Wisconsin State Senate
24th Senate District

Serving Wood, Portage, Adams,
Waushara, Monroe, and Jackson

PATRICK TESTIN
STATE SENATOR

DATE: April 17th, 2019

RE: **Testimony on 2019 Senate Bill 110/Assembly Bill 137**

TO: Members of the Senate Health and Human Services Committee and the Assembly Committee on Health

FROM: Senator Patrick Testin

I'd like to thank my colleagues from both houses for the opportunity to address this joint public hearing of the Senate Health and Human Services Committee and the Assembly Health Committee. I am asking you all to join me in supporting Senate Bill 110/Assembly Bill 137 (SB110/AB137), which will help improve access to vaccinations for children in medically underserved areas – particularly in the more rural parts of our state.

I introduced a similar bill to this last session with Rep. Jesse Kremer that was opposed by some in the medical field. During the development of SB110/AB137, we worked with stakeholders to eliminate any objections. This bill has earned the support from the Pharmacy Society of Wisconsin, Walgreens, and Concordia University.

SB110/AB137 enables pharmacists to administer vaccines to children of any age if that vaccine is prescribed by a physician, if the pharmacist has received training in how to administer vaccines to children under the age of 6, and if the prescription is issued within the 29 days immediately preceding the day on which the vaccine is administered.

Additionally, the bill enables pharmacists and pharmacy students supervised by pharmacists to give vaccines that are listed on the Center for Disease Control's immunization schedules.

Thank you again for your time; I look forward to earning your support for this bill.

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TONY KURTZ

STATE REPRESENTATIVE • 50th ASSEMBLY DISTRICT

2019 Assembly Bill 137/Senate Bill 110

Relating to: pharmacists and pharmacy students administering vaccines

Joint Hearing: Assembly Committee on Health & Senate Committee on Health and Human Services

Thank you to my colleagues from both the Assembly Committee on Health and the Senate Committee on Health and Human Services for holding a joint public hearing on my bill, Assembly Bill 137 (AB 137), and its companion, Senate Bill 110 (SB 110).

Often times when we are discussing healthcare policy in this building the words "access" and "affordability" get tossed around.

This bill (AB 137/SB 110) helps to address those words. I represent the 50th Assembly District, which is in a rural part of our state. This bill would help to increase access to immunization services for individuals who live in an area like my district. A pharmacist could perform any immunization as long as it is prescribed by a physician or is on the Center for Disease Control's immunization schedule.

Currently, a pharmacist is not allowed to immunize a child under six years of age; with additional training called for in this bill, a pharmacist would be allowed to provide immunizations to a young child. The caveat being that there needs to be a valid prescription written by a physician. Over half of the states already allow for pharmacists to immunize at any age.

Additionally, this bill would call for the pharmacist who performs the immunization to submit that record to the Wisconsin Immunization Registry. Currently, this is not done universally. By adding this requirement, a patient's doctor and a patient's pharmacist can see the immunization status for that individual. This is something that is already mandated for Medicaid patients, so it would not create an undue burden for the pharmacist to do so; it would actually provide consistency for patients across all health plans.

The real world applicability would mean that more people in less populated areas would be able to have access to immunizations, regardless of age.

I thank you for your time and for listening to my testimony. I would be honored to have earned your support of AB 137/SB 110.

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Rep.Kurtz@legis.wi.gov

STATE REPRESENTATIVE
JIMMY
ANDERSON
47TH ASSEMBLY DISTRICT

Testimony in Favor of Assembly Bill 137

Assembly Committee on Health | Senate Committee on Health and Human Services

April 17, 2019

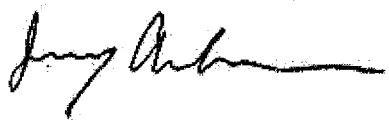
Chairman Sanfelippo, Chairman Testin, and committee members, thank you for the opportunity to provide this testimony in favor of Assembly Bill 137.

This bill is an important step in improving access to immunizations for all Wisconsinites. Unfortunately, especially in rural Wisconsin, some doctors have been struggling to provide all necessary immunizations for their patients while also maintaining the bottom line. A simple fix to help our neighbors attain better access to these important and often life-saving vaccinations was to allow licensed pharmacists to administer them if certain criteria are met. While this has been an effective approach, there are still some unnecessary restrictions on pharmacists that the state can eliminate without sacrificing quality of care.

Assembly Bill 137 will improve access to immunizations for all ages by easing some constraints on when and how pharmacists can provide them. It will also, however, ensure pharmacists are specially trained before administering vaccines to their youngest patients and forbid them from unilaterally going beyond federal Centers for Disease Control and Prevention recommendations.

Our health care system must continue to grow and improve, so allowing these health professionals to play a larger role in it is both necessary and appropriate.

Thank you again for the opportunity to express my support for Assembly Bill 137.



Jimmy Anderson

To: **Members, Senate Committee on Health & Human Services**
Members, Assembly Committee on Health

From: **Ryan A. Bender, PharmD**

RE: **Support Pharmacist Immunization Expansion (SB 110/AB 137)**

My name is Ryan Bender and I would first like to say thank you for giving me the chance to speak on behalf of my profession and the patients we serve. I have been a community pharmacist for nearly 15 years. For the last seven years, I have been the Director of Clinical Services, first for Hometown Pharmacy and now with Forward Pharmacy. Part of my job is to create the policies and procedures for administering vaccines and then train our pharmacists. I help my colleagues stay up to date on recommendations from the Advisory Committee on Immunization Practices, the group that develops recommendations on how to use vaccines in the United States. I also stay current on the CDC's storage and handling of vaccines, ensure CPR certification and immunization course completion for pharmacists that administer vaccines, develop policies for the safe handling and disposal of sharps in accordance with OSHA guidelines and procedures for the emergency management of vaccine reactions.

I am proud to say I have immunized thousands of patients, mostly against influenza, but also against pneumonia, shingles, tetanus, diphtheria, hepatitis, whooping cough and HPV. None of this would be possible without the physicians who have agreed to sign our protocol allowing pharmacists to vaccinate via a standing order rather than an individual prescription. The first part of SB 110 would eliminate this requirement and instead give pharmacists the authority in our state statutes to immunize patients six years of age and older without a standing order or individual prescription.

It can be difficult for a pharmacy to find a physician to sign a protocol. Whether it is the personal choice of the physician or a limitation placed on them by their organization, many doctors are reluctant to sign protocols. Often, this was in the areas of most need or medically underserved areas. With pharmacies in nearly every county of our state, we will provide access to those that can't make the trip to their nearest clinic.

In the case of patients under the age of six, getting a prescription from the child's provider would help to ensure routine checkups and well child visits are not skipped. Which brings me to the next part of SB 110: allowing pharmacists who have completed additional training to provide immunizations to patients under the age of six pursuant to an individual prescription.

Community pharmacists are just that: we are in the community. We are in communities with and without clinics and hospitals. We are open later in the evening and even on weekends. We see our patients on a monthly or even weekly basis, compared to semiannual or annual visits to the clinic. More opportunities to see our patients means more opportunities to provide vaccinations or to provide education to patients who may be hesitant to allow their child to be immunized. With so much disinformation available, now more than ever our patients need the trusted advice from the most trusted profession.

Pharmacists are qualified to administer vaccines. The Doctor of Pharmacy program, which is the only way to become a pharmacist now, is four years. This is on top of a minimum of two years of pre-pharmacy coursework. We are trained in chemistry, biology, biochemistry, microbiology, pharmacology and pharmacotherapy, as well as immunology. Our existing training allows us to vaccinate patients six years of age and older and we welcome the additional training that would allow us to help protect our youngest patients from vaccine-preventable diseases.

Not only are we qualified, but we are capable. We have the infrastructure, the space, the software and experience to provide immunizations. This bill would allow us, with addition training, the opportunity to extend this service to patients of all ages. We all got into this profession to care for patients, and providing vaccines to all patients over the age of six without a prescription and under the age of six with a prescription is a natural extension of the practice of pharmacy.

TO: Senate Committee on Health and Human Services

FROM: Thaddeus Schumacher, PharmD

Owner, Fitchburg Family Pharmacy

DATE: March 27, 2019

SUBJECT: Senate Bill 110

I would like to thank the committee for the opportunity to come and speak today. My name is Thad Schumacher, I am pharmacist and owner of Fitchburg Family Pharmacy and I have served on the Wisconsin Pharmacy Examining Board for the past eight years.

I applaud the legislature for supporting SB 110, which will increase access to vaccinations across our state. As a pharmacist working on the front lines of the healthcare team, I see how access to immunizations at the pharmacy is so impactful. When adult children bring their senior parents to the pharmacy for routine immunizations, we are able to persuade the adult children to vaccinate while they are present as well. At most pharmacies it is as easy as walking in and filling a prescription.

Where this bill will have the most impact is in the pediatric population, especially those kids under six years old. It is routine for us to have a mom and her three or four kids come in all at once for their flu vaccine. We get ready to take care of everyone, and the four-year-old is not able to get vaccinated with their siblings at the pharmacy, due to present law. So, the mom knows that she will have to make an appointment with their doctor, potentially take time off work, to vaccinate the youngest child.

The biggest advantage to passing SB 110, is that we will be prepared as a state to meet a crisis such H1N1 of years past, head on. We will have set up an infrastructure to vaccinate all Wisconsinites, with checks and balances, as well as a beneficial reporting system.

Thank you for supporting SB 110.

Walgreens

Walgreen Co.
2275A N. Mayfair rd.
Wauwatosa, WI 53226

To: Senate Committee on Health & Human Services
Assembly Committee on Health

From: Franklin LaDien, RPh
Healthcare Supervisor – Milwaukee North Area
Walgreens

Date: April 17, 2019

Re: Support of Senate Bill 110 / Assembly Bill 137

Thank you very much for allowing me to testify in favor of Senate Bill 110 and Assembly Bill 137. My name is Rocky LaDien and I am a healthcare supervisor for Walgreens.

This bill would increase patient access to immunizations by allowing pharmacists to immunize children under the age of 6 in limited circumstances, as well as decreasing administrative burdens when providing immunizations to patients ages 6 and older.

Wisconsin's immunization rates have fallen below both the state Department of Health Services and the federal Centers for Disease Control and Prevention goals. As demonstrated by America's Health Rankings, Wisconsin has room to improve: Wisconsin ranks 41st in number of pertussis cases, a vaccine-preventable disease and outside the top ten best states for adolescent vaccinations, including meningococcal, HPV, and Tdap vaccines.[1] In 2016, all 72 Wisconsin counties fell below Healthy People 2020's influenza vaccination rate goal of 70% for children, adolescents, and adults under age 65.

According to the federal Health Resources & Services Administration and the Wisconsin Department of Health Services, two-thirds of Wisconsin counties have areas considered medically underserved. By empowering pharmacists to provide expanded roles in these communities, we can assist in closing the access gap.

With accessible locations and expanded hours, pharmacies are an ideal location to provide preventative care services and population health interventions like vaccines. By expanding the availability of vaccines in pharmacies, patients will be able to access vaccines at a time that works for them. Pharmacies are a convenient setting as 95% of Americans live within 5 miles of a pharmacy. Walgreens has more than 225 locations in Wisconsin and we look forward to providing an expanded vaccine offering across the state.

Thank you again for the opportunity to testify in favor of SB 110/AB 137. I am happy to answer any questions you may have.

[1] America's Health Rankings. Wisconsin. America's Health Rankings. https://www.americashealthrankings.org/learn/reports/2017-annual-report/state-summaries-wisconsin. Published 2018. Accessed May 17, 2018.

April 17, 2019

Dear Health Committee Members of both the Senate and Assembly,

My name is Tara Czachor and I live in the Town of Lawrence. I thank both committees for their time and the opportunity to speak today. The bill being discussed today, SB110/AB137, is not a bill I support. Current law already allows pharmacists to administer vaccines to children, just not to children under age 6. I believe it should stay that way.

My first question/concern is in regards to what is driving this bill? There is not a lack of access to vaccinations in Wisconsin. Vaccinations are given at medical facilities at anytime; They are given at local health departments which are set up throughout the year. What is the motivation driving this bill if lack of access is not the issue? Why are we going to attempt to burden our already overworked pharmacists with more on their plates?

Initially, states in the U.S. only authorized pharmacists to administer the influenza vaccine. Given what is already known about corporate quotas and their effect on medication dispensing speed and prescription drug errors, there is legitimate reason to be concerned about the safety of vaccine delivery by pharmacists. There is nothing in this bill that safeguards the number of hours pharmacists or pharmacy students can work each day, nothing that limits the number of prescriptions they can fill each hour, nothing that requires break time during their shifts, or that provides whistleblower protection if they expose safety problems. By allowing overworked pharmacists and pharmacy students the ability to administer vaccines to children under age 6, we may be potentially creating a dangerous situation for children who are getting their vaccines in pharmacies without addressing these concerns.

My second, and greatest concern, is in regards to informed consent. Something the current bill does not include is how informed and parental consent are obtained during the vaccination process.

I propose the following amendments with regards to parental informed consent:

1. Parents are notified if the person administering the vaccine is a student. A parent must be able to decide whether or not they are comfortable with a student administering a vaccine to their child or if they would prefer someone with more experience.

2. Parents must receive the vaccine package insert, which is provided by the manufacturer, not just the CDC Vaccine Information Statement. I have provided an example of a vaccine package insert for the influenza vaccine.
3. Parents must receive the CDC's Vaccine Excipient and Media Summary, which is a summary of ingredients in each of the vaccines. I have attached this excipient list to my written testimony for your review.
4. Parents/guardians are provided with information in regards to the procedures available under the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. Section 300aa-1 et seq.) to seek possible recovery for unreimbursed expenses for certain vaccine injuries arising out of the administration of certain vaccines.This includes information on how to report a vaccine reaction should one occur.
5. The pharmacist must go over the patient's medical history, allergies, and discuss contraindications. We must not assume that the doctors have already gone over these items.

I would also propose that the pharmacy that is administering vaccinations to children under the age of 6 be required to:

1. Have all staff trained in CPR
2. Have onsite and readily available AED's (automated external defibrillators) for use in emergency situations
3. Have emergency procedures in place

This bill also allows for a pharmacist to administer any vaccine that is on the CDC schedule without a prescription. How would pharmacists ensure that the adult bringing the child in for a vaccination has the legal authority to do so? There are no safeguards in this bill that take this very concerning issue into consideration.

This bill mentions that the pharmacist has seven days to enter the information into the online Wisconsin Immunization Registry. Seven days is far too long of a time frame, especially considering the facility that is being proposed typically incentivizes vaccine uptake. If a pharmacist will be administering vaccinations to children under age 6, the information needs to be entered into the Wisconsin Immunization Registry the same day the vaccine is administered. Parents must be informed of their choice to opt out of the Wisconsin Immunization Registry if they choose.

To point out the validity of my concerns, I went to some local pharmacies in my area to speak with those working in the field. None of the pharmacists I spoke with knew of this bill nor wanted the added responsibility that comes with vaccinating children under age

6. I asked basic questions regarding their vaccination procedures. They did not have AEDs (automated external defibrillators), which are life saving devices that are in every medical facility. They did not have multiple copies of the vaccine package insert provided by the manufacturer. They had to open a new box of vaccine vials and handed me the one and only vaccine package insert from the box. There was only one. This is unacceptable.

Medical procedures, such as vaccinations, should be done in a medical facility equipped with life saving medical devices with medical staff trained in emergency situations. It is medically irresponsible for anyone other than a medical professional located in a medical facility with life saving devices to administer vaccines, especially for a vulnerable population such as children under the age of 6. There is nothing in this bill that discusses how long the child under age 6 is going to be monitored for anaphylaxis or syncope (fainting).

Instead of looking at ways in which we can increase compliance in people that are not up to date according to the recommended CDC vaccine schedule, why is this committee not addressing more serious concerns, such as a lack of double blind placebo controlled studies? Trust is being given to the same pharmaceutical companies that pay billions in settlements for other drugs because they are both ineffective and have devastating side-effects. The only course of action in the event of an adverse vaccine reaction is a non-mandatory post-marketing surveillance program. To report an adverse reaction to a vaccine, a doctor or parent must voluntarily submit a report to the Vaccine Adverse Event Reporting System, or VAERS. A Harvard study estimates that only between 1-10 percent of adverse reactions to vaccines are reported. There is nothing in this bill that requires that anyone who administers a vaccine have any training, knowledge or requirement to report any adverse vaccine reactions to VAERS. Who would hold the responsibility of reporting an adverse reaction? The doctor that prescribed the vaccination? The pharmacist who administered the vaccine? Or will this fall upon the shoulders of the family who is now dealing with a medical crisis with their child?

The intent of this bill may come from a good place, but words matter, and this bill holds a lot of ambiguity as it stands now. What appears to be a move in the best interest of public health is merely a disguise for expanding the profits of owners of pharmacies and the pharmaceutical industry. Vaccination rates in Wisconsin across the board are very high; the issue here is not access to vaccinations, but rather a continuing questioning of their effectiveness and safety. There are adverse reactions that occur during vaccinations and this medical procedure should be performed in a medical setting - not

a drug store. Adverse reactions do occur following vaccination, which is why there is a Vaccine Injury Compensation Program. This program has, to date, paid out over $4 billion dollars to families who have experienced vaccine injury and or death. I have included a copy of the most recent report from April 2019 of the HRSA Compensation Statistics.

As a mother and a parent, I can appreciate the need for our children and for public health to protect against communicable diseases, however the issues that this bill overlooks also carries the potential to create new problems. We, as Wisconsinites, should be demanding more from pharmaceutical companies, not giving them another avenue to sell more of their products in situations that are not medically optimal.

Respectfully,

Tara Czachor
Lawrence, WI

Vaccine Excipient & Media Summary

Excipients Included in U.S. Vaccines, by Vaccine

In addition to weakened or killed disease antigens (viruses or bacteria), vaccines contain very small amounts of other ingredients – excipients or media.

Some excipients are added to a vaccine for a specific purpose. These include:
Preservatives, to prevent contamination. For example, thimerosal.
Adjuvants, to help stimulate a stronger immune response. For example, aluminum salts.
Stabilizers, to keep the vaccine potent during transportation and storage. For example, sugars or gelatin.

Others are residual trace amounts of materials that were used during the manufacturing process and removed. These include:
Cell culture materials, used to grow the vaccine antigens. For example, egg protein, various culture media.
Inactivating ingredients, used to kill viruses or inactivate toxins. For example, formaldehyde.
Antibiotics, used to prevent contamination by bacteria. For example, neomycin.

The following table lists all components, other than antigens, shown in the manufacturers' package insert (PI) for each vaccine. Each of these PIs, which can be found on the FDA's website (see below) contains a description of that vaccine's manufacturing process, including the amount and purpose of each substance. In most PIs, this information is found in Section 11: "Description."

All information was extracted from manufacturers' package inserts.
If in doubt about whether a PI has been updated since this table was prepared, check the FDA's website at:
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

Vaccine	Contains
Adenovirus	human-diploid fibroblast cell cultures (strain WI-38), Dulbecco's Modified Eagle's Medium, fetal bovine serum, sodium bicarbonate, monosodium glutamate, sucrose, D-mannose, D-fructose, dextrose, human serum albumin, potassium phosphate, plasdone C, anhydrous lactose, microcrystalline cellulose, polacrilin potassium, magnesium stearate, cellulose acetate phthalate, alcohol, acetone, castor oil, FD&C Yellow #6 aluminum lake dye
Anthrax (Biothrax)	amino acids, vitamins, inorganic salts, sugars, aluminum hydroxide, sodium chloride, benzethonium chloride, formaldehyde
BCG (Tice)	glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, iron ammonium citrate, lactose
Cholera (Vaxchora)	casamino acids, yeast extract, mineral salts, anti-foaming agent, ascorbic acid, hydrolyzed casein, sodium chloride, sucrose, dried lactose, sodium bicarbonate, sodium carbonate
DT (Sanofi)	aluminum phosphate, isotonic sodium chloride, formaldehyde, casein, cystine, maltose, uracil, inorganic salts, vitamins, dextrose
DTaP (Daptacel)	aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion
DTaP (Infanrix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80)
DTaP-IPV (Kinrix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, VERO cells, a continuous line of monkey kidney cells, Calf serum, lactalbumin hydrolysate, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B
DTaP-IPV (Quadracel)	modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, formaldehyde, aluminum phosphate, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, MRC-5 cells, normal human diploid cells, CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, 2-phenoxyethanol, polysorbate 80, glutaraldehyde, neomycin, polymyxin B sulfate

Vaccine	Contains
DTaP-HepB-IPV (Pediarix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, glutaraldehyde, modified Stainer-Scholte liquid medium, VERO cells, a continuous line of monkey kidney cells, calf serum and lactalbumin hydrolysate, aluminum hydroxide, aluminum phosphate, aluminum salts, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B, yeast protein.
DTaP-IPV/Hib (Pentacel)	aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate, modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin. MRC-5 cells (a line of normal human diploid cells), CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, modified Mueller and Miller medium
Hib (ActHIB)	sodium chloride, modified Mueller and Miller medium (the culture medium contains milk-derived raw materials [casein derivatives]), formaldehyde, sucrose
Hib (Hiberix)	saline, synthetic medium, formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB)	complex fermentation media, amorphous aluminum hydroxyphosphate sulfate, sodium chloride
Hep A (Havrix)	MRC-5 human diploid cells, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic
Hep A (Vaqta)	MRC-5 diploid fibroblasts, amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride
Hep B (Engerix-B)	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate
Hep B (Recombivax)	soy peptone, dextrose, amino acids, mineral salts, phosphate buffer, formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein
Hep B (Heplisav-B)	vitamins and mineral salts, yeast protein, yeast DNA, deoxycholate, phosphorothioate linked oligodeoxynucleotide, phosphate buffered saline, sodium phosphate, dibasic dodecahydrate, monobasic dehydrate, polysorbate 80
Hep A/Hep B (Twinrix)	MRC-5 human diploid cells, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein
Human Papillomavirus (HPV) (Gardasil 9)	vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein
Influenza (Afluria) Trivalent & Quadrivalent	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multi-dose vials)
Influenza (Fluad)	squalene, polysorbate 80, sorbitan trioleate, sodium citrate dehydrate, citric acid monohydrate, neomycin, kanamycin, barium, egg proteins, cetyltrimethylammonium bromide (CTAB), formaldehyde
Influenza (Fluarix) Quadrivalent	octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride
Influenza (Flublok) Quadrivalent	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and *Spodoptera frugiperda* cell proteins, baculovirus and cellular DNA, Triton X-100, lipids, vitamins, amino acids, mineral salts
Influenza (Flucelvax) Quadrivalent	Madin Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethlyammonium bromide, and β-propiolactone, Thimerosal (multi-dose vials)
Influenza (Flulaval) Quadrivalent	ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials), phosphate-buffered saline solution
Influenza (Fluzone) Quadrivalent	formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials)

Vaccine	Contains
Influenza (Fluzone) High Dose	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde
Influenza (FluMist) Quadrivalent	monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA)
Japanese Encephalitis (Ixiaro)	aluminum hydroxide, protamine sulfate, formaldehyde, bovine serum albumin, host cell DNA, sodium metabisulphite, host cell protein
Meningococcal (MenACWY-Menactra)	Watson Scherp media containing casamino acid, modified culture medium containing hydrolyzed casein, ammonium sulfate, sodium phosphate, formaldehyde, sodium chloride
Meningococcal (MenACWY-Menveo)	formaldehyde, amino acids, yeast extract, Franz complete medium, CY medium
Meningococcal (MenB – Bexsero)	aluminum hydroxide, *E. coli*, histidine, sucrose, deoxycholate, kanamycin
Meningococcal (MenB – Trumenba)	defined fermentation growth media, polysorbate 80, aluminum phosphate, histidine buffered saline
MMR (MMR-II)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, vitamins, amino acids, fetal bovine serum, sucrose, glutamate, recombinant human albumin, neomycin, sorbitol, hydrolyzed gelatin, sodium phosphate, sodium chloride
MMRV (ProQuad) (Frozen)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride; potassium phosphate dibasic, neomycin, bovine calf serum
MMRV (ProQuad) (Refrigerator Stable)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells, sucrose, hydrolyzed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate, potassium chloride, neomycin, bovine serum albumin
Pneumococcal (PCV13 – Prevnar 13)	soy peptone broth, casamino acids and yeast extract-based medium, CRM197 carrier protein, polysorbate 80, succinate buffer, aluminum phosphate
Pneumococcal (PPSV-23 – Pneumovax)	phenol
Polio (IPV – Ipol)	Eagle MEM modified medium, calf bovine serum, M-199 without calf bovine serum, vero cells (a continuous line of monkey kidney cells), phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B
Rabies (Imovax)	human albumin, neomycin sulfate, phenol red indicator, MRC-5 human diploid cells, beta-propriolactone
Rabies (RabAvert)	chicken fibroblasts, β-propiolactone, polygeline (processed bovine gelatin), human serum albumin, bovine serum, potassium glutamate, sodium EDTA, ovalbumin, neomycin, chlortetracycline, amphotericin B
Rotavirus (RotaTeq)	sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal bovine serum, vero cells *[DNA from porcine circoviruses (PCV) 1 and 2 has been detected in RotaTeq. PCV-1 and PCV-2 are not known to cause disease in humans.]*
Rotavirus (Rotarix)	Vero cells, dextran, Dulbecco's Modified Eagle Medium (sodium chloride, potassium chloride, magnesium sulfate, ferric (III) nitrate, sodium phosphate, sodium pyruvate, D-glucose, concentrated vitamin solution, L-cystine, L-tyrosine, amino acids solution, L-glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red), sorbitol, sucrose, calcium carbonate, sterile water, xanthan *[Porcine circovirus type 1 (PCV-1) is present in Rotarix. PCV-1 is not known to cause disease in humans.]*
Smallpox (Vaccinia) (ACAM2000)	African Green Monkey kidney (Vero) cells, HEPES, 2% human serum albumin, 0.7% sodium chloride USP, 5% Mannitol USP, neomycin, polymyxin B, 50% Glycerin USP, 0.25% phenol USP
Td (Tenivac)	aluminum phosphate, formaldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate, sodium chloride, water

Vaccine	Contains
Td (Mass Biologics)	aluminum phosphate, formaldehyde, thimerosal, modified Mueller's media which contains bovine extracts, ammonium sulfate
Tdap (Adacel)	aluminum phosphate, formaldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, glutaraldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate, modified Mueller's growth medium
Tdap (Boostrix)	modified Latham medium derived from bovine casein, Fenton medium containing a bovine extract, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80
Typhoid (Typhim Vi)	hexadecyltrimethylammonium bromide, formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, semi-synthetic medium, sodium chloride, sterile water
Typhoid (Vivotif Ty21a)	yeast extract, casein, dextrose, galactose, sucrose, ascorbic acid, amino acids, lactose, magnesium stearate. gelatin
Varicella (Varivax) *Frozen*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, sodium phosphate monobasic, potassium phosphate monobasic, potassium chloride, EDTA, neomycin, fetal bovine serum
Varicella (Varivax) *Refrigerator Stable*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, urea, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
Yellow Fever (YF-Vax)	sorbitol, gelatin, sodium chloride, egg protein
Zoster (Shingles) (Zostavax) *Frozen*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed porcine gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride; neomycin, bovine calf serum
Zoster (Shingles) (Zostavax) *Refrigerator Stable*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed porcine gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
Zoster (Shingles) (Shingrix)	sucrose, sodium chloride, dioleoyl phosphatidylcholine (DOPC), 3-*O*-desacl-4'monophosphoryl lipid A (MPL), QS-21 (a saponin purified from plant extract *Quillaja saponaria* Molina), potassium dihydrogen phosphate, cholesterol, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, dipotassium phosphate, polysorbate 80

A table listing vaccine excipients and media *by excipient* is published by the Institute for Vaccine Safety at Johns Hopkins University, and can be found at http://www.vaccinesafety.edu/components-Excipients.htm.

Updates:

Trumenba: (added Aluminum phosphate)
RotaTeq: PI dated 2/2017
Rotarix: 6/11/18 (PI dated xx/xxxx)
Smallpox: 3/2018
Td (Tenivac): April 2013
Td (Mass Biologics): April 2009 (no change)
Tdap (Adacel): xxx/2017 (no change)
Tdap (Boostrix): 6/12/2018 (PI dated xx/xxxx) (no change)
Typhim Vi: March 2014 (added sodium chloride & buffered saline)
Ty21a: September 2013
Varicella Frozen: 2/2017
Varicella Refrigerator Stable: 2/2017
YF Vax: June 2016
Zostivax Frozen: xx/2018
Zostivax Refrigerator Stable: xx/2018
Shingrix: 10/2017

HRSA
Health Resources & Services Administration

Data & Statistics

The United States has the safest, most effective vaccine supply in history. In the majority of cases, vaccines cause no side effects, however they can occur, as with any medication—but most are mild. Very rarely, people experience more serious side effects, like allergic reactions.

In those instances, the National Vaccine Injury Compensation Program (VICP) allows individuals to file a petition for compensation.

What does it mean to be awarded compensation?
Being awarded compensation for a petition does not necessarily mean that the vaccine caused the alleged injury. In fact:

- Approximately 70 percent of all compensation awarded by the VICP comes as result of a negotiated settlement between the parties in which HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury.
- Attorneys are eligible for reasonable attorneys' fees, whether or not the petitioner is awarded compensation by the Court, if certain minimal requirements are met. In those circumstances, attorneys are paid by the VICP directly. By statute, attorneys may not charge any other fee, including a contingency fee, for his or her services in representing a petitioner in the VICP.

What reasons might a petition result in a negotiated settlement?

- Consideration of prior U.S. Court of Federal Claims decisions, both parties decide to minimize risk of loss through settlement
- A desire to minimize the time and expense of litigating a case
- The desire to resolve a petition quickly

How many petitions have been awarded compensation?
According to the CDC, from 2006 to 2017 over 3.4 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 6,253 petitions were adjudicated by the Court, and of those 4,291 were compensated. This means for every 1 million doses of vaccine that were distributed, 1 individual was compensated.

Since 1988, over 20,522 petitions have been filed with the VICP. Over that 30-year time period, 17,772 petitions have been adjudicated, with 6,465 of those determined to be compensable, while 11,307 were dismissed. Total compensation paid over the life of the program is approximately $4.1 billion.

VICP Adjudication Categories, by Alleged Vaccine
For Petitions Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/01/2006 through 12/31/2017

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2017 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
DT	794,777	1	0	5	6	4	10
DTaP	101,073,594	19	22	104	145	116	261
DTaP-Hep B-IPV	68,764,777	5	7	28	40	53	93
DTaP-HIB	1,135,474	0	1	2	3	2	5
DTaP-IPV	24,237,580	0	0	3	3	3	6
DTap-IPV-HIB	62,397,611	3	4	9	16	29	45
DTP	0	1	1	3	5	2	7
DTP-HIB	0	1	0	2	3	1	4
Hep A-Hep B	15,826,685	2	0	15	17	4	21
Hep B-HIB	4,787,457	1	1	2	4	1	5
Hepatitis A (Hep A)	176,194,118	8	7	42	57	32	89
Hepatitis B (Hep B)	185,428,393	9	11	64	84	76	160
HIB	119,947,400	3	1	8	12	10	22
HPV	111,677,552	14	14	106	134	175	309
Influenza	1,518,400,000	627	147	2,155	2,929	491	3,420
IPV	72,962,512	0	0	4	4	3	7
Measles	135,660	0	0	1	1	0	1
Meningococcal	94,113,218	1	5	39	45	10	55

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Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2017 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
MMR	101,501,714	23	14	83	120	124	244
MMR-Varicella	24,798,297	9	0	13	22	15	37
Mumps	110,749	0	0	0	0	0	0
Nonqualified	0	0	0	3	3	36	39
OPV	0	1	0	0	1	5	6
Pneumococcal Conjugate	228,588,846	19	3	29	51	33	84
Rotavirus	107,678,219	17	4	20	41	13	54
Rubella	422,548	0	1	1	2	0	2
Td	65,170,306	10	7	61	78	25	103
Tdap	248,258,803	88	17	257	362	72	434
Tetanus	3,836,052	10	1	41	52	20	72
Unspecified	0	1	1	4	6	589	595
Varicella	116,063,014	8	7	30	45	18	63
Grand Total	3,454,269,356	881	276	3,134	4,291	1,962	6,253

Notes on the Adjudication Categories Table

The date range of 01/01/2006 through 12/31/2017 was selected to reflect petitions filed since the inclusion of influenza vaccine in July 2005. Influenza vaccine now is named in the majority of all VICP petitions.

In addition to the first vaccine alleged by a petitioner, which is the vaccine listed in this table, a VICP petition may allege other vaccines, which may form the basis of compensation.

Vaccine doses are self-reported distribution data provided by US-licensed vaccine manufacturers. The data provide an estimate of the annual national distribution and do not represent vaccine administration. In order to maintain confidentiality of an individual manufacturer or brand, the data are presented in an aggregate format by vaccine type. Flu doses are derived from CDC's FluFinder tracking system, which includes data provided to CDC by US-licensed influenza vaccine manufacturers as well as their first line distributors.

"Unspecified" means insufficient information was submitted to make an initial determination. The conceded "unspecified" petition was for multiple unidentified vaccines that caused abscess formation at the vaccination site(s), and the "unspecified" settlements were for multiple vaccines later identified in the Special Masters' decisions

Definitions

Compensable – The injured person who filed a petition was paid money by the VICP. Compensation can be achieved through a concession by the U.S. Department of Health and Human Services (HHS), a decision on the merits of the petition by a special master or a judge of the U.S. Court of Federal Claims (Court), or a settlement between the parties.

- **Concession**: HHS concludes that a petition should be compensated based on a thorough review and analysis of the evidence, including medical records and the scientific and medical literature. The HHS review concludes that the petitioner is entitled to compensation, including a determination either that it is more likely than not that the vaccine caused the injury or the evidence supports fulfillment of the criteria of the Vaccine Injury Table. The Court also determines that the petition should be compensated.
- **Court Decision**: A special master or the court, within the United States Court of Federal Claims, issues a legal decision after weighing the evidence presented by both sides. HHS abides by the ultimate Court decision even if it maintains its position that the petitioner was not entitled to compensation (e.g., that the injury was not caused by the vaccine).
  For injury petitions, compensable court decisions are based in part on one of the following determinations by the court:
  1. The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or
  2. The injury is listed on, and meets all of the requirements of, the Vaccine Injury Table, and HHS has not proven that a factor unrelated to the vaccine more likely than not caused or significantly aggravated the injury. An injury listed on the Table and meeting all Table requirements is given the legal presumption of causation. It should be noted that conditions are placed on the Table for both scientific and policy reasons.
- **Settlement**: The petition is resolved via a negotiated settlement between the parties. This settlement is not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries, and, in settled cases, the Court does not determine that the vaccine caused the injury. A settlement therefore cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Petitions may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable; a desire by both parties to minimize the time and expense associated with litigating a case to conclusion; and a desire by both parties to resolve a case quickly and efficiently.
- **Non-compensable/Dismissed**: The injured person who filed a petition was ultimately not paid money. Non-compensable Court decisions include the following:
  1. The Court determines that the person who filed the petition did not demonstrate that the injury was caused (or significantly aggravated) by a covered vaccine or meet the requirements of the Table (for injuries listed on the Table).
  2. The petition was dismissed for not meeting other statutory requirements (such as not meeting the filing deadline, not receiving a covered vaccine, and not meeting the statute's severity requirement).
  3. The injured person voluntarily withdrew his or her petition.

Petitions Filed, Compensated and Dismissed, by Alleged Vaccine, Since the Beginning of VICP, 10/01/1988 through 4/01/2019

Vaccines	Filed Injury	Filed Death	Filed Grand Total	Compensated	Dismissed
DTaP-IPV	11	0	11	3	3
DT	69	9	78	26	52
DTP	3,286	696	3,982	1,273	2,709
DTP-HIB	20	8	28	7	21
DTaP	454	82	536	225	252
DTaP-Hep B-IPV	85	37	122	41	52
DTaP-HIB	11	1	12	7	4
DTaP-IPV-HIB	43	21	64	14	29
Td	206	3	209	123	75
Tdap	690	6	696	352	72
Tetanus	137	2	139	75	47
Hepatitis A (Hep A)	104	7	111	55	31
Hepatitis B (Hep B)	694	60	754	274	419
Hep A-Hep B	32	0	32	16	5
Hep B-HIB	8	0	8	5	3
HIB	44	3	47	17	20
HPV	388	15	403	130	165
Influenza	5,023	167	5,190	2,869	466
IPV	268	14	282	8	269
OPV	282	28	310	158	152
Measles	143	19	162	55	107
Meningococcal	73	2	75	43	8
MMR	974	61	1,035	402	584
MMR-Varicella	50	2	52	20	13
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	187	15	202	53	50
Rotavirus	94	5	99	59	23
Rubella	190	4	194	71	123
Varicella	103	9	112	63	30
Nonqualified1	101	9	110	3	101
Unspecified2	5,426	9	5,435	9	5,399
Grand Total	**19,225**	**1,297**	**20,522**	**6,465**	**11,307**

[1] Nonqualified petitions are those filed for vaccines not covered under the VICP.
[2] Unspecified petitions are those submitted with insufficient information to make a determination.

Petitions Filed

Fiscal Year	Total
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	215
FY 2002	958
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	448
FY 2011	386
FY 2012	401
FY 2013	504
FY 2014	633
FY 2015	803
FY 2016	1,120
FY 2017	1,243
FY 2018	1,238
FY 2019	602
Total	**20,522**

Adjudications

Generally, petitions are not adjudicated in the same fiscal year as filed.
On average, it takes 2 to 3 years to adjudicate a petition after it is filed.

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	88	174
FY 2002	104	104	208
FY 2003	56	100	156
FY 2004	62	247	309
FY 2005	60	229	289
FY 2006	69	193	262
FY 2007	82	136	218
FY 2008	147	151	298
FY 2009	134	257	391
FY 2010	180	329	509
FY 2011	266	1,740	2,006
FY 2012	265	2,533	2,798
FY 2013	369	649	1,018
FY 2014	371	192	563
FY 2015	517	137	654
FY 2016	697	179	876
FY 2017	696	185	881
FY 2018	538	189	727
FY 2019	185	51	236
Total	**6,465**	**11,307**	**17,772**

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Awards Paid

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 1989	6	$1,317,654.78	$54,107.14	0	$0.00	0	$0.00	$1,371,761.92
FY 1990	88	$53,252,510.46	$1,379,005.79	4	$57,699.48	0	$0.00	$54,689,215.73
FY 1991	114	$95,980,493.16	$2,364,758.91	30	$496,809.21	0	$0.00	$98,842,061.28
FY 1992	130	$94,538,071.30	$3,001,927.97	118	$1,212,677.14	0	$0.00	$98,752,676.41
FY 1993	162	$119,693,267.87	$3,262,453.06	272	$2,447,273.05	0	$0.00	$125,402,993.98
FY 1994	158	$98,151,900.08	$3,571,179.67	335	$3,166,527.38	0	$0.00	$104,889,607.13
FY 1995	169	$104,085,265.72	$3,652,770.57	221	$2,276,136.32	0	$0.00	$110,014,172.61
FY 1996	163	$100,425,325.22	$3,096,231.96	216	$2,364,122.71	0	$0.00	$105,885,679.89
FY 1997	179	$113,620,171.68	$3,898,284.77	142	$1,879,418.14	0	$0.00	$119,397,874.59
FY 1998	165	$127,546,009.19	$4,002,278.55	121	$1,936,065.50	0	$0.00	$133,484,353.24
FY 1999	96	$95,917,680.51	$2,799,910.85	117	$2,306,957.40	0	$0.00	$101,024,548.76
FY 2000	136	$125,945,195.64	$4,112,369.02	80	$1,724,451.08	0	$0.00	$131,782,015.74
FY 2001	97	$105,878,632.57	$3,373,865.88	57	$2,066,224.67	0	$0.00	$111,318,723.12
FY 2002	80	$59,799,604.39	$2,653,598.89	50	$656,244.79	0	$0.00	$63,109,448.07
FY 2003	65	$82,816,240.07	$3,147,755.12	69	$1,545,654.87	0	$0.00	$87,509,650.06
FY 2004	57	$61,933,764.20	$3,079,328.55	69	$1,198,615.96	0	$0.00	$66,211,708.71
FY 2005	64	$55,065,797.01	$2,694,664.03	71	$1,790,587.29	0	$0.00	$59,551,048.33
FY 2006	68	$48,746,162.74	$2,441,199.02	54	$1,353,632.61	0	$0.00	$52,540,994.37
FY 2007	82	$91,449,433.89	$4,034,154.37	61	$1,692,020.25	0	$0.00	$97,175,608.51
FY 2008	141	$75,716,552.06	$5,191,770.83	74	$2,531,394.20	2	$117,265.31	$83,556,982.40
FY 2009	131	$74,142,490.58	$5,404,711.98	36	$1,557,139.53	28	$4,241,362.55	$85,345,704.64
FY 2010	173	$179,387,341.30	$5,961,744.40	59	$1,933,550.09	22	$1,978,803.88	$189,261,439.67
FY 2011	251	$216,319,428.47	$9,572,042.87	403	$5,589,417.19	28	$2,001,770.91	$233,482,659.44
FY 2012	249	$163,491,998.82	$9,241,427.33	1,020	$8,649,676.56	37	$5,420,257.99	$186,803,360.70
FY 2013	375	$254,666,326.70	$13,543,099.70	704	$7,012,615.42	50	$1,454,851.74	$276,676,893.56
FY 2014	365	$202,084,196.12	$12,161,422.64	508	$6,824,566.68	38	$2,493,460.73	$223,563,646.17
FY 2015	508	$204,137,880.22	$14,445,776.29	118	$3,546,785.14	50	$3,089,497.68	$225,219,939.33
FY 2016	689	$230,140,251.20	$16,225,881.12	99	$2,741,830.10	59	$3,502,709.91	$252,610,672.33

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Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 2017	706	$252,245,932.78	$22,045,785.00	131	$4,441,724.32	52	$3,363,464.24	$282,096,906.34
FY 2018	522	$199,658,492.49	$16,658,440.14	111	$5,091,269.45	58	$5,220,096.78	$226,628,298.86
FY 2019	276	$119,344,851.56	$8,091,796.70	41	$1,985,117.67	30	$2,064,009.07	$131,485,775.00
Total	**6,465**	**$3,807,498,922.78**	**$195,163,743.12**	**5,391**	**$82,076,204.20**	**454**	**$34,947,550.79**	**$4,119,686,42.89**

NOTE: Some previous fiscal year data has been updated as a result of the receipt and entry of data from documents issued by the Court and system updates which included petitioners' costs reimbursements in outlay totals,

"Compensated" are petitions that have been paid as a result of a settlement between parties or a decision made by the U.S. Court of Federal Claims (Court). The # of awards is the number of petitioner awards paid, including the attorneys' fees/costs payments, if made during a fiscal year. However, petitioners' awards and attorneys' fees/costs are not necessarily paid in the same fiscal year as when the petitions/petitions are determined compensable. "Dismissed" includes the # of payments to attorneys and the total amount of payments for attorneys' fees/costs per fiscal year. The VICP will pay attorneys' fees/costs related to the petition, whether or not the petition/petition is awarded compensation by the Court, if certain minimal requirements are met. "Total Outlays" are the total amount of funds expended for compensation and attorneys' fees/costs from the Vaccine Injury Compensation Trust Fund by fiscal year.

Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult petitions related to that vaccine have been filed, thus changing the proportion of children to adults receiving compensation.

86R13486 SRA-D

Texas

By: Zedler

H.B. No. 4274

A BILL TO BE ENTITLED
AN ACT

relating to informed consent to immunizations for children.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Sections 32.102(a) and (c), Family Code, are amended to read as follows:

(a) Before administering an immunization to a child, a health care provider must obtain the informed consent of a [~~A~~] person authorized to consent to [~~the~~] immunization of the [~~a~~] child [~~has the responsibility to ensure that the consent, if given, is an informed consent~~]. The person authorized to consent is not required to be present when [~~the~~] immunization of the child is requested if a consent form that meets the requirements of Section 32.002 has been given to the health care provider.

(c) As part of the information given in the counseling for informed consent, the health care provider shall provide [~~information to inform~~] the person authorized to consent to immunization information regarding:

(1) the benefits and risks of immunization, including any vaccine information statement required by the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. Section 300aa-1 et seq.);

(2) [~~of~~] the procedures available under the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. Section 300aa-1 et seq.) to seek possible recovery for unreimbursed expenses for certain injuries arising out of the administration of certain vaccines; and

(3) the vaccine excipient and media summary published by the Centers for Disease Control and Prevention for each immunization to be administered.

SECTION 2. This Act takes effect September 1, 2019.

86R13084 JG-F

Texas

By: Hall

S.B. No. 2350

A BILL TO BE ENTITLED
AN ACT

relating to the prohibited administration of certain vaccinations.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter A, Chapter 161, Health and Safety Code, is amended by adding Section 161.0045 to read as follows:

Sec. 161.0045. ADMINISTRATION OF CERTAIN VACCINES PROHIBITED. A health care provider may administer a vaccine only if:

(1) the study relied on by the United States Food and Drug Administration for approval of the vaccine evaluated the safety of the vaccine against a control group that received:

(A) a placebo; or

(B) another vaccine or other substance approved by the United States Food and Drug Administration based on a study that evaluated the safety of that vaccine or substance against a control group that received a placebo for that study;

(2) the study relied on by the United States Food and Drug Administration for approval of the vaccine evaluated the safety of the vaccine for a sufficient time to identify potential autoimmune, neurological, or chronic health conditions that may arise on or after the first anniversary of the date the vaccine is administered;

(3) the vaccine has been evaluated for the vaccine's potential to:

(A) cause cancer;

(B) mutate genes;

(C) affect fertility or cause infertility; and

(D) cause autism spectrum disorder;

(4) the department has posted on the department's Internet website a disclosure of any known injuries or diseases caused by the vaccine and the rate at which the injuries or diseases have occurred; and

(5) the chemical, pharmacological, therapeutic, and adverse effects of the vaccine and the rate of injury of the vaccine when administered with other vaccines have been studied and verified.

SECTION 2. This Act takes effect September 1, 2019.

REFERENCE TITLE: informed consent; vaccinations.

State of Arizona
House of Representatives
Fifty-fourth Legislature
First Regular Session
2019

HB 2471

Introduced by
Representative Barto: Senator Boyer

AN ACT

AMENDING TITLE 32, CHAPTER 32, ARTICLE 1, ARIZONA REVISED STATUTES, BY ADDING SECTION 32-3226; AMENDING SECTIONS 36-672 AND 36-673, ARIZONA REVISED STATUTES; RELATING TO IMMUNIZATIONS.

(TEXT OF BILL BEGINS ON NEXT PAGE)

Be it enacted by the Legislature of the State of Arizona:

Section 1. Title 32, chapter 32, article 1, Arizona Revised Statutes, is amended by adding section 32-3226, to read:

32-3226. Informed consent; vaccines

A HEALTH PROFESSIONAL WHO ADMINISTERS VACCINES MUST PROVIDE ALL OF THE FOLLOWING INFORMATION TO THE PATIENT OR, IF THE PATIENT IS A MINOR, THE PATIENT'S PARENT OR LEGAL GUARDIAN OR PERSON IN LOCO PARENTIS OF THE MINOR BEFORE ADMINISTERING A VACCINE:

1. THE BENEFITS AND RISKS OF EACH VACCINE.
2. THE VACCINE MANUFACTURER'S PRODUCT INSERT.
3. THE CENTERS FOR DISEASE CONTROL AND PREVENTION'S VACCINE EXCIPIENT AND MEDIA SUMMARY.
4. HOW TO REPORT A VACCINE-ADVERSE EVENT.

Sec. 2. Section 36-672, Arizona Revised Statutes, is amended to read:

36-672. Immunizations; department rules; required information

A. Consistent with section 15-873, the director shall adopt rules prescribing required immunizations for school attendance, the approved means of immunization and indicated reinforcing immunizations for diseases, and identifying types of health agencies and health care providers ~~which~~ THAT may sign a laboratory evidence of immunity. The rules shall include the required doses, recommended optimum ages for administration of the immunizations, persons who are authorized representatives to sign on behalf of a health agency and other provisions necessary to implement this article.

B. The director, in consultation with the superintendent of public instruction, shall develop by rule standards for documentary proof.

C. ANY INFORMATIONAL OR EDUCATIONAL MATERIALS THE DEPARTMENT DEVELOPS OR PROVIDES TO PARENTS AND GUARDIANS SHALL INCLUDE ALL OF THE INFORMATION REQUIRED TO BE PROVIDED FOR INFORMED CONSENT PURSUANT TO SECTION 32-3226.

~~C.~~ D. Immunization against the human papillomavirus is not required for school attendance.

Sec. 3. Section 36-673, Arizona Revised Statutes, is amended to read:

36-673. Duties of local health departments; immunization; reimbursement; training; informed consent

A. A local health department in cooperation with each school within the county shall provide for the required immunization of pupils attending school.

B. A local health department shall provide immunizations required for school attendance at no cost to the pupil or pupil's parent, guardian or person in loco parentis. In order to receive reimbursement for the cost of the immunization from the pupil's or parent's private health insurance coverage, the local health department may enter into a contract governing the terms of reimbursement and claims with the corresponding private health care insurer. The local health department may enter into a contract with a private health care insurer on its own, in conjunction with other local health departments or through a qualified intermediary. If the local health department chooses not to contract with a private health care insurer, or does not respond to the request to contract from a private health care insurer within ninety days ~~of~~ AFTER the request, the insurer is not required to reimburse the local health department for the immunization. If a private health care insurer declines or does not respond to a request to contract with a local health department, with a coalition of other local health departments or through a qualified intermediary within ninety days ~~of~~ AFTER the request to contract, the private health care insurer must reimburse the local health department at the rate paid to an in-network provider.

C. A local health department, on request by a school nurse and approval by the school administrator, shall train and authorize the school nurse to administer required immunizations.

D. A pupil ~~shall~~ MAY not be immunized without the informed consent of the parent, guardian or person in loco parentis of the pupil AS PROVIDED IN SECTION 32-3226. A pupil who is at least eighteen years of age or is emancipated may consent to immunization.

VACCINE INFORMATION STATEMENT

Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Influenza ("flu") is a contagious disease that spreads around the United States every year, usually between October and May.

Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.

Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms vary by age, but can include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Flu can also lead to pneumonia and blood infections, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

Flu is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk.

Each year **thousands of people in the United States die from flu**, and many more are hospitalized.

Flu vaccine can:

- keep you from getting flu,
- make flu less severe if you do get it, and
- keep you from spreading flu to your family and other people.

2 Inactivated and recombinant flu vaccines

A dose of flu vaccine is recommended every flu season. Children 6 months through 8 years of age may need two doses during the same flu season. Everyone else needs only one dose each flu season.

Some inactivated flu vaccines contain a very small amount of a mercury-based preservative called thimerosal. Studies have not shown thimerosal in vaccines to be harmful, but flu vaccines that do not contain thimerosal are available.

There is no live flu virus in flu shots. **They cannot cause the flu.**

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against three or four viruses that are likely to cause disease in the upcoming flu season. But even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Flu vaccine cannot prevent:

- flu that is caused by a virus not covered by the vaccine, or
- illnesses that look like flu but are not.

It takes about 2 weeks for protection to develop after vaccination, and protection lasts through the flu season.

3 Some people should not get this vaccine

Tell the person who is giving you the vaccine:

- **If you have any severe, life-threatening allergies.** If you ever had a life-threatening allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Most, but not all, types of flu vaccine contain a small amount of egg protein.
- **If you ever had Guillain-Barré Syndrome (also called GBS).** Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.
- **If you are not feeling well.** It is usually okay to get flu vaccine when you have a mild illness, but you might be asked to come back when you feel better.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get a flu shot do not have any problems with it.

Minor problems following a flu shot include:

- soreness, redness, or swelling where the shot was given
- hoarseness
- sore, red or itchy eyes
- cough
- fever
- aches
- headache
- itching
- fatigue

If these problems occur, they usually begin soon after the shot and last 1 or 2 days.

More serious problems following a flu shot can include the following:

- There may be a small increased risk of Guillain-Barré Syndrome (GBS) after inactivated flu vaccine. This risk has been estimated at 1 or 2 additional cases per million people vaccinated. This is much lower than the risk of severe complications from flu, which can be prevented by flu vaccine.
- Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Ask your doctor for more information. Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety/**

5 What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 and get the person to the nearest hospital. Otherwise, call your doctor.
- Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/flu**

Vaccine Information Statement

Inactivated Influenza Vaccine

08/07/2015

42 U.S.C. § 300aa-26

Office Use Only

School of Pharmacy
UNIVERSITY OF WISCONSIN-MADISON

April 15, 2019

State Senator Patrick Testin
Chair, Senate Committee on Health & Human Services
Assembly Committee on Health
Wisconsin State Capitol, 2 East Main St.
Madison, Wisconsin

Dear State Senator Testin:

I am a professor at the University of Wisconsin-Madison School of Pharmacy. I joined the faculty 21 years ago after completing my fellowship in Clinical Pharmacology and Vaccine Research at the Mayo Clinic. Since then, I have been active in teaching immunization to more than 3,000 pharmacists and pharmacy students, and my research lab investigates vaccine responses in immunosuppressed populations. I serve on the Wisconsin Council on Immunization Practices, am the contributing editor for the Vaccine Update in the *Journal of the American Pharmacists Association*, and have participated in a number of emergency preparedness planning committees.

Thank you very much for bringing SB 110/AB 137 to a public hearing. This legislation is crucial to increasing access to vaccinations across our state. Pharmacists are an easily accessible healthcare provider for patients across the state, in areas both rural and urban, and are uniquely positioned to provide immunization services to patients.

This bill seeks to increase patient access to immunizations by 1) allow pharmacists to immunize children under the age of 6, and 2) decreasing administrative burdens when providing immunizations to patients ages 6 and older.

Under current law, pharmacists in Wisconsin can immunize patients over the age of 6. This differs from the majority of states, which allow, in certain circumstances, pharmacists to immunize patients of any age. This bill will create the allowance for pharmacists to immunize patients of any age, but will have specific restrictions for patients under the age of 6 in acknowledgement of this unique population of children. First, the bill requires that a patient under 6 has a valid prescription order for their immunization. This ensures that the patient has visited a provider and is not skipping their regular check-ups or Well Child Visits. Second, the bill only allows the prescription to be valid for 30 days. Timing immunizations correctly is crucial, and this bill will help prevent an immunization from being given at the wrong time. Finally, the bill requires that pharmacists who immunize patients under 6 must undergo training in immunizing children under 6. This will ensure that pharmacists are well trained and can safely administer immunizations to children.

This bill also decreases administrative burdens to immunizing patients over the age of 6 by eliminating the requirement for a pharmacist to have a delegation protocol from a physician in order to provide an immunization. These protocols vary between pharmacies, as each physician sets the criteria for which vaccines may be provided, when, and to whom. These protocols limit a pharmacist's ability to provide all

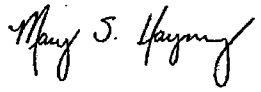
recommended vaccines to children and adults. This bill eliminates this burden and limitation by allowing pharmacists to follow the CDC's Advisory Committee on Immunization Practices (ACIP) immunization schedule. This will lessen the administrative burden on pharmacies while maintaining patient safety and allowing patients to receive immunizations they are approved to receive by ACIP at another access point.

Many pharmacists have asked me for help and advice to find a physician with whom to collaborate on their immunization protocols. As physicians become increasingly affiliated with health systems, they often are limited in their ability to collaborate with independent pharmacists who are not part of their particular health system. The protocol implementation may be delayed while the health system's legal team reviews it. Research has documented pharmacists' adherence to the ACIP recommendations. Lifting the immunization protocol requirement will help pharmacists provide quality immunization services to their patients.

Pharmacists are well positioned to expand access to immunizations, as more than 90% of Americans live within 5 miles of a pharmacy. Additionally, pharmacies are often open late, on weekends, and rarely require an appointment in order to receive an immunization – all factors that can greatly increase access for patients.

Thank you again for the opportunity to provide testimony in favor of AB 137 / SB 110.

Sincerely,



Mary S. Hayney, PharmD, MPH
Professor of Pharmacy (CHS)
University of Wisconsin School of Pharmacy

Good morning and thank you for your time. My name is Judith Jolly and I am a resident of Pardeeville Wisconsin. I came out today to testify against Senate Bill 110/ Assembly Bill 137.

Current law allows children 6 years of age and older to be vaccinated by pharmacists, however, there is no language to ensure that an individual or parent receives informed consent. Under the National Childhood Vaccine Injury Act of 1986, vaccine providers are required by law to give a patient or legal representative (ie parent) the appropriate Vaccine Information Statement (VIS) PRIOR to each dose of vaccine, including each dose of a multi-dose series, regardless of a person's age. Again, there is no language in the current law or in SB110/AB137 of this legal requirement. SB110/AB137 only requires a 12 hour course of study and training, approved by the Accreditation Council for Pharmacy Education or the pharmacy board. This legislature cannot just assume that pharmacists will be properly trained or that the board rules actually cover everything required under the National Childhood Vaccine Injury Act of 1986.

There is no language in SB110/AB137 requiring pharmacists to screen persons for allergies or contraindication to vaccination. Additional, as the current law does not require pharmacists to maintain a health record on each person they vaccinate and no language in SB110/AB137 requiring pharmacists to report adverse reactions to child's doctor or even to the Vaccine Adverse Events Reporting System (VAERS), as required by federal law, these reactions may go uncharted and unreported. Further, while SB110/AB137 requires pharmacists to enter data into the Wisconsin Immunization Registry within 7 days, it does not require pharmacists to double check in the registry prior to vaccine administration. As a result, an infant or young child may be at risk of receiving unnecessary and potentially harm inducing additional doses of vaccines.

Unlike a child's health care provider, pharmacists do not have any health history on a child. They may not be made fully aware of a child's medical history, allergies, or history of a previous vaccine reaction. This lack of knowledge can potentially place an infant or child at risk.

Vaccination is a medical procedure that needs to be performed in an environment of privacy, and one where safety is a priority. Vaccination of a young child is not the same as vaccination of a fully informed and

consenting adult. Vaccination sites for infants and young children differ from older children and adults, with the anterolateral thigh muscle considered the primary muscle for vaccine administration for most children under two years of age. As a result, clothing may need to be removed in order to safely vaccinate an infant or young child. Not all pharmacies are equipped with private rooms to ensure that a child's privacy is fully protected. Moreover, infants and children rarely sit still during invasive medical procedures such as vaccine administration and without a designated room or additional staff to accommodate the unique challenges involved in vaccinating infants and young children, this has significant potential to place a young child at a greater risk for injury.

Should an infant or child develop an acute reaction following vaccination, additional trained medical staff and adequate life-saving medical equipment may not necessarily be readily available to a pharmacist or pharmacy student. I have personally witnessed an adult experience an immediate reaction following vaccination at a local pharmacy that required EMS response. I saw first-hand how difficult and stressful the situation was for the pharmacist and staff, the vaccine recipient, and even concerned members of the general public who happened to be nearby.

Adverse events following vaccination can and do occur, and in most instances, there is no way to predict who will react, when, and how severely the reaction may be. As a result, vaccination of infants and young children must take place in a safe environment where there are a sufficient number of trained healthcare professionals close by to ensure that any adverse events are attended to promptly to ensure the safety and well-being of the infant or child. Further, should an adverse event occur, details of the event can be recorded promptly in the child's medical record and reported to the Vaccine Adverse Events Reporting System (VAERS), as required by law.

Public pharmacies are not an appropriate or safe environment for the administration of vaccines to infants and young children and I encourage you to vote "no" to SB 110/AB137. Thank you for your time.