

I will try to get through these questions as quickly as I can, Dr. McCabe. And I wasn't sure if Dr. Klein was still testifying, but let me ask you, since based on your testimony you seem to be a

practicing physician with the situation as well.

I guess in line with some of Representative Pashinski's questions, I'm trying to still get an exact sense of when the switchover to the interchanges take place and why if you are writing "brand medically necessary" on the prescription.

DR. McCABE: It is a question that we have been trying to answer for years as well.

I have had one instance where I know it was done purposefully, because a patient obtained their prescription back from the pharmacist, and the pharmacist had actually put a white sticky over the part where I had written "brand medically necessary."

Other times, we don't know why it is being done, despite what we write. But as you heard from Dr. Hershkowitz, it is probably not the initial filling of the prescription, because it is there in plain writing; it is probably coming with their refills.

And the other instance is when the drugs may be filled at the pharmacy, and based on the instruction of that person's insurance company that now a generic is available, they are not even given the option for the brand name.

REPRESENTATIVE REICHLEY: When you write the

prescription "brand medically necessary" and take it into the pharmacist, does the pharmacist then call in to the insurance company and say, okay, with this patient I have been asked to give them the XYZ drug; the insurance company says, we're not going to pay for that; we are only paying for the generic, and then the pharmacist substitutes the generic?

DR. McCABE: That is most likely what happens, although they may not have to call. They have a pretty complex computer system that they may just go in and enter it and then it kicks out that, no, they can't have the brand name based on this insurer.

REPRESENTATIVE REICHLEY: Now, the situations you have encountered, are they all in private medical insurance situations, or are some of them Medicaid? And is there an age range of people that you are treating who experience this difficulty, or is it just in older patients? younger patients?

DR. McCABE: It is across the board. It is all age ranges. It is Medicaid, Medicare -- well, Medicare recently, but they haven't had their own prescription plan before -- and all the private insurers.

REPRESENTATIVE REICHLEY: Okay. So it is

not exclusively a private insurance issue that comes up.

DR. McCABE: No.

REPRESENTATIVE REICHLEY: Somebody mentioned Medco. Are there situations where if people go to purchase their drugs in bulk, this becomes more of a concern?

DR. McCABE: Well, what happens is, it is very rare you can get them in bulk at a local pharmacy. It is almost always mail-away.

REPRESENTATIVE REICHLEY: Right.

DR. McCABE: So you don't even know what they are giving you until you receive it in the mail, and by then, it may be 2 more weeks until you could argue and get a brand name sent, because 2 weeks is about the average turnaround time to get a prescription through the mail for the long-term, 3-month supply.

REPRESENTATIVE REICHLEY: I think we have heard from perhaps Dr. Hershkowitz that there is in place right now a prohibition upon a pharmacist changing or doing an interchange. Are there any situations in which the pharmacist is legally entitled to say, the doctor goofed; this is wrong; this is the best thing for the patient?

DR. McCABE: To my knowledge, no, they are not allowed to do that.

REPRESENTATIVE REICHLEY: If House Bill 98 went into law, how would it impact your prescribing procedures or your habits?

DR. McCABE: Well, I think what it will do is it will generate a fair amount of work for a lot of people, but that work is needed to protect our patients. So it is going to require pharmacists having to make contact. It is going to require us signing consent or approval to use a generic if we feel so, and there probably is going to be some required time in between of us discussing with our patients the pros and cons of the generic.

So we realize it is going to add more paperwork, if you will, to us, but it is a necessity to continue to care for these patients.

REPRESENTATIVE REICHLEY: Okay. This is my last question.

I understand it probably wouldn't change much in the way that you do things; if you are writing "brand medically necessary" now, you are probably going to continue to do that. But as you might imagine, the committee members received a lot of information from people across the board on this

issue, and one of the assertions is that it will delay the ability of patients to receive drugs if the pharmacist now has to check with an insurance provider to see if there is, or check back with you to see if there is an alternative medication that can be prescribed that doesn't have adverse side effects. What is your response to that assertion?

DR. McCABE: I do expect that there can be a delay. In most cases, I do not expect it to be detrimental, because patients should be going in for refills while they still have maybe 2 or 3 days' worth of medicine left anyway. So if it adds an extra day, that shouldn't really make a big difference in that situation.

If it is a person coming in for their very first prescription, a delay of starting the medicine by 1 or 2 days is probably not going to make a big difference.

REPRESENTATIVE REICHLEY: What about a person like Mrs. Little? Not that she would run out of the medications, but her daughter, if she doesn't get that medication and has a grand mal seizure, that could potentially be fatal. What do you do in that situation?

DR. McCABE: Well, again, we educate our

patients and we tell them that they have to stay on top of when refills are necessary, because we frequently get the phone call, I don't have any left; can you call this in emergently?

So the one thing is going to be patient education. I have already started that with my patients on these drugs that we know are coming up to the end of their patent life. So I have been telling them to watch for changes in drugs, watch for difference in costs, and to contact me if anything happens.

I'm also most likely going to be doing more blood levels on these patients, which is going to defray from the costs of savings with the generic because now I'm going to have to watch their blood levels more closely from when they are on their brand name to their generic.

And one of the other issues we will be bringing up is, don't wait until the last minute, because there may be a delay.

REPRESENTATIVE REICHLEY: All right. Thank you.

CHAIRMAN OLIVER: Thank you very much.

I do want to say that from this point on, I'm going to ask the questioners, please be as brief

as possible. We are way behind our schedule.

Representative Waters.

REPRESENTATIVE WATERS: Thank you, Mr. Chair.

I wanted to ask a couple of brief questions, and that is, you mentioned the computer system. In the system, to your knowledge, when they go in there looking for a brand-name drug and it is refused based on what the insurance company said and what is in the system, is there an equivalent substitute that is given to you that will automatically help the pharmacist know that this is the one that will be the safest to give the patient, or is it all just speculation?

DR. McCABE: I think the short answer is, most of it is speculation.

The closest, theoretically, would be the generic equivalents. But we have had cases where they want to substitute a completely different drug claiming that it is similar, and that, most of the time, is based on the drug company's formulary and what drugs they want us to use.

And as you have heard, every patient is an individual, and therefore, we can't make the assumption that they are equal.

REPRESENTATIVE WATERS: For physicians, I know that Mcare is something and physician liability problems. What, if at all, factors in when it comes down to, for instance, like a patient that receives the wrong kind of medication as a result of that while they are operating some kind of machinery, a car or whatever, causes death maybe to themselves or to another innocent person? What is the liability, to your knowledge, incurred there?

And I am finished. Thank you, Mr. Chair.

DR. McCABE: Well, I think the best example I can give is the case from Pennsylvania that is included in your handout, where because of that substitution being done without the physician's knowledge, came to a $950,000 settlement in favor of that patient, or that patient's family because the patient himself had died, and that was not including any physicians. That was mostly through the pharmacy and the drug companies that that money had to be paid.

But in this current litigious society, the sky is the limit, and you could be looking at lawsuits much higher than that in a patient who really wants to, for lack of a better word, sue the system.

REPRESENTATIVE WATERS: Thank you.

Thank you, Mr. Chairman.

CHAIRMAN OLIVER: Thank you very much.

Thank you very much, Doctor, for appearing today.

DR. McCABE: Thank you.

CHAIRMAN OLIVER: The next person scheduled to testify is Dr. Brad Klein from Jefferson Hospital.

DR. KLEIN: The Thomas Jefferson University Hospital.

Good morning. My name is Brad Klein. I am actually the President for the Pennsylvania Neurological Society, representing the interests of over 750 neurologists in Pennsylvania, as well as a practicing neurologist in Philadelphia.

I would like to thank Chairman Oliver and the members of the House of Representatives Health and Human Services Committee for allowing us to speak in favor of House Bill 98.

You have heard a lot of testimony, and I do not want to repeat what has been said before, so I will cut down my testimony a little bit. You have my full testimony, though, if you would like to read through it.

If a pharmacist is allowed to substitute one

brand or generic drug for another -- generic to generic, or brand to generic -- the person with epilepsy, as you have heard, is placed at risk for breakthrough seizures, seizure-related injuries, and even death.

Breakthrough seizures financially burden patients in the health-care system, as you have heard, due to unnecessary ambulance transportation, ER visits, hospital admissions, laboratory and diagnostic testing.

As you can see, the costs associated with breakthrough seizures have the potential to be monumental, financially as well as on a personal level. What matters most is that a person with epilepsy has access to the exact drug, generic or brand, that is proven to work for him or her, new or old.

This legislation is supported by multiple national and State organizations, including the national Epilepsy Foundation, the Epilepsy Foundation of Central/Western PA, the Epilepsy Foundation of Eastern PA, the American Academy of Neurology, the Pennsylvania Neurological Society, as well as the Pennsylvania Medical Society.

And perhaps to respond slightly to

Representative Manderino's comments, the physician community, the leadership across all the counties in this State, have also supported this bill, whether or not you are a neurologist, a primary-care doctor, a hematologist. So there is some interest by other physicians that are not neurologists that this is an important issue as well.

Some may oppose this legislation on the grounds that it adds unnecessary or burdensome steps in order for a person to obtain a prescription AED. However, these extra precautions go a long way to ensuring patient and public safety, which is of the utmost importance.

If the pharmacy does not have the same AED prescribed, the pharmacy should make all attempts to ensure the patient's safety by obtaining the same drug where available. If not, this legislation ensures effective communication to the patient and the physician regarding potential substitution.

This does not imply that the patient is required to purchase a brand-name drug equivalent or that the generic AED will not be prescribed. It does, however, mean the physician is able to decide which drug to prescribe that is best for the patient to control their seizures. For these reasons, we do

not expect the State to incur significant expenditures due to this legislation.

The State of Tennessee recently adopted similar legislation without a significant financial impact to the State or Federal level or a significant cost of health insurance premiums, according to James W. White, the Executive Director of the Fiscal Review Committee for the Tennessee General Assembly.

In conclusion, I would encourage you to consider carefully the life threatening and costly risks with epilepsy that the patient as well as the general public face when access to the right anticonvulsant drugs as prescribed by the individual's physician is hindered.

It is the organizations that I mentioned above as well as my own opinion that the physician should have the freedom to prescribe the AED that will work best for the person with epilepsy without fighting barriers such as the current drug substitution process or formularies requiring lengthy preauthorizations that may delay the patient's ability to get the drug they need.

Again, the Pennsylvania Neurological Society strongly supports the use of generic medication for epilepsy patients. However, the patient should have

the right to not fear any unexpected drug change, denial of a drug by their insurer, or how he or she will afford the medicine to prevent them from seizing.

I sincerely thank you for the time to listen to our testimony.

CHAIRMAN OLIVER: Thank you very much.

DR. KLEIN: Thank you.

CHAIRMAN OLIVER: Any questions from any of the members? If not, thank you so much for appearing.

DR. KLEIN: Thank you very much. I appreciate it.

CHAIRMAN OLIVER: The next person to testify will be Patricia Epple, Executive Director of the Pennsylvania Pharmacists Association.

You may proceed.

MS. EPPLE: Good afternoon.

Thank you, Chairman Oliver, Chairman Kenney, and committee members.

I have with me Dr. Sasich. We are going to combine our testimony together.

Thank you very much for this opportunity to testify on behalf of the Pennsylvania Pharmacists Association.

If adopted, House Bill 98 would circumvent the current generic substitution law in Pennsylvania, which has been in place and worked well since 1976.

Please know that the Pennsylvania Pharmacists Association has the utmost sympathy for individuals who have epilepsy, and we sincerely appreciate the need to effectively control their seizures.

Unfortunately, this bill only unnecessarily complicates the prescription process and may actually cause more problems for patients. While we can appreciate the good intentions of the bill's sponsor, the Pennsylvania Pharmacists Association is opposed to this bill for the following reasons.

One, current law already does provide protection and gives the full authority to physicians to determine when and if generic substitution is appropriate. Pharmacists may absolutely not substitute a generic drug if the physician indicates that they may not. They also may not switch from brand to brand, and also cannot substitute between generic to generic.

From what we have been told, this bill was introduced for the purpose of allowing prescribers to control the specific brand of medication that is

dispensed to a patient. That ultimate authority is already in the hands of the physician. If the physician wishes to have a specific brand dispensed, he or she may easily write either "brand necessary" or "brand medically necessary." This is a very simple matter and is written right on the face of the prescription. If the physician wishes to even specify a specific generic manufacturer, they may also indicate that, and a pharmacist must follow these instructions. There is no wiggle room; this is an absolute, and this is true even on refills.

Proponents of this bill have told our association that they know of circumstances where pharmacists have switched a prescription from a brand to a generic when the brand was indicated on the prescription form. We have heard this even this morning. I'm asking for the proof of this claim, and up until now, had not received any hard proof of that.

Furthermore, if it is being done, then that pharmacist should be reported to the State Board of Pharmacy for not following the law. We fully support and encourage a reprimand by the State Board of Pharmacy for any pharmacist who is not in compliance with current law. The fact remains, the physician is

in control to prescribe a particular brand drug or a specific generic at any point in time.

Our second reason for opposing this is that it would place an unnecessary burden on the pharmacist by requiring a duplication of effort through another approval and consent process if an interchange is necessary because of insurance coverage. Instead of simply indicating "brand" on the prescription, the physicians' offices would now be burdened by a repetitive need, because we would contact them for that written consent in addition to the prescription that has already been received. This proposal would set up unnecessary roadblocks for patient care.

This requirement will also cause possible delay in treatment for a patient while the pharmacist tries to contact the physician to obtain the required written consent if an interchange is necessary because of insurance coverage. This could be especially problematic if the patient is having someone else deliver and pick up the prescription, since the patient's written prior consent is also needed. If a prescription is provided to the pharmacy in the evening or the weekend, obtaining this consent could be impossible, preventing the

pharmacy from dispensing the medication and unnecessarily delaying treatment, which clearly is not appropriate for a patient with epilepsy and who needs their seizures controlled.

It will also cause confusion when prescribed for off-label uses. Antiepileptic drugs are frequently prescribed for what is known as off-label uses. This is when a physician prescribes a drug for something other than its FDA-approved indication.

FDA regulations permit physicians to prescribe approved medications for other than their intended indications. Some of the drugs indicated for seizure control are frequently used by physicians for migraine prevention, anxiety, insomnia, panic disorders, alcoholism, glaucoma, pain management, and congestive heart failure. How would a pharmacist know when they receive a prescription for an anticonvulsant that it is for epilepsy? Physicians do not include the diagnosis on the prescription.

With this proposal, you could have a situation where a patient who needs the medication for something else is needlessly held up from receiving care while the patient tries to obtain the written prior consent, only to ultimately find out it was not needed because it was not for the treatment

of epilepsy.

Generics are a cost effective and safe alternative, and the FDA has approved generics for the treatment of epilepsy. These generics have met the FDA's rigorous approval process. With today's rising health-care costs, it is often crucial to have generics available for care. For many patients, it is purely a financial issue. The use of the generic may be the only way they can afford any medication based on what their insurance coverage provides. Any suggestion that the generic is inferior may not be appropriate when medication adherence is crucial to stability.

Allowing brand manufacturers to "carve out" entire therapeutic classes from generic substitution laws establishes a troubling and dangerous precedent. What drug class will be next?

Similar legislation has been introduced and largely defeated in many States this year across the country as a major effort by pharmaceutical companies to protect their market share for drugs going off patent. Restricting access to cost-saving generic drugs, when appropriate, will only increase the cost to patients, insurance programs, and taxpayers who fund Commonwealth prescription drug programs.

Pennsylvania's PACE program, for example, is a program that requires the use of generics, unless prior authorization is obtained from the program. Part of the success of the PACE program is its ability to control costs through the promotion of cost-effective, safe generics.

For all of these stated reasons, the Pennsylvania Pharmacists Association urges you to oppose House Bill 98 and stand by the current generic substitution law in the Commonwealth.

And now Dr. Sasich is going to go into a little bit more detail.

DR. SASICH: Good afternoon, everyone.

Mr. Chairman, members of the committee, thank you very much for the opportunity to speak on this very important topic in public health policy.

My name is Larry Sasich, and I'm the Chairman of the Department of Pharmacy Practice at the LECOM School of Pharmacy in Erie, Pennsylvania.

In the 10 years prior to joining the LECOM faculty, I was a research associate with Public Citizen, a research-based public interest group located in Washington, DC.

My primary responsibilities included the Food and Drug Administration; drug policy, and that

also accompanied generic drug policy; and communicating drug safety information to consumers.

I currently serve as the consumer representative on the FDA's Science Board, which is an advisory committee to the FDA's Commissioner. I am also a consultant to the Saudi Arabian Food and Drug Authority.

In the interest of full disclosure, I have no conflicts of interest in this matter, and I paid my own expenses to speak here today.

My testimony will focus on two areas, first on what is driving House Bill 98, highlighting that States have experienced lobbying pressure in the past by the pharmaceutical industry and advocacy organizations supported by industry funding attempting to protect market share for top-selling drugs that were about to lose their patent exclusivity. Second will be an examination of the FDA's generic drug approval process and the evidence, if any, that generic drugs have ever harmed consumers.

There is nothing new in the politics of pharmaceuticals, and I will briefly cover these.

Historical precedence and economics predicts the introduction of House Bill 98. Table 1 in my

written testimony lists five top-selling drugs approved by the FDA for the treatment of epilepsy and their estimated dates for patent expirations. These five drugs accounted for almost $6 billion in retail sales in 2007. Any barriers enacted that hinder consumers' access to generic drugs will only protect the sales of brand-name products and will not improve or protect the public's health.

In 1996, DuPont Merck petitioned the Food and Drug Administration asking for a change in the standards used to approve generic drugs to protect its brand-name blood thinner Coumadin from generic competition. Failing to obtain FDA support, DuPont Merck sponsored the formation of the Health Alliance for Narrow Therapeutic Index Patient Safety in 1997. This group was apparently created to advance the concept that generic drugs are not as safe as brand-name pharmaceuticals. The alliance became a leader in efforts to enact legislation on a State-by-State basis that would restrict consumer access to so-called generic Narrow Therapeutic Index medications, including generic Warfarin.

The Epilepsy Foundation is promoting model legislation in a number of States that is very similar to that proposed by the Health Alliance for

Narrow Therapeutic Index Patient Safety more than a decade ago.

Regrettably, the media regularly reports that physicians, professional trade organizations, and patient groups are paid to prescribe and promote drugs. Industry influence is pervasive, and the effect can be characterized as negative from a public policy standpoint.

Pennsylvania has recent experience in this regard. The former chief pharmacist for the State was arraigned in November of 2006 on felony and misdemeanor charges related to his accepting of money from drug companies whose drugs he put on the State formulary.

The Epilepsy Foundation is estimated to have received funding from the pharmaceutical industry that approached $50 million of its $80 million annual budget in 2006. There is a need to acknowledge the significant financial forces that are at play in this debate. Brand-name epilepsy medications individually generate hundreds of millions of dollars annually for their manufacturers.

My written testimony outlines the FDA standard for approval of generic drugs.

Briefly, generic drugs must have exactly the

same active ingredients as its brand-name counterpart; be identical in strength, dosage form, and route of administration; have the same use indications; meet the same manufacturing standards; and be bioequivalent.

The bioavailability of a drug product is demonstrated if the product's rate and extent of absorption, as determined by comparison of measured parameters -- for example, concentration of the active drug ingredient in the blood, urinary excretion rates, or pharmacological effects -- do not indicate a significant difference from the brand-name product's rate and extent of absorption.

The procedures and methods used to deem products as generic equivalents and being bioequivalent have been in place for years and have served the public interests. The determination of bioequivalents relies in part on statistical testing. Because of the nature of statistical testing, there is always a chance for error.

I would also like to say that for brand-name products, there is a range, an acceptable range of concentration of the active ingredient for a drug that meets, a brand-name drug that meets the current standards by the United States Pharmacopeia, and that

is labeled at 100 milligrams. I can almost guarantee you that there is not 100 milligrams in every dosage form. There is an acceptable range. It is just impossible to produce products with that level of precision.

There does not appear to be any rigorous scientific evidence that indicates that generic drugs are less safe than their brand-name counterparts. The "Medical Letter on Drugs and Therapeutics," a highly respected, independent source of drug information, reviewed generic drugs in its October 14, 2002, issue. The editors concluded that, quote, "No well-documented therapeutic differences between brand-name originals and FDA-approved generics have been reported."

In summary, it must be recognized that substantial financial forces are influencing this debate. It must also be recognized that uncontrolled clinical observations and opinion are the least reliable form of evidence that generic epilepsy drugs present a risk to patients.

Important public health policy legislation must be based on rigorous scientific evidence, not on clinical impressions, experience, or opinion. The question that you as Legislators must ask is, where

is the rigorous evidence that generic epilepsy drugs have harmed patients?

Thank you, and I would be happy to answer any questions.

CHAIRMAN OLIVER: Representative Manderino.

REPRESENTATIVE MANDERINO: Thank you, and thank you for your testimony.

My first questions are for Ms. Epple, and I'll be very blunt.

I do not find it credible to say that it is not happening. Not only did we hear from these folks, I had an incident in my district office just last week with one of my staff people, who got in an argument with a pharmacist because she had brand name, medically only -- it had nothing to do with epilepsy drugs -- and there was a substitution, and the pharmacist just basically told her, I'm allowed to substitute.

So something is happening. My question is, what is happening? And I see your testimony said -- and I think most people understand that you can't substitute brand for generic, but it is happening, or generic for generic -- you didn't write that in your testimony, but you said that you can't even substitute generic for generic. That is happening,

too. So what is it that is allowing this to happen, because it is happening across the board. I don't think it is one or two errant pharmacists thumbing their nose at the law. Something is happening, and I'm missing what it is.

DR. SASICH: Well, I think we have to examine a basic scientific principle of trying to prove cause and effect. Because the rooster crows doesn't make the sun rise, right? And so going back and you see a patient with a seizure and immediately say it is the drug---

REPRESENTATIVE MANDERINO: Let me interrupt. That was not my question.

My question, Ms. Epple, is, what is current Pennsylvania law and how is it written so that these things are happening? You are saying they aren't happening; I'm not believing they are not happening. So either everybody is out there blatantly violating the current law, or people are interpreting the current law differently than this absolute standard that we seem to be articulating today. What is happening?

MS. EPPLE: I do not know what is happening. I can't answer that for you. I know that the members of our association whom I talked to tell me that they

are not doing it. I know you are running across situations; I can't address that.

The law does very specifically say they cannot---

REPRESENTATIVE MANDERINO: Okay.

MS. EPPLE: ---when the physician writes "brand medically necessary."

REPRESENTATIVE MANDERINO: Okay. Let me ask a specific question: My physician writes "brand medically necessary" on my prescription, and when I go to the pharmacist to pick up that prescription, should I expect that if the doctor wrote -- I do not even know, I don't take any medication; give me a brand name of something -- Zoloft on the form, that what should be in my bag is Zoloft, and the pharmacist should say to me, "Ms. Manderino, that will be $400, please," and then when I say, "My copay is only $20," they say, "But your insurance doesn't cover Zoloft; $400, please." Isn't that the conversation that should be happening---

MS. EPPLE: Yes.

REPRESENTATIVE MANDERINO: ---that would make me aware that because -- and nobody else made any decisions. My doctor said Zoloft; you filled Zoloft. I don't care what my insurer said about

whether they are going to pay for that. The conversation happens at that point where I immediately know now what the issue is, right?

MS. EPPLE: Yes. I got a little lost there in your scenario, but if the physician wrote "brand medically necessary" and your insurance was going to pay for it, then actually nothing should happen. You should get the brand, and you should pay whatever the copay for your brand is on your insurance coverage.

REPRESENTATIVE MANDERINO: Right.

MS. EPPLE: The problem that we do run into is when a patient, one, the copay may be more than they want to pay and they go, whoa, wait a minute; I only paid $10 the last time, why am I now paying $30, $35? And then the pharmacist says, well, that is because you want the brand. You know, then at that point it becomes the patient's decision.

REPRESENTATIVE MANDERINO: Correct.

MS. EPPLE: And if the patient says, well, you know, I'll take that generic, the pharmacist still has to go back, though, and get that approved by the physician to not follow that brand.

REPRESENTATIVE MANDERINO: Okay.

So the way House Bill 98 is drafted, as I read it, assuming what you told us is correct, that

these substitutions aren't happening and can't happen by law, the pharmacist should never have to exercise anything that is written in House Bill 98.

MS. EPPLE: Yeah, because it is saying -- okay; follow me through this example.

REPRESENTATIVE MANDERINO: Go ahead.

MS. EPPLE: If the physician writes "brand medically necessary" right now and the insurance coverage either won't cover it or the copay is too high, the pharmacist has to pick up the phone and check with the physician to see if they can dispense a generic.

Under this bill -- and say the physician said okay. If they said no, then they would have to do all the prior authorization and things like that. But let's say he or she did say okay. At this point then, we would need the physician not to just say it on the phone but to fax us something in writing that says it's okay. Then we would have to make sure that the patient gave the same written consent as well, not just a verbal okay. And if they weren't along, if they weren't the person picking up the prescription, then we would have to wait until we got that. So that is where the delay factor comes in.

REPRESENTATIVE MANDERINO: Okay. But you

could choose as a pharmacist to handle that differently. You could choose as a pharmacist to dispense what the physician said to dispense, and then if the patient bulks at the point of sale of paying for it, now the burden is on the patient to go back to their doctor and get those forms.

MS. EPPLE: And I hear you, but in reality that is not what happens. Patients, when they come pick up their prescription, expect the pharmacists to do those things for them. So the expectation would be that we obtain that consent from the pharmacist.

REPRESENTATIVE MANDERINO: But don't you think if it's a matter of life and death, patients wouldn't expect that?

MS. EPPLE: Yes and no, but again, delays, things being what they are, the pharmacist is going to have to do those things, I think.

REPRESENTATIVE MANDERINO: Okay. Thank you.

My next question is for Dr. Sasich. I hope I said that right. Just a very basic question about generics.

You said they have to have the same active ingredients, which was always my understanding.

DR. SASICH: Exactly.

REPRESENTATIVE MANDERINO: My question is,

are they even allowed to have the same inactive ingredients? I mean, whether my medicine has gone off patent or not, somebody can't go out there and replicate my exact identical thing, including all the inactive ingredients, the binders and all that kind of stuff, or can they?

DR. SASICH: There can be different inert ingredients, but they have to meet the same standards.

REPRESENTATIVE MANDERINO: Can they replicate the exact inert ingredients?

DR. SASICH: No. The question is, do they perform the same?

REPRESENTATIVE MANDERINO: I understand that's the standard. I'm just asking a manufacturer question.

DR. SASICH: The generic manufacturer has to give the FDA prior notification if it changes an inactive ingredient, the same way that a brand-name manufacturer must.

REPRESENTATIVE MANDERINO: Right.

If I am AstraZeneca and I make XYZ -- I don't even know the names of drugs; I'm sorry -- but I make this particular drug and now the patent has expired, and some other company wants to make the

same drug---

DR. SASICH: Okay.

REPRESENTATIVE MANDERINO: ---are they allowed? Not the equivalent, not the acting equivalent, not the same effectiveness; the exact same drug from what it is bound in to what it looks like to what its inactive ingredients are. Am I even allowed to make the exact same drug?

DR. SASICH: An exact copy?

REPRESENTATIVE MANDERINO: Yes.

DR. SASICH: And so it appears to be the same?

REPRESENTATIVE MANDERINO: Yes.

DR. SASICH: I think that would probably violate copyright rules.

REPRESENTATIVE MANDERINO: Correct. Okay.

So that is in essence why there is always something different about a generic. I'm not talking in its tested effect.

DR. SASICH: Okay.

REPRESENTATIVE MANDERINO: I'm talking about it in its actual ingredients.

DR. SASICH: Well, we are talking about---

REPRESENTATIVE MANDERINO: Active, inactive, the stuff that binds it together, the stuff that---

DR. SASICH: Yeah, they can be different, but they have to meet the same standards.

REPRESENTATIVE MANDERINO: Can they be identical? I understand they can be different.

DR. SASICH: Oh, yeah. I don't see any reason why they couldn't be identical.

REPRESENTATIVE MANDERINO: Okay.

DR. SASICH: But if you made the tablet look the same and put the same logo or monogram on it, I think you would violate copyright rules.

REPRESENTATIVE MANDERINO: The same question different.

I'm AstraZeneca -- I don't know if anybody is here; I don't mean to keep picking on them. That is the one that came to my head. I make a brand-name drug; it is my biggest seller.

DR. SASICH: Okay.

REPRESENTATIVE MANDERINO: Do I only ever make it in one plant or do I make it in two different plants?

DR. SASICH: Well, you could make it in more than one plant.

REPRESENTATIVE MANDERINO: In reality, do they?

DR. SASICH: Well, all of the parts of a

drug can come from all over the world. The inactive ingredients and the active ingredients could come from China; they could come from Southeast Asia; they could come from North America. All of those individual ingredients could be shipped to Puerto Rico where the product is finally made and then distributed within the United States.

REPRESENTATIVE MANDERINO: And from 1999 to 2008, I could have changed those suppliers a zillion times in the making of the same product?

DR. SASICH: Yeah, but there would have to be prior notification, because all of those ingredients, including the active ingredient, have to meet FDA approval standards. That is part of the drug approval process.

REPRESENTATIVE MANDERINO: Okay, because I was trying to put in context the testimony I heard earlier about generics coming from different sources and if it is the exact same identical generic as compared to an equivalent.

DR. SASICH: Well---

REPRESENTATIVE MANDERINO: Is the argument the same for a brand name, is what I am trying to understand.

DR. SASICH: Well, you know, it could be. I

mean, this is called counterfeiting, and this is certainly a problem.

We have a problem with Heparin, which is an old drug, but somebody decided for economic reasons that they could increase their margin by substituting another drug.

REPRESENTATIVE MANDERINO: Okay; I was not articulating correctly, because I wasn't talking about counterfeiting. I was talking about a company making a product, that is their product, that is their brand name.

DR. SASICH: Okay.

REPRESENTATIVE MANDERINO: Can that product over, whatever -- over the course of time, over the course of being manufactured in different places, over the course of where they get the suppliers for the ingredients of that -- can that particular drug have something about it that could be slightly different than its own drug, just like a generic can?

DR. SASICH: Certainly, but no matter where the brand-name product is made, whether or not it is in Philadelphia or Puerto Rico or in China, it should be meeting the same FDA standards for performance. We call this dosage performance.

REPRESENTATIVE MANDERINO: Okay. So when

one of the prior testifiers said, if my patient is on a generic and the generic they get this month needs to be the same generic they get next month--

DR. SASICH: Yes.

REPRESENTATIVE MANDERINO: ---is that an issue of the same generic manufactured by the same company, or were these -- maybe you are not the right person to ask -- were these, again, equivalents being substituted, generic A made by company B for generic C made by company D? Do you understand my question?

DR. SASICH: I think I do, and the different generic drug manufacturers have to meet the same standards to call a drug a generic equivalent, and in some cases these different generic products are tested against other generic drug products.

The thyroid replacement hormones are a good example of this, where there are ratings that allow pharmacists and physicians to say that generic brand A is equivalent to generic brand B.

REPRESENTATIVE MANDERINO: But just -- I'm sorry, Mr. Chairman. I need to understand this to process everything.

Generic brand A manufactured by generic company A is always generic, so I could prescribe generic brand A made by company A, and if I say

"no substitution available," I should always get generic brand A by company A, not generic brand B by company B.

DR. SASICH: You could -- go ahead.

MS. EPPLE: Yes; yes, that is correct.

REPRESENTATIVE MANDERINO: Okay.

MS. EPPLE: You could do that. That is not done very often when they are prescribing generics, but it could be done. And if it is written that way, the pharmacist would need to follow that.

If they didn't have it available, which I did hear was alluded to in the conversation, then before they would make a change, they would need to get that approved by the physician.

REPRESENTATIVE MANDERINO: Okay. Thank you.

Thank you very much, Mr. Chairman, for your indulgence.

CHAIRMAN OLIVER: Representative Taylor.

REPRESENTATIVE TAYLOR: Thank you, Mr. Chairman, and I will try to move it along and simplify it.

It seems to me that the more testimony I hear, the more this issue isn't really about the cause and effect in generics versus brand name; it is about your testimony earlier, Patricia, about whether

or not the pharmacists are doing what they are supposed to do at the right end, and it sounds to me, if I were the judge here, I would say that at least in some cases, it is not. So it is supposed to happen and it is not, and if you think this bill is not the answer, what is the answer to protect these folks from that occurring?

I don't think it really gets into the makeup of generics. I think that is a discussion for another time. And for anybody that is due to testify about this in the future and today, we don't really need to know that, I don't think. Tell us how to solve this then.

MS. EPPLE: Well, I think that there are two things. I mean, I'm not at all one for punitive situations, but obviously if there are pharmacists out there who are violating the law, they need to be reported.

I think the other two things that are also prevalent here is that it is an insurance issue; we all know that. I mean, that has been testified to by the physicians. If the insurance company is not paying for something or the payment is too high, that becomes an issue. So there is something there.

REPRESENTATIVE TAYLOR: But it still

wouldn't change how the pharmacist behaves, right?

MS. EPPLE: Yeah, because---

REPRESENTATIVE TAYLOR: Whether they are paying for it or not, the pharmacist has---

MS. EPPLE: They have to follow with it. But the fact of the matter is, if the patient's insurance company isn't providing that coverage and if they have to pay for it cash out of pocket and it is too much, then the pharmacist is going to try to get the physician to, you know, write their approval or call in their approval to dispense a generic. So insurance coverage is an issue.

REPRESENTATIVE TAYLOR: Just to clear that up, when that happens -- and I know Kathy talked about this a little bit -- so everybody is informed at that point?

MS. EPPLE: Oh, absolutely. Again, now if a physician did not write "brand medically necessary," if they just wrote the drug name, which is the generic name actually, and they didn't write "brand medically necessarily," or if they specified a brand but didn't write "brand medically necessary" -- "generic substitution is allowed" is on the prescription pad -- if they didn't do that and the insurance bounces back, well, we'll only pay this

much, you know, dispense the generic, then the pharmacist would dispense the generic. But again, the physician did not write "brand medically necessary," so the pharmacist was allowed.

REPRESENTATIVE TAYLOR: Should the physician write that, is the insurance company still then entitled to deny if they are not covered?

MS. EPPLE: Yes, yes, yes.

REPRESENTATIVE TAYLOR: I mean, I don't even---

MS. EPPLE: Yes.

REPRESENTATIVE TAYLOR: Its fully not about generics versus its---

MS. EPPLE: It's about insurance coverage.

DR. SASICH: It is about the cost of drugs.

REPRESENTATIVE TAYLOR: Right. So what would be the answer, assuming that they did pay for it? I mean, in terms of the pharmacist not following what the physician indicated.

MS. EPPLE: Well, I think the one situation that presents itself here is that we heard about a particular disease that has very serious consequences, that has to be monitored closely by a physician, and I think if there are situations where they feel that, you know, the brand may be necessary,

maybe that has to be considered.

But the other thing is, we have to look at total drug costs in this country, too, and if generics are a cost-effective, safe alternative, you know, we have to be able to consider those or maybe consider trying patients on those. But that becomes a physician-patient decision, and that is where we run into problems these days, is the insurance companies often -- have to, for very good reasons -- delve into that to provide, you know, all this therapy, because we don't want the consequences either.

REPRESENTATIVE TAYLOR: Do you know of any situations where in a civil matter where the pharmacist is held liable for changing it when they should not have?

MS. EPPLE: I am not aware of any at this point in time. I am aware of situations in this country where pharmacists have been held liable for other things. It is rare, but they could be, but not in the situation that you are naming.

REPRESENTATIVE TAYLOR: If that were the case, they would probably not be making that mistake too often.

MS. EPPLE: Again, if they are reported to

the Board of Pharmacy, you know, on this situation, then they won't take it upon themselves to change.

I don't think any pharmacist is really taking it, you know, on their own to change, but I have heard situations just this morning, so those need to be reported.

REPRESENTATIVE TAYLOR: Thank you, Mr. Chairman.

CHAIRMAN OLIVER: Representative Reichley.

REPRESENTATIVE REICHLEY: Thank you, Mr. Chairman.

Just picking up on John's last point, Pat, isn't it in a sense a liability protection for the pharmacists, because if there is an adverse effect on the patient down the road and the pharmacist says, well, the doctor told me I could give this drug, and the doctor says, no, I didn't, that you have the written order from both the doctor and the patient to provide so the pharmacist is covered?

MS. EPPLE: Well, right now, when they get that prescription, if it doesn't say "brand medically necessary," they can dispense the generic.

REPRESENTATIVE REICHLEY: I understand that part.

MS. EPPLE: But if they did, if they did

that without knowledge, then that would be an issue. But even so now, on issues with the insurance coverage, if they would get an okay to dispense something else because of insurance coverage, that is documented on the prescription for many reasons, both for auditing purposes for insurance companies, but to document exactly what occurred. So that pharmacist is documenting that they got an okay from a physician to do that.

REPRESENTATIVE REICHLEY: Okay.

MS. EPPLE: They are just not having to get it back from the doctor's office, and they are not having to get another written paper from a patient. But it is being documented that they did that.

REPRESENTATIVE REICHLEY: Well, I think in terms of potential liability and then damages that could be found against the pharmacist, you would want that coverage.

But you made quick reference to the ability to report pharmacists. How many actual penalties are handed down by the Pharmacy Board for changing a prescription without additional proof?

MS. EPPLE: Representative Reichley, I am not aware of any right now, but I think certainly that would be a question you could put to the

Bureau of Professional and Occupational Affairs and see if there are any statistics on that. I am not aware of any.

REPRESENTATIVE REICHLEY: And what is the penalty?

MS. EPPLE: That I don't know.

REPRESENTATIVE REICHLEY: Is your license pulled?

MS. EPPLE: That I don't know, because a lot of those decisions happen in closed session at the State Board.

REPRESENTATIVE REICHLEY: And not to disrespect your point, but it might be sort of a paper tiger to say, well, we have this board out there that can do this, but if nobody gets reported and nobody gets penalized and nothing is done, it doesn't really affect the mechanism.

MS. EPPLE: Well, I guess the question is, have they been reported? I am sure that if they have been reported and they have gone through the process, something has been done. I don't know what those penalties are. I don't know the statistics. I don't even know whether I'm entitled to them, but I would think that this committee might be.

REPRESENTATIVE REICHLEY: I would just think

that since you are the professional organization for the pharmacists, you would hear about that.

My last question is, does the pharmacist get any kind of different dispensing fee if you use the brand name as opposed to generic?

MS. EPPLE: No.

REPRESENTATIVE REICHLEY: Okay. Thank you. Thank you, Mr. Chairman.

CHAIRMAN OLIVER: Representative Pashinski.

REPRESENTATIVE PASHINSKI: Thank you, Mr. Chairman.

Could we just stay on this subject just for one more question?

Is there any kind of responsibility by law on the part of the physician to report either to the Pharmacy Board or to another agency when a pharmacist is substituting when they are not supposed to?

MS. EPPLE: I'm not real familiar with the medical code of conduct, but I would tend to think that might be the case.

REPRESENTATIVE PASHINSKI: Could I ask the doctors that are here that same question?

DR. HERSHKOWITZ: Not that I know, and I wouldn't even know who to report to.

REPRESENTATIVE PASHINSKI: But I'm just

saying, if the results of substituting a pharmaceutical agent caused such great harm to Tanner, you wouldn't take it upon yourself to pursue who did what?

DR. HERSHKOWITZ: Well, again, I do not know, I mean, I just thought that in the end this was all going to be paid for.

REPRESENTATIVE PASHINSKI: And you are saying if this is life threatening---

DR. HERSHKOWITZ: If the liability is mine, because I'm the one prescribing the drugs---

REPRESENTATIVE PASHINSKI: But they substituted on you. You did your job. You prescribed the right drug.

DR. HERSHKOWITZ: In fact if it comes down to a time where the insurance company will not pay and the patient needs to get a generic -- and we are not against generics. We just want to give the same one every time if that's going to happen.

And I don't even know where these drugs are being made from. So to say that physicians can write down "I would like generic B from South Africa and only that" is crazy, because we don't know where they come from. We do not have access to, these are all the generic, new formulations.

REPRESENTATIVE PASHINSKI: But you do know the one that you have been using that has been effective, and that's the one---

DR. HERSHKOWITZ: But I don't. That is why I say to the patient, have a good relationship with your pharmacist, because I just know it was a pink-and-white capsule, but the next time there is one that is green. So I don't know that.

CHAIRMAN OLIVER: Okay. Pardon me, please.

REPRESENTATIVE PASHINSKI: All right. Then that is something---

DR. HERSHKOWITZ: I don't have access to that information. You know, CVS doesn't say, you know, we have these three.

REPRESENTATIVE PASHINSKI: I'm just saying, if I want Bayer Aspirin---

CHAIRMAN OLIVER: We will end this discussion right now.

REPRESENTATIVE PASHINSKI: Yes, sir.

CHAIRMAN OLIVER: It should be between you and the people at the table.

DR. HERSHKOWITZ: I'm sorry.

REPRESENTATIVE PASHINSKI: Thank you, Mr. Chairman. I appreciate that.

I guess the point that I was making was if

I'm ordering Bayer Aspirin, I expect to get Bayer Aspirin. It may not come out of the same lot, but I expect to get Bayer Aspirin.

But I wanted to know whether there was a responsibility of the physician to report someone that is not conducting the very important job of prescribing what the physician prescribes. It seems to me that that is something that we should look at.

Dr. Sasich, could you explain please for me, on page 4, "The Epilepsy Foundation is estimated to receive funding from the pharmaceutical industry that approached $50 million of its $80 million annual budget...."

DR. SASICH: Those came from public documents from the Securities and Exchange Commission, the Form 990s that all public interest organizations are required to make publicly available.

REPRESENTATIVE PASHINSKI: So the pharmaceutical companies are funding the Epilepsy Foundation $50 million.

DR. SASICH: Correct, for 2006.

REPRESENTATIVE PASHINSKI: Okay.

Are you aware of any major pharmaceutical companies that purchased or created their own generic

companies?

DR. SASICH: Oh, yeah. Yes, they are starting to get into this business with some fervor right now.

These are called authorized generics, and this may be viewed as anticompetitive behavior, because it kind of makes an end run around giving other manufacturers the opportunity to be able to get into the marketplace, when the idea behind the generic drugs was to bring price competition in to the pharmaceutical marketplace to lower prices.

REPRESENTATIVE PASHINSKI: Right. Okay. Thank you.

And the last thing, I was questioning testing before, whether the testing is adequate in order to determine whether these drugs can actually do what they are supposed to. What is your opinion of the testing?

DR. SASICH: Yes, they can, if it is done correctly, if there is proper oversight, and there is no shortcutting on the part of manufacturers.

We have had problems with the quality of both generic and brand-name pharmaceuticals. In the late 1990s, we had hundreds of thousands of doses of

brand-name Dilantin come off the market that manufacturing procedures were shortcutted. The executives of the company knew this.

So this can happen in any segment of the pharmaceutical industry, brand name or generic. Unfortunately, we do not have the Food and Drug Administration that has the resources to be able to ensure the safety of the drug supply in this country, and the food supply, for that matter.

REPRESENTATIVE PASHINSKI: Well, it seems to me with the recent problems we have had with drugs from China and food from China, the FDA needs more resources.

I want to thank all of you very much.

DR. SASICH: Thank you.

REPRESENTATIVE PASHINSKI: Thank you, Mr. Chairman.

CHAIRMAN OLIVER: Thank you very much for appearing today.

Now we would like to say that we have 20 minutes with three people to testify. We have to be out of this room by 1:30. So I would say to you, I do not want to cut anybody off, but I want you to be as brief as possible.

You may proceed.

MR. MOHALL: First of all, good afternoon, and I am today representing the Pennsylvania Association of Chain Drug Stores, or PACDS. I want to thank the House Health and Human Services Committee for considering our comments on this bill.

My name is Rick Mohall. I'm a pharmacist, and I am the Director of Field Clinical Services for Rite Aid.

I speak today on behalf of PACDS, which consists of community-based chain pharmacy companies, as diverse as Weis Markets, Rite Aid, and Target. Together, PACDS member companies operate over 1,400 community pharmacies in the Commonwealth.

Though we understand that this bill was introduced with the best intentions, community pharmacy believes that this bill would create duplicative and unnecessary requirements that would discourage the use of cost-saving generic drugs for the treatment of epilepsy while increasing costs to the consumer and creating delays in filling their prescription.

It also seems to be in conflict with the laws governing the PACE and Medicaid program requirements around substitution, and we therefore respectfully ask the committee to consider our

comments explaining these issues.

In the interests of time, I will deviate from the written statements, as my colleagues have addressed much of this with the committee already. But I would like to add a couple of comments.

One, if you look at the example of a prescription that we have given with my testimony, you can very clearly see what has been going on in Pennsylvania, and I believe my colleague said since 1976. Am I correct in that? And this has worked very well within the Commonwealth to allow a physician, whenever he or she wishes, to specify "brand necessary" or "brand medically necessary."

I have heard comments that pharmacists have deviated from this. I was a community pharmacist for 21 years before I was in my current role. I do not know of any pharmacist who would not call a physician if an insurance conflict existed before substituting the product. I cannot say for certain that they are not out there, but I certainly do not know of any.

I also would very much like to address the refill question and one of the delays in therapy that I see may be created with this law.

First of all, what happens to a patient when a doctor writes, and I'll use Tegretol as an example,

on a prescription, the physician signs the prescription, and does not -- let me repeat -- does not write "brand necessary," and a pharmacist sees that that patient has indeed been on the generic drug.

Let us say it is a Saturday. It is a brand-new prescription. We would then still have the requirements, if I'm reading this bill correctly, to have a written consent from the doctor, a written consent from the patient. What if we cannot reach the prescriber? I do see that creating a potentially harmful therapeutic effect, when we already have existing laws that allow the doctor to clearly tell us whether substitution is or is not okay.

I would also like to comment on the refill question. When a pharmacist enters into a computer system, any system that I have seen for "brand medically necessary," there is a code entered into that system. Why is that so? It is required by every insurance carrier I know of to process the product. So there is a code in the system that says, and it happens to be one, "brand medically necessary," that would tell a pharmacist on every refill that the doctor did indeed write "brand medically necessary."

And let me go one step further. In our particular next-gen system at Rite Aid and many other systems used by community pharmacies throughout the Commonwealth, there is a scanned copy of the prescription available on the screen. The pharmacist can indeed see that scanned copy and see that it was indeed written "brand medically necessary."

So I do not really -- I think those issues are compensated for by the way all of our pharmacy systems work.

I would also like to address the fact that the FDA -- and this is in my statement -- has put out a specific statement on the therapeutic equivalence of drugs prescribed for an epilepsy patient. In a 2008 letter, they expressed that there was "no scientific evidence that demonstrates a particular problem with this group of products." In fact, there are "frequently circumstances other than the switch that may cause untoward response."

And I would also like to point out that the American Medical Association, representing physicians, also reviewed published scientific literature on this matter, and that a 2000 report concluded that generic antiepileptic drugs are equivalent to their brand-name counterparts, and in

2007 the AMA published a position statement reaffirming support for the conclusions in the 2002 report.

So I guess in summary what I would like to say is that we have a mechanism in place that takes care of this system as it stands. The bill is duplicative in that it asks for a mechanism that already exists. It could very easily cause a delay in therapy, and both groups that I think we all count on to determine our decisions and our scientific-based evidence, which I want to stress on these issues -- the FDA and the physicians, the AMA, who do decide on this therapy -- both support the substitution of these products.

Thank you. Any questions?

CHAIRMAN OLIVER: Thank you very much.

Representative Taylor.

REPRESENTATIVE TAYLOR: Thank you, Mr. Chairman. Very briefly.

Sir, if you could just follow an example for me, and I think this will clear some things up for me.

MR. MOHALL: Sure.

REPRESENTATIVE TAYLOR: The physician writes on the pad the brand name. It doesn't say it has to

be.

MR. MOHALL: Right.

REPRESENTATIVE TAYLOR: The pharmacist substitutes a generic.

MR. MOHALL: The pharmacist would not substitute a generic. If a physician wrote "brand necessary"---

REPRESENTATIVE TAYLOR: No, no; I'm saying he doesn't.

MR. MOHALL: I'm sorry; okay.

REPRESENTATIVE TAYLOR: I'm saying the pharmacist then, he or she then---

MR. MOHALL: Substitutes a generic.

REPRESENTATIVE TAYLOR: ---substitutes a generic.

MR. MOHALL: Yes.

REPRESENTATIVE TAYLOR: That generic turns out to be effective for some time---

MR. MOHALL: Yes.

REPRESENTATIVE TAYLOR: ---but there is never a prescription actually written for it, all right?

MR. MOHALL: There is not a prescription -- if you are asking, is there a prescription written for that---

REPRESENTATIVE TAYLOR: No; wait. Follow me.

MR. MOHALL: Okay; okay.

REPRESENTATIVE TAYLOR: What can we do to prevent the generic from changing?

MR. MOHALL: Well, I guess I would question---

REPRESENTATIVE TAYLOR: Because there was never a prescription actually written for it.

MR. MOHALL: Well, I guess I would---

REPRESENTATIVE TAYLOR: The physician wanted A; it turned out to be B. B is okay, and suddenly it turns into C. What can we do to prevent that?

MR. MOHALL: Well, I guess I would question the need to prevent that.

Again, the FDA tests all generics. So just to use examples, let's say that Mylan had a generic form of Tegretol on the market and Teva also wanted to apply for a generic form of Tegretol, that drug has to go through the same testing and be deemed therapeutically equivalent by the FDA for the brand Tegretol. So the drugs are deemed therapeutically equivalent for the brand-name product, and I do not believe there is evidence that suggests otherwise.

REPRESENTATIVE TAYLOR: The sooner you

answer my question, you are just saying that you think there is no need for it.

MR. MOHALL: That is exactly right.

CHAIRMAN OLIVER: Representative Waters.

REPRESENTATIVE WATERS: Thank you, Mr. Chairman.

As a representative of the Pennsylvania Association of Chain Drug Stores, let me go to, you know, the original concept of this hearing was to deal with the epilepsy and the effects that these drugs are having on people who suffer from epilepsy and their family members.

And you as a drug store, as a pharmacy, what is happening with your members to make sure that you are being policed? Is there a -- do you self-police, or is there an independent agency or department?

MR. MOHALL: We do self-police.

REPRESENTATIVE WATERS: You self-police?

MR. MOHALL: We do self-police.

REPRESENTATIVE WATERS: You self-police. Have there been any violations at all that you would report?

MR. MOHALL: I do not have statistics on that. I really do not.

REPRESENTATIVE WATERS: You do not have

statistics, but that does not mean that it is not---

MR. MOHALL: Again, sitting here today, to my knowledge, I do not know of a pharmacist who illegally substitutes generic for brand. I do not.

REPRESENTATIVE WATERS: But we did hear testimony from some of the parents and other people who are here today that said that substitutions do take place and that it is having a negative impact on the patients.

MR. MOHALL: Well, without seeing those prescriptions, I really do not know how I can comment.

Were the prescriptions written correctly? I will use an example of the prescription I have in front of you. Again, the words "brand medically necessary" or "brand necessary" have to be written. Did a physician just sign on the bottom line? I do not know that.

Did the pharmacist call someone within the prescriber's office to talk about it when an insurance company would not pay for a brand or a consumer could not afford a brand? I do not know that.

I would want to see examples of this happening, why this is happening, if it is happening,

before I could address that question.

REPRESENTATIVE WATERS: Okay. Well, we do have some testimony here, some evidence here, and I guess you can examine that if you so see fit to do so. But I thank you so much for your testimony.

Thank you, Mr. Chairman.

CHAIRMAN OLIVER: Thank you very much, Mr. Mohall, for your testimony.

MR. MOHALL: Thank you.

CHAIRMAN OLIVER: The last two speakers on the agenda are Kevin Tucker and Dr. Eric Davis.

Between the two of you, you have 10 minutes.

DR. DAVIS: I get to go first.

CHAIRMAN OLIVER: So you may proceed.

DR. DAVIS: All right. Thank you, Mr. Chairman and members of the committee, for the opportunity to speak here today.

In an effort to save time and---

CHAIRMAN OLIVER: Thank you very much.

DR. DAVIS: ---I will forego the testimony that I had and hit on some important points here in this.

We have already talked about that physicians currently have full authority to determine whether a prescription is written for the brand medically

necessary. That has been talked about, so I'm going to skip that part and move on to the scientific part of it.

And scientifically speaking, there have been no well-controlled clinical trials presented to the FDA that have shown that the interchange of one of the antiepileptic drugs determined to be therapeutically equivalent to the branded drug has led to an increased risk of seizures. It just has not been shown. What has been presented are anecdotes in the form of case reports and surveys, and these are not scientific.

The FDA states, and this is a quote from them, "products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product." And here is the important part: "Any differences that could exist should be no greater than one could expect if one lot of the innovator's product was substituted for another."

In other words, the difference in therapeutically equivalent drugs is no more, because there is variability, but it is no more than what you would have in one lot to another lot.

Now, Pennsylvania already defers to the FDA when assessing bioequivalents, and the FDA published a letter, and there are three points to consider in that letter when it comes to substitution.

One is, additional clinical tests or examinations by health-care provider are not needed. Two is, special precautions are not needed when a formulation or a manufacturing change occurs for a drug provided that change is approved according to the FDA, and this recently happened with one of the branded antiepileptic drugs. They changed their formulation. They did the exact same bioequivalency testing that the generics use to get approved in order for that formulation or that manufacturing change to be marketed. And the third point is, it is not necessary for the health-care provider to approach any one therapeutic class of drug products differently from other classes when there has been a determination of the therapeutic equivalence by the FDA.

And we are talking about antiepileptics today, and there are not just 10 drugs. I believe one of the Representatives here asked about how many. According to the Epilepsy Foundation's Web site, there are approximately 25 different antiepileptic

medications, and most of these medications have what is called a wide therapeutic range. But although all of these drugs are for treating epilepsy, only about 50 percent of their use is for epilepsy, and I think that point was brought out in passing. But these drugs are also used to treat chronic pain, bipolar disorder, migraine headaches, neuropathies, and panic disorders.

And one of the newer medications, just an example, Gabapentin, it is estimated that 83 percent of its use is for something other than epilepsy. So it is really unfair and it is unscientific to group all of these drugs, you know, into a group and say that we are going to set this particular class aside.

I do not think I'm going to go into the additional time or burden placed on the pharmacists.

One point I would like to make is, and I believe the physicians who spoke here earlier really made the point clear, that epilepsy is a very difficult disease to treat, but there are many variables that come into play that have nothing to do with the formulation.

One fact is that approximately 30 percent of patients with seizure disorders are never free of seizures. That is a big percentage -- almost a

third.

There was a study in a paper written that showed that up to 50 percent of patients do not completely comply with their prescribed treatment, and if a patient misses 1 day of their medication, they have effectively missed 14 percent of their dose for the week. If they miss 2 days, that is 28 percent of their dose.

Things like emotional stress and lack of sleep can lower seizure thresholds. External sights, like flashing lights and video games, they can bring on seizures. Over-the-counter medications, supplements, other prescription medications, alcohol, and even certain food interactions can lower drug levels and possibly influence seizure control.

And an important point that was brought up from a Harvard study showed that approximately one-third of patients on fixed incomes will intentionally miss doses of medications used to treat chronic illnesses in an effort to stretch their prescriptions and save money.

Let me make a couple more points and then I'll hand it over to you, because I know we are short. This is hard.

CHAIRMAN OLIVER: You just took up some of

his time.

DR. DAVIS: Okay.

MR. MOORE: And, Mr. Chairman, I talk slow.

CHAIRMAN OLIVER: Pardon me?

MR. MOORE: I said, unfortunately, I talk slow.

CHAIRMAN OLIVER: Well, I hope you can talk a little faster.

DR. DAVIS: So I will conclude my remarks with that and turn it over to my colleague.

MR. MOORE: Thank you, Mr. Chairman.

My name is Jerry Moore. I'm the Director of State Government Affairs for Teva Pharmaceuticals.

Teva Pharmaceuticals is the world's largest generic company, with its U.S. headquarters based here in Pennsylvania. We do make a lot of our drugs right here in Pennsylvania, not that we make them all here, but we do make a lot of them right here in Pennsylvania.

Just like the branded companies make some here in the United States, some they make in Puerto Rico, some they make some other places, but the fact is, we go through the same criteria that the branded companies do to make sure that the quality of our drugs are the best they can be.

It is important, and I have heard people say it multiple times today, you have got an agency, the State Board of Pharmacy, in Pennsylvania. It was created to protect the public, not to protect the pharmacists.

In another life, I ran one of those boards of pharmacy in another State. It was there to protect the public. Did pharmacists ever break the law? Yes. Did they get sanctioned? Yes. What kinds of sanctions? They could have been from a letter, a warning letter. It could be a fine. It could be a suspension of their license. If it were severe enough, it could be a revocation.

So you have something in place, you have current laws that protect the public, and if the physicians say dispense is written, then that is the way the pharmacist ought to do it, and I think you have heard testimony that I think the majority of the time that happens.

Is there a rogue out there? There is always that possibility. But the generic industry is out there making quality drugs, and we want to make quality drugs for the citizens of Pennsylvania as well as everybody else in the U.S.

And with that, Mr. Chairman, I want to say

thank you.

CHAIRMAN OLIVER: You finished right on time.

MR. MOORE: Well, I would rather finish quick before you cut me off.

CHAIRMAN OLIVER: Thank you very much, both of you gentlemen, for testifying today, and that concludes this meeting today.

Thanks so much to all the participants as well as the members. Thanks so much.

(The hearing concluded at 1:32 p.m.)

I hereby certify that the proceedings and evidence are contained fully and accurately in the notes taken by me on the within proceedings and that this is a correct transcript of the same.

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Debra B. Miller, Reporter