Testimony on HB 817

House Professional Licensure Committee

3/28/12

Rick Mohall, R.Ph., Director of Clinical Services

Rite Aid Corporation

Pennsylvania Association of Chain Drug Stores

Good morning, my name is Rick Mohall, I am a pharmacist and the Director of Clinical Services for Rite Aid Corporation. I am also representing the Pennsylvania Association of Chain Drug Stores. As the Director of Clinical Services for Rite Aid Corporation I am directly involved in our Immunization Program, as well as our Medication Therapy Management and Diabetes programs.

I would like to take this opportunity to thank Rep. Seth Grove for introducing this bill and Rep. Julie Harhart for giving us the chance to convey our support to the Committee.

I am here to advocate for the passage of HB 817. Current law allows pharmacists to provide vaccinations to adults. Pharmacists have been doing so, safely, for many years. In fact, approximately 659,000 immunizations were administered in PA by pharmacists in 2011 (Source: WK Health Source® Pharmaceutical Audit Suite, data drawn 3/23/12).

HB 817 would provide parents the option to have their children and/or adolescents immunized by a licensed pharmacist immunizer. This bill in no way prevents parents from choosing to have their children immunized at their primary care physician's office. What it does do is increase access for parental choice, increases convenience for accessing services after working hours and on the weekends, and takes a significant step in helping raise immunization rates to save lives. With approximately 2800 chain and independent pharmacies in Pennsylvania, HB 817 would provide widespread and convenient access points for the Commonwealth's children and adolescents to life saving vaccines in a safe environment by a licensed pharmacist immunizer.

Pharmacist Qualifications

Pennsylvania's pharmacists are highly-trained health care professionals having completed either 5 or 6 years at an accredited school of Pharmacy to obtain their degree. Their expertise is in medication therapy – including, but not limited to, immunizations.

In addition to their training at accredited Schools of Pharmacy, pharmacists also complete an extensive immunization training course developed by the American Pharmacists Association with assistance from the CDC, which is recognized and accepted by all 50 State Boards of Pharmacy and the District of Columbia. This training includes proper screening to determine the types of immunization needed by an individual, as well as procedures for handling emergency anaphylactic reactions. This course does train pharmacists on pediatric and adolescent immunizations as well as on adult immunizations.

In addition to their educational background and the American Pharmacists Immunization Training Program, all immunizing pharmacists are required to be trained to provide Cardio-Pulmonary Resuscitation (CPR) and must remain current (every 2 years) on this training.

While adverse reactions to immunizations are rare, the most common being syncope, pharmacists' training around anaphylactic reactions also involves the proper use and administration of epinephrine,

the treatment of choice for anaphylactic reactions. It should be noted that nurses, currently authorized to immunize children and adolescents in PA, bring only epinephrine to handle anaphylactic reactions even when providing immunizations without the direct supervision of a physician.

Healthcare Provider Partnership

We recognize and applaud the efforts of physicians, registered nurses and licensed practical nurses in providing immunizations to children, adolescents and adults with our Commonwealth. We do wish to point out that the inclusion of a pharmacist within that mix of healthcare providers for children of any age group would increase access points and increase immunization rates within our state. Our current program at Rite Aid mandates communication to a Primary Care Physician in regard to all immunizations provided one is identified. We absolutely recognize the value of this communication and hope that this will become a two-way communication so that all providers can improve immunization rates for all citizens of Pennsylvania. We would also welcome participation in the state's Immunization Registry Program.

Reasons to Increase Access to Immunizations for Children and Adolescents

I am certain that the goal of this committee and all interested parties testifying regarding this bill is to improve the health and well-being of our Commonwealth's most valuable asset, our children.
That said our goal should be to provide as many safe access points to life saving immunizations, through qualified healthcare professionals, including pharmacists, as possible.
The following points highlight the need for additional access points through community pharmacy:

- Since 2005, six new vaccines or vaccine recommendations were made by Advisory Committee for Immunization Practices (ACIP)/CDC for children and adolescents.
- In the 2009 influenza pandemic, the CDC reported 348 pediatric deaths associated with influenza; in the 2010-2011 flu season 115 deaths of children under the age of 18 occurred; and in the current year 5 influenza related deaths have occurred in the pediatric age group.
- Vaccine coverage for adolescents in PA, while better than the national average, has not reached the goals established by the US Department of Health and Human Services' *Healthy People 2020* report.
- As reported by the PA Department of Health, since 2008 there have been multiple outbreaks of pertussis (whooping cough) in PA counties. This is a serious illness in adolescents and can be fatal in infants. There was a very recent outbreak in a school district in the local area.
- Flu-Surv Net reported a hospitalization rate, due to influenza, of 45.7 per 100,000 children aged 0-4 years old and 8.9 per 100,000 for children aged 5-17 for the 2010-2011 influenza season. There are other cases of influenza that don't result in hospitalizations but are treated in the Emergency Room. The average visit to an emergency room costs $383. The cost of an influenza vaccine is approximately $30. Our goal should also be that no child is hospitalized or has to be treated in an emergency room for a vaccine preventable disease

- Pharmacists have demonstrated their value in states where they can provide immunizations to any age group. In California the state went from 10 Pertussis deaths in children in 2010 to none in 2011 based on regulatory requirements for school age children and improving access points to the Tdap vaccination through the use of Community Pharmacy.
- In PA there are close to 2800 pharmacies located in both urban and rural areas. Pharmacies are a significant and important access point for health care services in rural communities. Many pharmacies provide access to needed immunizations during evening and weekend hours, on a walk-in, no-appointment-needed basis. With pharmacies providing this convenient option to working families, I believe we can partner to significantly increase pediatric and adolescent immunization rates in the great state of Pennsylvania.

FOR IMMEDIATE RELEASE

August 19, 2010

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The Society for Adolescent Health and Medicine (SAHM) Advocates for Ways to Improve Immunization Rates and Halt Disease Outbreaks

Deerfield, IL — In light of today's report of the National Immunization Survey results, the Society for Adolescent Health and Medicine (SAHM) encourages increased efforts in fully immunizing all adolescents.

The report issued by the National Immunization Survey (NIS) shows progress in increasing immunization rates among teens 13-17 years of age. However, rates remain unacceptably low for those vaccines that are targeted specifically to prevent disease in adolescents: meningococcal meningitis (53.6 %), human papillomavirus (44.3% received one dose, while only 26.7% received all three recommended doses), tetanus/diphtheria/pertussis (Tdap) (55.6 %). Low rates among adolescents may be responsible for the epidemic of pertussis (whooping cough) that is presently occurring in California.

"Adolescents, in particular, are in a unique position to serve as reservoirs for disease and transmit disease to others," notes Dr. Amy Middleman, SAHM's liaison to the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention. "We know that transmission from adolescents and young adults is responsible for a significant number of cases of pertussis in infants, so properly immunizing adolescents can play a major role in stopping the epidemic and preventing the deaths we see in outbreaks similar to the one occurring in California now." She adds, "It is critical that adolescents receive all vaccines recommend for their age group, including the Tdap vaccine."

Current estimates for 2010 are that California may see its highest number of pertussis-related deaths in fifty years, having already had eight deaths, seven of which were infants under two months old. Other states have also seen increasing numbers of cases, including Arizona, Georgia, Idaho, Michigan, Minnesota, New York, North Carolina, Ohio, Oregon and South Carolina. Routine vaccinations, as recommended by the CDC and advocated by SAHM, will help reduce the spread of pertussis and deaths related to the disease.

A variety of challenges face providers and public health authorities in vaccinating adolescents. SAHM recommends the following steps to help providers overcome these barriers: 1) Vaccinate adolescents at every opportunity possible, regardless of the reason for a medical visit; 2) Make sure vaccinations are a priority for comprehensive health visits, including sports physicals; 3) Utilize standing orders which instruct office staff to vaccinate adolescents when indicated, even if a provider forgets; 4) Utilize a vaccine reminder and recall system to get patients to return for additional vaccines when they need them; 5) Lobby for and utilize centralized statewide vaccine registries where all adolescents can have their vaccine status documented; 6) support the use of school-located programs and other alternative sites to provide immunization services for those with less access to comprehensive services, and 7) educate patients at every opportunity about the benefits of vaccines. SAHM urges patients and parents to talk to

their providers about vaccines including the efficacy and safety of this most important primary prevention tool.

"The bottom line is these diseases can and should be prevented. We must continue to create strong initiatives to get teens vaccinated," concluded Dr. Middleman.

To obtain more information or to speak to an expert, contact Kasia Chalko at SAHM headquarters.

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The Society for Adolescent Health and Medicine is a multi-disciplinary organization of health professionals who are committed to advancing the health and well-being of adolescents. Through education, research, clinical services and advocacy activities, members of SAHM strive to enhance public and professional awareness of adolescent health issues among families, educators, policy makers, youth-serving organizations, students who are considering a health career, as well as other health professionals. Learn more at www.adolescenthealth.org.

References: Centers for Disease Control and Prevention
http://www.cdc.gov/vaccines/vpd-vac/pertussis/dis-faqs.htm

Unprotected People #76
Pertussis

Newborn's Death Emphasizes Need to Consider Pertussis in Differential Diagnosis of Coughing Adults

Lynne Baker suspects she contracted pertussis from a coughing customer in a bookstore about two weeks before giving birth to her son Nelyn on April 7, 2004. "She coughed all through labor," her husband reports. "Overnight, it got worse and worse."

Still, when Lynne and Nelyn left the hospital for their home in suburban Atlanta, Lynne's cough had not been attended to. Twelve days after Nelyn's birth, on her second visit to her family physician, Lynne received antibiotics. Four days later, Nelyn began coughing and was hospitalized the following day. The next morning, April 25, he died. It wasn't until May 5, when the Bakers returned from burying some of Nelyn's ashes in Michigan, that they learned the cause of death. The results of bacterial cultures started during his hospitalization indicated Nelyn had died from pertussis.

The CDC's "Pink Book" describes the onset of pertussis as "insidious," meaning it develops "so gradually as to be well established before becoming apparent." Studies indicate pertussis accounts for approximately 20-30 percent of instances of coughs lasting more than two weeks in adults and adolescents, and that adults are often found to be the first case in a household with multiple pertussis cases. This seems to have been what happened in the Baker household: Lynne believes she not only passed the disease to her newborn son but spread it to her two teenage children, her mother, and several members of her extended family in Michigan.

For adults, the disease is usually mild. For infants, however, it is anything but. During 1997–2000, 63 percent of infants under six months of age diagnosed with pertussis required hospitalization, and infants this age accounted for 90 percent of pertussis deaths. It is for this reason that it is imperative that all physicians, not just those who provide primary care for children, become knowledgeable about the diagnosis, treatment, and reporting requirements for pertussis. Had pertussis been suspected as the cause of Lynne's persistent cough during labor and the weeks following, it's likely she and her immediate family would have been treated with antibiotics at once. Nelyn might now be alive.

Physicians now have new adolescent and adult vaccines that can indirectly help protect infants from pertussis. The Food and Drug Administration recently approved two single-dose tetanus-diphtheria-pertussis booster vaccines. GlaxoSmithKline's Boostrix was approved in May 2005 for use in persons ages 10–18 years; sanofi-pasteur's Adacel was approved in June 2005 for use in those 11–64 years of age.

Long-ago bane of whooping cough making a stealthy resurgence

By M.A.J. McKenna

On the edge of the woods behind their house in Alpharetta [Georgia], Lynne and Phil Baker have made a garden for their son Nelyn.

Phil piled up the rock wall enclosing it. Friends brought the dark red chrysanthemums and brilliant marigolds, and Lynne planted them.

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In the center is a tiny Japanese maple. The parents chose it in tribute to their baby son because it is a species that will always stay small.

As will Nelyn. He died April 25 [2004]. He was 18 days old.

He was killed by a disease that his family did not know still existed, one that 60 years of vaccination has failed to suppress.

Because of his death, the Bakers have become crusaders. They are driven to tell others about his brief life and quick illness, hoping that no other parents will be taken by surprise.

Nelyn Frend Theodore Baker died of whooping cough.

"I never," said Lynne, "never, never, never want this to happen to another child."

Signature Symptom

Whooping cough—the clinical name is pertussis—is a severe bacterial infection of the airways. It is highly infectious, lasts for weeks, and has one overwhelming symptom: it causes uncontrollable coughing fits. In the midst of a spasm, sufferers can crack ribs, vomit, and turn blue from lack of oxygen.

Its name comes from the first breath patients take when a paroxysm ends, an urgent crow that sounds like nothing else in medicine.

The signature sound of whooping cough has passed out of most Americans' memory. Once, though, the disease was one of the most common causes of death in childhood. Before a vaccine was introduced in the 1940s, there were more than 175,000 cases every year in the United States.

The vaccine had an immediate, dramatic effect, cutting adult and child cases of the disease to about 1,000 a year by 1976. Then, in the 1990s, the number of cases began to inch upward again.

Last year [2003], according to the Centers for Disease Control and Prevention, there were 11,647 known U.S. cases, a 30-year high. One-fifth of the cases last year were in children less than a year old. Nineteen [persons], almost all [of them] children, died.

Attractive Opposites

Lynne and Phil Baker are 36 and 39; they have been together since shortly after they met in high school. Their 17-year marriage is a union of opposites. He is from a small family whose roots in rural Pennsylvania go back 200 years; she belongs to a sprawling Michigan clan of Polish immigrants.

He designs information systems; she is a photographer. He is tall and sturdy and has a relaxed self-possession instilled by nine years in the Marines. She is fair and very slender, with a whimsical sense of humor.

Together they raised two children: Brandon, 16, and Lorren, 14. Lynne wanted a third for years, and in July 2003 she learned she was pregnant.

In March, about two weeks before her due date, Lynne went to her part-time job in a bookstore. A customer came to her register. She remembers he was typical for Alpharetta: white, well dressed, well off. And coughing.

"Oh great," she remembers thinking. "By the time I have this baby, I'm going to be sick."

She was right. But she had no idea how sick she would become.

Nationwide Outbreaks

Lynne had no way of knowing that, during her pregnancy, local newspapers around the country were reporting outbreaks of illness.

Children and teens were sick in 19 states: Oklahoma, South Carolina, Texas, New York, Pennsylvania, Illinois, Maine, Missouri, Wisconsin, Ohio, New Jersey, Tennessee, New Mexico, Massachusetts, Minnesota, Colorado, Arkansas, California, and Washington.

The outbreaks were all whooping cough, unrelated cases demonstrating the hidden persistence of a once desperately feared disease.

The last two months of Lynne's pregnancy were difficult, with early contractions suppressed with drugs. In the first week of April, she felt a catch in

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her throat. On the day of her delivery, the raspiness bloomed into a cough.

"She coughed all through labor," Phil said. "Overnight, it got worse and worse."

Nelyn was born April 7. He had a perfectly round head, abundant dark hair, and eyes that seemed to focus immediately. Lynne and Phil happily took him home. But Lynne was still coughing so hard she feared her episiotomy stitches would burst. A week after the birth, on a day when her sisters Julie Conway and Lisa Ginter arrived to celebrate, she went back to the doctor.

She had only a low fever, she seemed well between coughing bouts, and a chest X-ray showed nothing. Her illness looked like a cold, or an asthma-like condition related to the drug that had stopped her contractions.

Five days later, still coughing, she went back to her family physician. He gave her antibiotics. Lynne was nursing; the doctor warned that Nelyn might not like the taste of the drug in her breast milk.

Four days later, Nelyn started to fuss after feeding. Then he was listless. In the evening, he began to cough.

In the middle of the night, his fingers and toes turned blue.

The next morning, Phil and Lynne took their son to his pediatrician. Within an hour, they were in an ambulance, speeding down [Georgia 400 freeway] to Children's Healthcare of Atlanta's Scottish Rite Hospital. Nelyn was rushed upstairs to intensive care.

"They told us at first he would be in the hospital for two days," Lynne said, her voice breaking. "And then he got sicker, and they said maybe five days. And then seven days.

"The next morning, as the sun was rising, Nelyn died. His cause of death was recorded as pneumonia.

A Time to Mourn

The families—Lynne's parents and seven siblings, Phil's mother and sister, and dozens of cousins—arrived almost immediately. Some drove through the night. Others traded in tickets they had bought for trips to meet the baby. They bunked throughout the house.

Phil's employer sent a vanload of food and flowers. Neighbors came to mourn. Lynne's sisters crept through the gathering, picking up baby gifts and stashing them out of sight.

It was the end of April. The subdivision was coated with pollen. So no one found it unusual that Lorren and Brandon came down with respiratory infections, or that Lynne's mother was hospitalized briefly with breathing problems.

On April 28, more than 100 people crammed into the house for a wake. Two days later, the family set off slowly for the Detroit suburbs, where Lynne and Phil met and most of Lynne's family still live. Lisa did not go with them; she flew home early with what she thought was a cold.

In Michigan, there was a larger wake, and then the funeral. Nelyn was buried with his cousin Machiej, who had died at the age of 2. They placed the baby's ashes over the toddler's heart.

On May 5, the Bakers made the 12-hour drive back to Georgia. They found a message asking them to call the Fulton County Department of Health and Wellness.

Back in Michigan, Lynne's sister Julie had developed a racking cough since the funeral. She was coughing so hard when her phone rang the morning of May 6 that she could hardly answer it.

The caller was Lynne, crying and gasping for breath.

"They know what killed Nelyn," she wailed. "He died of whooping cough."

Julie was stunned, and then angry.

"That can't be right," she snapped. "We were immunized. We can't get whooping cough."

She was right: All eight children in their family had been vaccinated in childhood, and each had had their own children vaccinated in turn.

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But she was also wrong. They were not protected.

Protection Ends

Pertussis has a little-known trick. Immunity to the disease—from vaccination or infection—does not last.

A child who has had a full series of shots is protected roughly until puberty. But infants too young to be vaccinated, toddlers with one or two shots, and teenagers and adults are all undefended.

That vulnerability explains a small outbreak of pertussis among four teens in one school in DeKalb County [Georgia] last year. According to the DeKalb County Board of Health, their childhood shots had worn off.

In teens and adults, the disease can be a mild illness—with no coughing fits, no distinctive whoop, and no compelling reason to see a physician. No doctor's visit means no lab test, no formal diagnosis, and no notification to authorities. As a result, even though every state requires pertussis to be reported, the CDC estimates that nine-tenths of cases go unrecognized. Absent strong symptoms or a confirmatory test, patients have no idea what they may be carrying and spreading. Whooping cough is kept alive by those who never realize they have it and accidentally pass it on to others, many of whom develop severe cases.

A Dire Discovery

Fulton County's discovery, made from bacterial cultures started by the hospital during Nelyn's treatment, triggered an emergency.

Pertussis symptoms can be slow to develop, and patients are infectious for weeks once symptoms start. The Bakers' friends, co-workers, and extended family in four states—Georgia, Michigan, Pennsylvania, and Texas—were at risk of developing the disease and passing it on.

In Alpharetta, the Bakers pulled Lorren and Brandon from school and took them immediately to the doctor. In Michigan, Julie and her husband and children were taken through the back door of their pediatrician's office, sent to a hospital, and then closed in an isolation unit inside an emergency room.

Both families were ordered by health departments to stay home for a week.

Each extended-family member was put on powerful antibiotics, but it was not enough. The young children were protected by their immunizations, but at least seven of the teens and adults fell ill.

Julie was hit the hardest. She still cannot exercise or draw a deep breath, and regularly doubles over in coughing fits that leave her retching.

The Bakers have no way of knowing how the disease entered their family, or who infected whom. The drugs given to Lynne, Brandon, and Lorren before Nelyn fell ill wiped the bacteria from their systems before they were tested.

But Lynne believes she knows. She thinks she gave the disease to her sisters when they came to celebrate the birth; she suspects they passed it to their mother in Michigan and that it spread among her family at the wake. She is sure she gave it to her children, including her newborn son.

"I don't blame myself," she said. "Someone gave it to me. But I am haunted by how many people we may have given it to before we realized what was going on."

Special Places

Before Nelyn was buried, Lynne and Phil held back part of his ashes. They took some to Phil's mother, who lives on the family land in northwest Pennsylvania, and spread some by a creek on the property where Phil takes the children every year. They kept the rest, tucked into a cherrywood vessel carved by Lynne's father.

When they are ready, they will add Nelyn's ashes to the garden built in his memory.

"He will be in all the places that have special importance for us," Phil said. "It will help, I think."

Recently, Lynne sat by the garden, smoothing its carefully tended surface and thinking about the need to warn others about whooping cough.

"I never imagined this was possible, but I want people to know it is possible," she said. "This is out there, and it is spreading."