2021 HOUSE HUMAN SERVICES

HB 1468

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

HB 1468
1/25/2021

Relating to informed consent and notice of risks associated with vaccines; and to provide a penalty

Chairman Weisz opened the hearing at 4:05 p.m.

Representatives	Attendance
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	P
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Vaccine exemption form
- Vaccine exemption detailed document

Rep. Kathy Skroch, District 26 (4:07) introduced the bill, testified in favor, and submitted testimony #3173 & #3176.

Kari Roller (4:14) testified in favor.

Brodi Alt, Watford City (4:20) testified in favor and submitted testimony #2670

Alexis Wangler, Co-Founder & President Health Freedom North Dakota (4:20) testified in favor.

Willow Hall (4:32) testified in favor.

Kolette Kramer, Denbigh North Dakota (4:35) testified in favor and submitted testimony #3187.

Jay Schroeder, South Heart (4:35) testified in favor.
Dr. Bob Zajac, New Kingdom Healthcare, Eden Prairie, MN (4:36) testified in favor.

Christine Miller, Bismarck (4:41) testified in favor and submitted testimony #2959.

Travis Zablotney, Minot (4:45) testified in favor.

Julia Petrovic, Rugby (4:49) testified in favor and submitted testimony #3199.

Tara Dukart, Hazen (5:02) testified in favor.

Dr. Ana Tobiasz, Maternal Fetal Medicine Physician Sanford Health (5:06) testified in opposition and submitted testimony #2583.

Dr. Joan Connell, Pediatrician Bismarck North Dakota (5:14) testified in opposition and submitted testimony #2515.

Courtney Koebele, Executive Director North Dakota Medical Association (5:29) introduced **Misty Anderson, President of the North Dakota Medical Association.**

Misty Anderson, President of the North Dakota Medical Association (5:29) testified in opposition and submitted testimony #3048.

Kathy Anderson, President North Dakota American Academy of Pediatrics (5:33) testified in opposition and submitted testimony #2822.

Parag Kumar, Pediatrician Sanford & UND School of Medicine (5:41) testified in opposition and submitted testimony #3049.

Molly Howell, Immunization Director North Dakota Department of Health (5:57) testified in opposition and submitted testimony #2530.

Additional written testimony: #2234, #2309, #2326, #2355, #2363, #2389, #2450, #2452, #2462, #2469, #2474, #2477, #2481, #2507, #2517, #2537, #2538, #2539, #2558, #2568, #2575, #2586, #2594, #2597, #2606, #2613, #2620, #2621, #2630, #2646, #2652, #2654, #2663, #2667, #2673, #2690, #2693, #2738, #2755, #2757, #2758, #2763, #2768, #2798, #2801, #2824, #2827, #2859, #2866, #2915, #2919, #2937, #2938, #2957, #2962, #2965, #2972, #2980, #2981, #3013, #3020, #3060, #3111, #3113, #3126, #3157, #3179, #3213, #3225, #3230, #4248

Chairman Weisz adjourned at 6:00 p.m.

Tamara Krause, Committee Clerk

HB 1468 INFORMED CONSENT FOR VACCINATION

Testimony-House Human Services Committee

Representative Kathy Skroch, District 26

67th Legislative Session

Chairman Weisz and members of the Human Services Committee,

For the record, I am Representative Kathy Skroch, District 26, Lidgerwood, ND, representing portions of Dickey, Ransom, Richland and all of Sargent counties of North Dakota.

Thank you, Chairman Weisz and members of the Human Services Committee, for allowing me to appear before you today to introduce HB1468 which creates a new section in Chapter 23-12 of NDCC.

This bill is being introduced on behalf of and by the request of concerned constituents from District 26 and from across the state of North Dakota.

The following concerns were raised and were addressed in part by this bill. There were complaints of the lack of sufficient information being provided to individuals, parents and guardians at the time vaccinations are being administered. Concerns were raised that insufficient information about the risks and side effects was being provided, was not received until after injections were received or not having received the information at all. In addition, time was not provided for individuals to ask questions or receiving answers prior to giving consent for immunizations.

Additionally, parents and individuals complained of: frequently being ill informed about the **medical, religious or philosophical** exemptions found in **section 23-07-17.1** of North Dakota Century Code; no access to forms; receiving no information about the requirements necessary to qualify for an exemption. Parents, patients and employees have felt rushed, bullied, pressured, and even threatened to accept immunization injections.

This in fact has been witnessed by medical and health professionals who often do not dare identify themselves for fear of retaliation. I have received written testimony from an employee who was forced to leave a former place of employment because of raising these concerns to a supervisor. Due to fear of being terminated from a current health related occupation, this witness will not put signature to this written testimony.

Section 23-07-17.1 is about a parent's or individual's rights for exemptions based on **religious, medical or philosophical grounds** but it is not a well protected right. **Subsection 6 and 7,** which has been provided, allows for a health officer to easily overrule any exemption.

In these situations, it is even more important for individuals, especially parents or guardians making decisions on behalf of their minor children, to be well informed of both the benefits and risks of vaccinations. In addition, when consent is granted, a parent, guardian or individual will be more prepared, more vigilant, should an adverse reaction occur and report these events to their medical provider.

Since the drafting of this bill some changes were necessary. Amendments were prepared to make these changes. A fiscal note was also requested. These along with links to sources are provided below (or see handout with amendments).

Thank you for the opportunity to introduce HB 1468 before the committee today. This is an important bill to address informed consent to vaccinate and I encourage a DO PASS recommendation from the committee. Thank you.

Representative Kathy Skroch

District 26

Lidgerwood, ND

Requested a fiscal note, this cannot be prepared until after amendments have been adopted by the committee and Amendment drafts proposed;

1. Include the definition for biologics unless it can be referenced else ware in code.

2.Page 1, line 13, after **a**. (insert) "a current vaccination immunization statement (VIS) or a vaccine package insert upon the request by the individual;" and

3. Page 2, line 2 after available (or where this would fit in in proper form) or on line 5, after that, "uses tactics that threaten, coerce, intimidate, bully or force an individual to receive a vaccine (under pressure or against their will), or for the purpose of coercing or pressuring a parent or guardian to grant permission for a minor child or ward against their (will or wishes) or violates this section" is guilty of an infraction.

REFERENCES:

https://www.icandecide.org/ican_lawsuits/the-food-and-drug-administration-fda-admits-it-has-never-licensed-any-influenza-vaccine-for-use-by-pregnant-women-and-does-not-have-a-single-trial-supporting-the-safety-of-this-practice/

https://physiciansforinformedconsent.org/

10/27/2020 Physicians for Informed Consent Publishes Influenza (Flu) Vaccine Risk Statement "9 Flu Vaccine Facts"

10/3/2020 Physicians for Informed Consent Provides Key Information in Medical Board of California Hearing, Aims to Protect Patients at Risk of Vaccine Side Effects

9/22/2020 Physicians for Informed Consent Sends Cautionary Letter to UC Board of Regents Regarding Its New Flu Shot Mandate, Emphasizes Lack of Scientific Basis

8/13/2020 Physicians for Informed Consent Publishes New Educational Document on Risk of Aluminum in Vaccines

6/5/2020 Physicians for Informed Consent (PIC) Compares COVID-19 to Previous Seasonal and Pandemic Flu Periods

3/6/20 Physicians for Informed Consent Reports on ResearchGate: Landmark FDA Paper on Aluminum Safety in Vaccines Has Crucial Math Error

3/6/20 Erratum in "Updated aluminum pharmacokinetics following infant exposures through diet and vaccination"

3/4/20 Best Practices for Physicians Recommending a Medical Exemption to Vaccination

Select Language

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(https://physiciansforinformedconsent.org/soon-it-may-become-illegal-for-california-mds-to-protect-children-in-their-practice-from-vaccine-injuries-or-deaths/#)

Soon, It May Become Illegal for California MDs to Protect Children in Their Practice from Vaccine Injuries or Deaths

Physicians for Informed Consent Doctors and Scientists Alert California Legislators

NEWPORT BEACH, CALIF. (PRWEB) MARCH 29, 2019

Although medical doctors and vaccine manufacturers have been protected from liability for vaccine injuries and deaths since the National Childhood Vaccine Injury Act of 1986 (https://www.congress.gov/bill/99th-congress/house-bill/5546), soon California doctors may no longer be able to protect their patients from vaccine injuries or deaths.

In 2015, California removed the personal belief exemption to vaccination for both private and public school attendance (https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160SB277), and the responsibility of recommending a medical exemption to at-risk children then fell on their physicians. Now, SB 276 (https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201920200SB276) seeks to prevent medical doctors from using their expertise and knowledge to protect at-risk children in their practice from vaccine injuries and deaths.

"If SB 276 becomes law, children at risk of severe vaccine injuries will be at the mercy of public health officials with whom they have no patient-doctor relationship, and past, current, and future medical exemptions will only be approved if a child's medical circumstances are found on a short government checklist," explained PIC Founder and President Dr. Shira Miller.

Physicians for Informed Consent has sent an open letter to California legislators opposing SB 276 (https://physiciansforinformedconsent.org/wp-content/uploads/2019/03/PIC-Oppose-SB276-3-27-19.pdf), citing that it is unscientific and unethical. "The chance of dying from measles in the United States is 1 in 10,000, based on data from the pre-vaccine era—when about 4 million U.S. children got measles every year," said Dr. Miller. "1 in 10,000 is about the same chance as being struck by lightning once in your lifetime. The problem is that the risk of dying or being permanently disabled by the measles, mumps, and rubella (MMR) vaccine has not been proven to be less than 1 in 10,000. This makes mandating the MMR vaccine unscientific and unethical."

"We all want healthy children," Dr. Miller continued, "and one of the best ways to accomplish that is by educating parents and doctors, not by using bad science and medical bullying, which are the antithesis of the ethical principle of informed consent—upon which modern medicine hinges."

"We all want healthy children," Dr. Miller continued, "and one of the best ways to accomplish that is by educating parents and doctors, not by using bad science and medical bullying, which are the antithesis of the ethical principle of informed consent—upon which modern medicine hinges."

Physicians for Informed Consent (https://physiciansforinformedconsent.org/) is a nationally recognized 501(c)(3) nonprofit educational organization representing hundreds of doctors, as well as scientists and attorneys, whose mission is to safeguard informed consent in vaccination. In addition, its Coalition for Informed Consent consists of over 150 member organizations which represent millions of Americans.

Click here (https://www.prweb.com/releases/soon_it_may_become_illegal_for_california_mds_to_protect_children_in_their_practice_from_vaccine_injuries_or_deaths/prweb16142003.htm) to view this press release on PRweb.
Click here (https://physiciansforinformedconsent.org/news) to view more PIC news.

Posted in Measles (https://physiciansforinformedconsent.org/category/measles/), Press Release (https://physiciansforinformedconsent.org/category/press-release/)
Tagged California (https://physiciansforinformedconsent.org/tag/california/), MMR (https://physiciansforinformedconsent.org/tag/mmr/), Vaccine Injury (https://physiciansforinformedconsent.org/tag/vaccine-injury/), Vaccines (https://physiciansforinformedconsent.org/tag/vaccines/)

the Defender™
CHILDREN'S HEALTH DEFENSE NEWS & VIEWS

01/22/21 • BIG PHARMA › VIEWS

Eagle Scout Sues Merck, Alleges Gardasil HPV Vaccine Destroyed His Life

This is the fifth Gardasil lawsuit Baum Hedlund and CHD Chairman Robert F. Kennedy, Jr. filed against Merck, challenging the company's dangerous and defective HPV vaccine for causing severe and life-changing injuries.

By Robert F. Kennedy, Jr.

five miles with ease. At six, he taught himself to speed read and handed in a book report on a 600-page novel.

Michael was a committed boy scout and member of his middle school's cross-country team. He pursued his passions for robotics, played in his school band and practiced Tae Kwon Do, earning his second-degree black belt at age 14, just months before he received the Gardasil HPV vaccine.

He raised service dogs for the disabled and earned his certification in first aid with special training in emergency preparedness.

After the vaccine, that all went away.

Years of Merck's relentless marketing persuaded Kathy Colbath to allow her child to receive Gardasil. Merck falsely claimed that Gardasil was safe and effective, and that it would protect children against certain cancers. Merck's advertising said that good mothers must vaccinate their teenagers with Gardasil or face tragic consequences.

In the months following his first injection, exhaustion and extreme fatigue forced Michael away from the sports and hobbies that had been centerpieces of his life. He had trouble staying awake during the school day.

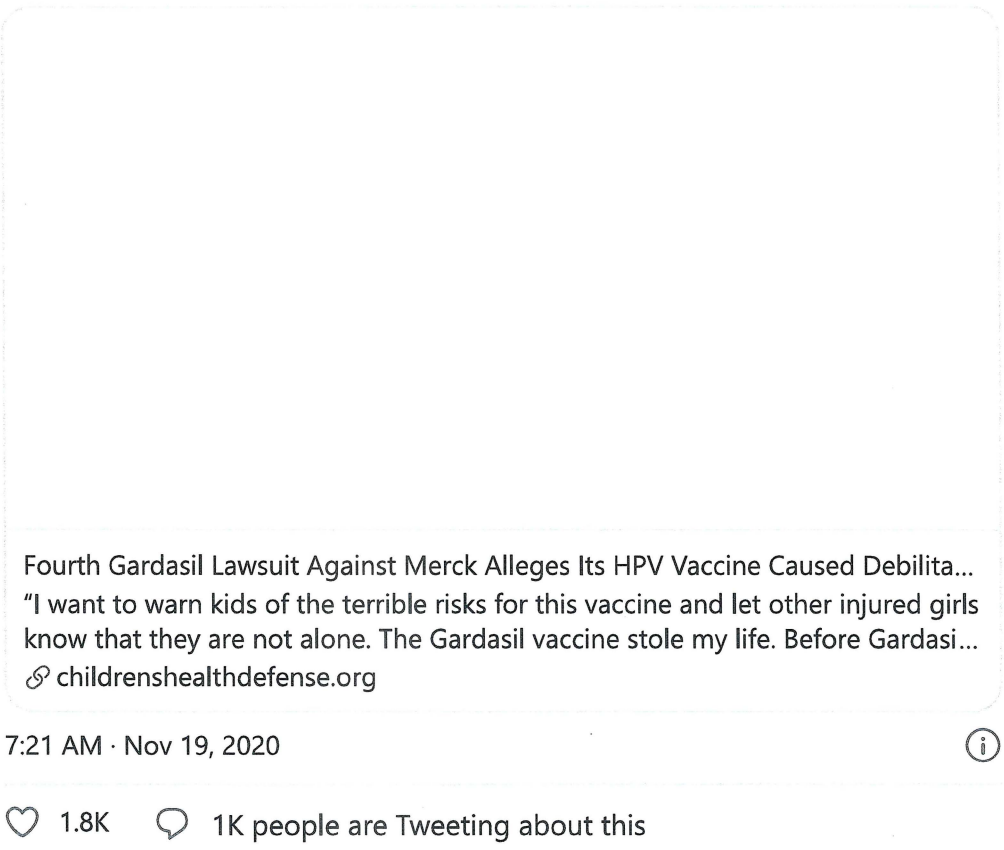
After his second Gardasil injection, Michael developed severe foot pain in both feet, so severe that he needed crutches to attend school. He had trouble waking up in the morning and getting out of bed.

As his symptoms worsened, multiple physicians and specialists treated him for migraine headaches; body pains and muscle aches; chronic fatigue; hypersomnolence (sleeping 15-22 hours in a 24-hour period), sleep drunkenness, unrefreshing sleep; excessive sweating, lightheadedness, and tachycardia; tunnel vision on standing; difficulty with concentration and memory; confusion and brain fog; intermittent or episodic paralysis, numbness; and stomach pains.

Michael's post-Gardasil injuries and diagnoses, including postural orthostatic tachycardia syndrome (POTS), idiopathic hypersomnia (IH), myalgic encephalomyelitis / chronic fatigue syndrome (ME / CFS), complex regional pain syndrome (CRPS) and gastroparesis, kept him from his passions, sports and hobbies. He missed most of high school and only his formidable self-discipline allowed him to complete his school work at home — he could not walk or move unassisted, he earned his Eagle Scout award using a knee scooter.

Robert F. Kennedy Jr
@RobertKennedyJr

#TheDefender #BigPharma #ProfitsOverPeople



Only this unusual talent and drive allowed him to earn admission into the University of California San Diego (UCSD), as a data science major. He can only take a class or two at a time.

Michael is currently taking a daily regimen of 10 strong medications. He can only walk about 500 steps per day.

If Mrs. Colbath had known that Gardasil could create these health issues, she never would have allowed him to receive it.

This is the fifth Gardasil lawsuit Baum Hedlund and I have filed against Merck challenging the company's dangerous and defective HPV vaccine for causing severe and life changing injuries. In addition to Mike's case filed this week, we have filed cases on behalf of Sahara Walker of Wisconsin, Zach Otto of Colorado and Julia Balasco of Rhode Island. While each case is unique, they share common threads: All of our clients were happy, healthy, bright, active kids with unlimited potential until they received the Gardasil HPV vaccine. We look forward to getting these cases in front of a jury as soon as possible.

Good afternoon Mr. Chairman and committee members.

My name is Brodi Alt and I'm writing to you in support of House Bill No. 1468.

This bill is important to me because informed consent is the backbone of ethics in medicine. As a Registered Nurse of 6.5 years, I have administered many vaccinations. Along with administering vaccinations, I provided patients the Vaccine Information Statement, known as the VIS, which you have a sample of in front of you. This single sheet of paper includes a small amount of information pertaining to the vaccine, including possible reactions. Although this short list is factual, it is not all-inclusive. Patients need to be fully aware of adverse reaction should they occur, which are laid out for full review in the package insert and include conditions like diabetes, seizures, paralysis, eczema, food allergies, death - the list goes on and on. *These* are the adverse reactions patients need to be aware of.

I'd like to draw your attention to section 13.1, which is highlighted for you in blue. This section in every insert states that said vaccine has not been evaluated for its carcinogenic or mutagenic potential or its potential to impair fertility. In other words, it is unknown whether the vaccine can cause cancer, induce mutations, or impair fertility. This information is not disclosed on the VIS sheet. I ask that you take a look at the difference in information presented in the two documents and decide for yourself which information you would appreciate knowing before consenting.

Why in my 4 years of education, did I spend so little time learning about vaccinations? I spent countless hours having to memorize and understand potential side effects of all classes of medications and procedures, in preparation to properly educate my patients. Educating patients is a critical part of my job, yet I walked away with my Bachelors of Science in Nursing knowing nothing about vaccine reactions.

Nursing is known as the most trusted profession, which I deeply value and makes me proud of what I do. Although I have educated myself on vaccine adverse effects, I am one of the few. Because of this, the package insert should be presented to the patient for full disclosure. Patients deserve more information than what they are provided. And they deserve to be informed *before* consenting.

Thank you for your time.

Brodi Alt

Watford City, ND

2:00 monday

I am in favor of HB 1468 and urge you to send this on with a "Do Pass".

25 years ago when I started having children, when you took your child in for immunizations, you received color coded sheets for each shot being given. Over time, they have recommended that you print them off the CDC's website. Or if you ask, they will try and print one for you. The handout is not the same as the vaccine insert. I would encourage all parents to know exactly what is being injected into their children's bodies, the possible side effects, and any long term medical issues that may arise that the vaccine could have triggered.

I also agree that after reviewing the vaccine insert, the parent should then be asked if they want the child to receive the vaccines and told that if they do not want one or all of the immunizations, that they can sign an exemption form and the child can still attend daycare and school, or that an adult may still work.

We've talked about the availability of exemption forms and if parents are being told they can request one or use one. I requested a student handbook from my local school district, the letter that goes out to Kindergarten students, their policy on immunizations, and the exemption forms but have not received the information.

Another stressful time in a woman's life is when she is pregnant and in labor. Many questions are not asked ahead of time and decisions need to be made in the heat of the moment. Some are actually considered a "given" unless the mother specifically states that she does NOT want her baby to be vaccinated at birth. So if they don't give out the information, they will assume she does want the baby to be. Many mothers never even know and are not given a sheet about the Hep B shot that their child receives. This bill would increase awareness and save the mom from making a decision while in active labor or recovering from the labor.

Holette Kramer,
Denbigh, ND

Christine Miller
922 East Owens Avenue Apt 8
Bismarck, ND 58501

January 25, 2021

Regarding: HOUSE BILL 1468 – A BILL for an Act to create and enact a new section to chapter 23-12 of the North DakotaCentury Code, relating to informed consent and notice of risks associated with vaccines; and to provide a penalty.

Dear Committee Members,

I am in favor of passing HB 1468 because above all the freedoms I enjoy as an American and as a citizen of North Dakota, is the freedom and responsibility to protect my own personal health, by choosing to accept or reject any and all medical advice, procedures, tests, drugs or vaccines. I also cherish the right to make these decisions for my children. These are rights I believe all human beings should be afforded.

I remember in my childhood that my mother would always get very sick and often ended up in the hospital after receiving a flu vaccine. She was asthmatic and the flu vaccine always exacerbated her asthma. I didn't think much of it as a child, and I wasn't the least bit skeptical about vaccines until I had my first child. Previous to having my own children in the early 2000's, I had worked with children for many years as a Nanny and I had nieces and nephews. I knew that children in the 80's received around 10 - 12 vaccines from birth until they reached school age. So, when I took my first born to the doctor for her first well-baby visit in 2002, I was astonished that they wanted to give her 8 vaccines at one time! (Today's children receive 72 or more vaccines from birth till they reach adulthood). I remember a sick feeling of dread and a mother's intuition that 8 vaccine injecting into a tiny baby at one time was safe. I asked the doctor if it was safe to inject so many vaccines into a 10 lb infant. I will never forget her response. She said it was like “pee in the ocean.” I was handed a sheet of paper about each vaccine which listed only a few possible adverse reactions such as fever, soreness at the injection site, and crying. Nothing I read seemed too alarming. Still, the feeling of dread in my stomach did not subside, but I made the choice to trust the doctor, in part based on the information that I received on those hand-outs, and I went ahead with the vaccines for my baby. Fortunately, my baby had no serious side effects in the days immediately following her vaccinations, but I did notice that she developed a stuffy nose that would not subside and it eventually became apparent to her doctor that she was now allergic to dairy, which she had not been prior to those vaccines. From the time of those vaccine at her two month doctor visit my baby could no longer tolerate milk so I had to be dairy free while nursing her and supplement with soy formula.

Later in life this daughter developed many health conditions which I will not elaborate on to protect her privacy, but I will say that these conditions are related to a genetic mutation that runs in my family and makes a person more susceptible to adverse vaccine reactions, and I will elaborate on that later in this testimony. For now I will say that had I had the knowledge then that I do now, which I would have if doctors were legally required to give proper Informed Consent before administering vaccines, I would have not had my daughter vaccinated and she would not have suffered the lifelong, vaccine-induced afflictions that she has suffered.

When my second child was born, I was not terribly hesitant about vaccines because my firstborn had survived without serious injury (I was not aware yet that

vaccines likely caused her milk allergy, and other issues, and I was also not aware that many vaccine induced adverse effects do not occurrence immediately). My second child also had no immediate serious side effects but weeks after her vaccines she developed a severe case of eczema. I am not exaggerating when I tell you that her entire face was covered in huge red welts. The only parts of her face that were not

covered in angry welts were the tip of her nose, her eyelids, and her lips. Needless to say, I was panicked. Her doctor said that this was the worse case of eczema she had ever seen in an infant. Fortunately, treatment cleared up this first outbreak, but my daughter continued to suffer from painful eczema outbreaks throughout her life. At four months of age my baby daughter received her second round of vaccines. Days later I found her limp and grey in her crib. At the doctor's office I was told that she went limp and turned grey from a high fever and that she had Rotavirus. No mention was made that vaccines could have had anything to do with it. I have since learned that the vaccine insert for most childhood vaccines, which parents never see because the law does not require them this information to be provided) plainly states that SIDS (Sudden Infant Death Syndrome) is a possible avers reaction from childhood vaccines. I will never know what really happened to my daughter that day. But what I do know is that I never received truthful, and complete information about the benefits or risks of vaccines before my children were vaccinated at their well-baby exams.

I will note here that there was nothing on the vaccine information hand-outs that I received at the doctor's office about the possibility of vaccines causing eczema or food allergies. I have since learned that the vaccine package inserts do list allergies and eczema as possible adverse reactions to vaccines, but this information was not given to me.

I have also learned that the current CDC Vaccine Schedule has never been studied! There are no studies at all to examine the safety of administering numerous vaccines at the same time. Children in my day received fewer than 15 vaccines from birth till adulthood. Today's children receive 72 or more! But the safety of injecting so many vaccines at once has never been studied!!

My niece's children were much more severely effected by vaccines. My first great-nephew had no mental or physical health problems whatsoever until he was about 2 years old when he developed an eye tick which the doctor initially said was probably normal and not to worry about it. Sadly, it was not normal and my formerly happy and healthy nephew became deluged with anxiety and phobias. He would not sleep alone, nor leave his mother's side, ever. He became terrified of normal daily objects like the television and radio. He developed a phobia of riding in a car. He began having behavioral problems and his life became unbearable. He also developed severe eczema and food allergies which he did not have prior. After years of searching for answers my sister finally found a doctor who diagnosed him with a condition called PANDAS. PANDAS stands for Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections. This condition is as terrifying as it sounds. To be brief, this disease causes a child's body to react to strep throat infection by producing antibodies that attack the brain instead of the strep infection, PANDAS, the doctor told us, is caused by vaccines. My nephew's genetic testing showed that it was the Prevnar vaccine that triggered his PANDAS. My nephew's life was ruined by this condition.

Sadly, two years later his baby brother became lethargic and nearly catatonic after his 12 month vaccines. He stopped walking and talking and would do nothing but lay on the floor or sleep all day. He was admitted to the hospital where he spent 6 days. A CAT Scan showed brain swelling which vaccine inserts document is a possible side effect of almost all childhood vaccines (which I might add is not listed on the vaccine information hand-outs given out at doctor's office visits).

The doctors said there was nothing they could do but wait. He was behaving very much like an autistic child and we feared the worst. He had to relearn how to walk, and he spent weeks in what looked like some sort of daze. He just wasn't the same child and we all thought he might never recover. Fortunately my great-nephew was one of the lucky ones. It took months, but he did recover for the most part; but like his brother he developed fears and anxieties, as well as food allergies, and eczema.

Due to the severity and hopelessness of my first-nephew's condition (PANDAS), my sister and niece began a long journey of research and visits with many medical specialists. Eventually they learned that some people have a genetic mutation called MTHFR. This is a defect that prevents the body from performing normal processes which require methylation. (There are 250 or more processes in the body which rely on methylation). One significant problem with methylation defects is that they prevent the body from detoxing so toxins accumulate in the body and brain. How is this related to vaccines? Well, vaccines contain preservatives which are toxins to the human brain and body. People with MTHFR mehtylation defects cannot detox after vaccinations which leads to all kinds of physical and mental diseases and disabilities. It is worth noting here that vaccine ingredients are rarely, if ever, disclosed to patients or parents of children before vaccines are administered.

It is likely that I also have an MTHFR mutation because both of my great-nephews do and genetic testing showed they have a double mutation, meaning they got a copy from both sides of the family, and one of my daughters has been diagnosed with it as well. For this reason, and others, I have decided not to take vaccines for the last 19 years and I have no doubt that that decision has been the right decision for me.

In addition to avoiding vaccines, I am a person who cherishes my right to choose when it comes to my health. It would be my worst nigthmare to live in a state or country in which I did not have Health Freedom.

Unlike myself, I have a sister who fears nothing when it comes to medical treatment. She had gastric bypass surgery in 2005 and suffered some very serious complications requiring numerous surgeries to correct. She's also undergone back surgery and a surgery to fix a broken arm. As most sisters would, I'd always call her the day before or morning of her surgery to tell her I was thinking of her and praying for her. I would ask, “What kind of surgery are you having. What are they going to do?” Her typical response was something like, “I don't know, something with my intestines.” I was always flabbergasted that she could be so unconcerned!

I, on the other hand, will take my doctors advice home with me and research for days or weeks or months before deciding. I am keenly aware that, while most doctors are well-meaning and wish me no harm, that they are human beings and they make mistakes. And I understand that science is not infallible and that knowledge of science and medicine changes over time. I don't go to a doctor and think of him or her as a god or all-knowing being like my sister does. I feel a burden to research my illnesses and treatments to determine what is best for myself.

I am grateful that being an American and a citizen of North Dakota allows me to take my healthcare into my own hands - for the most part. I am very thankful that when a doctor advises me to have surgery, I am given an Informed Consent form which lays out all the possible complications so that I can make a decision based on truthful and adequate information. I am also grateful that when my doctor prescribes a medication, I am given an informative drug information sheet that comes with my prescription so I can decide if I feel comfortable with the risks and benefits of that particular medication.

Unfortunately, vaccine administration is not treated the same way as surgery and prescribed drugs. Information on ingredients, and efficacy, and on adverse reactions is not given to patients before vaccines are administered. All that is given is a one page fact sheet with very minimal information usually including only the most common and least serious side effects. No ingredients are revealed to patients or parents. No information on the benefits to risk ratios are disclosed. The truth about efficacy is not revealed. Patients who receive vaccines and parents who consent to vaccines for their children are doing so blindly, and that is wrong and should be criminal.

When I go grocery shopping, I read labels. Manufacturers are required to list all ingredients. Why are vaccines manufacturers not required to do the same?

I am very fearful about losing my right to decide for myself if a vaccine is safe for my body. Like my mother, I have severe asthma and I have chosen up to this time to avoid vaccines because they made my mother so sick and because the one time I did get a flu vaccine in my adult life, I also became very sick. It is quite likely that I have the MTHRF genetic mutation that runs in my family which means I am at high risk of developing serious adverse reactions and even life long debilitating diseases or conditions if I take a vaccine.

In closing, please do pass HB 1468. Patients should have the right to know what is being injected in to their bodies and they should have the right to consent based on truthful, complete, and unbiassed information. Vaccines should only be administered when proper Informed Consent is provided.

Sincerely,

Christine Miller

January 25th, 2021

Legislative testimony for HB 1468

Thank you for allowing me to speak to you today. My name is Julia Petrovic and I live in Rugby. I am here today to speak with you about House Bill1468 which deals with true informed consent prior to receiving vaccinations. I want you to know that I strongly support this bill.

1. Are Vaccines Effective? What is the meaning of "effective" when applied to vaccines?

Webster's Dictionary: "effective"- adequate to accomplish a purpose,- producing the intended or expected result, - fulfilling a specific function.

Yes, vaccines are effective , BUT....

<Researchers investigate the ability of injected matter to stimulate the production of an antibody.

<...but the presence of an antibody DOES NOT guarantee protection from the illness.

EFFECTIVE DOES NOT mean PROTECTIVE

I would like to use the Tetanus Vaccine as an example.

What is Tetanus?

- Tetanus is a condition manifested by severe muscle spasms with the slightest movement. The muscle spasms can involve the muscles of the neck and severe clenching of the teeth, hence the name "lock jaw"

- The Tetanus is caused by a toxin made by spores of bacteria, *clostridium tetani.*

- The spores release an extremely potent toxin called *tetanospasmin.*

- It can take 2-14 days for the toxin to migrate along the neuron to the spine cord

A PROPER WOUND CARE is essential! Keep the wound open, because tetanus bacteria will thrive in anaerobic environment. Proper bleeding of the wound is ESSENTIAL! Bleeding clears out the clostridium tetani spores and brings oxygen and white blood cells to neutralize the bacteria.

2. Tetanus Factoids:

- There is no diagnostic laboratory test for tetanus, the diagnostic is entirely clinical (observing the muscle spasms)

-Clostridium Tetani is recovered from wounds in only about 30% of cases of clinical studies

-The organism is sometimes isolated from patients with dirty wounds but DO NOT have clinical tetanus

- Tetanus can occur with "protective" levels of antitoxin (>0.1 IU/dl)

Reference: Manual for the Surveillance of Vaccine-Preventable Diseases, Chapter 16: Tetanus

So, **effective does not mean PROTECTIVE.**

The next time you hear a vaccine is "effective" think...

"When a foreign matter is injected into a person , an antibody is generated to assist in the elimination of the foreign matter. Do I want to risk the potential vaccine side effects- which can include death-to develop an antibody that probably does nothing to to keep me from getting sick?"

Package inserts are the only proper document for TRUE INFORMED CONCENT.

Lets refer to a copy of a package insert of DAPTACEL (Diphteria and Tetanus Toxoids and Acellular Pertusses Vaccine Absorbed).

-Dosage and Administration, -Contraindications, -Warning and Precautions, - Adverse Reactions, -Data from Post-Marketing Experience, -Drug Interaction, -Use in specific Population, etc.

5.5 Limitations of the Vaccine effectiveness

Vaccination with DAPTACEL may not protect all individuals

6.1 Data from Clinical Studies. ...the safety of Daptacel was compared with DT and a whole-cell pertussis DTP Vaccine. No golden standard of randomized double-blind placibo!

8.4 Daptacel is not indicated for use in infants below 6 weeks of age or children 7 years of age or older, Safety and effectiveness of Daptacel in these age groups have not been established.

13.1 DDaptacel has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.

Useful info:

www.vaccinesafety.edu (John Hopkins University website on package inserts)

drugs.com (lists 270 oral drugs that can interact with the flu vaccine)

Conclusion:

I hope I successfully demonstrated how important a true informed consent is and how crucial it is for a patient to know all the risks and potential benefits to receiving a vaccine. Some side effects of a vaccine can be quite life changing, and not in a good way.

Thank you very much for your time.

Selective References:

Tetanus in the Fully Vaccinated

1.Crone , NE, Reder AT. "Severe tetanus in immunized patients with high anti-tetanus titers." Neurology, April 42(4).761-4.1992

2.Shimoni, Zvi., et. al." Tetanus in a immunized patient." British Medical Journal (BMJ), Vol. 319. October 16, 1999.

3. Beltan, Alvaro, et.al."A case of Clinical Tetanus in a Patient with a Protective Anti-tetanus Antibody Level." Southern Medical Journal (SMJ), Vol. 100, Issue 1, 2007.

4. Ergonul O, et al. " An unexpected tetanus case." Lancet Infect. Dis. Jun: 16 (6):746-752.2016.

Sanofi Pasteur
253 - DAPTACEL®

Full Prescribing Information

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use DAPTACEL safely and effectively. See full prescribing information for DAPTACEL.

DAPTACEL (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed)
Suspension for Intramuscular Injection
Initial U.S. Approval: 2002

INDICATIONS AND USAGE

- DAPTACEL is a vaccine indicated for active immunization against diphtheria, tetanus and pertussis as a five dose series in infants and children 6 weeks through 6 years of age (prior to 7th birthday). (1)

DOSAGE AND ADMINISTRATION

- The five dose immunization series consists of a 0.5 mL intramuscular injection administered at 2, 4, 6 and 15-20 months of age, and at 4-6 years of age. (2.1, 2.2)

DOSAGE FORMS AND STRENGTHS

- Suspension for injection, supplied in single dose (0.5 mL) vials (3)

CONTRAINDICATIONS

- Severe allergic reaction (e.g. anaphylaxis) after a previous dose of any diphtheria toxoid, tetanus toxoid, or pertussis-containing vaccine, or any component of DAPTACEL. (4.1)
- Encephalopathy within 7 days of a previous pertussis-containing vaccine with no other identifiable cause. (4.2)
- Progressive neurologic disorder until a treatment regimen has been established and the condition has stabilized. (4.3)

WARNINGS AND PRECAUTIONS

- Carefully consider benefits and risks before administering DAPTACEL to persons with a history of:
  - fever ≥40.5°C (105°F), hypotonic-hyporesponsive episode (HHE) or persistent, inconsolable crying lasting ≥3 hours within 48 hours after a previous pertussis-containing vaccine. (5.2)
  - seizures within 3 days after a previous pertussis-containing vaccine. (5.2)
- If Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following DAPTACEL. (5.3)
- For infants and children with a history of previous seizures, an antipyretic may be administered (in the dosage recommended in its prescribing information) at the time of vaccination with DAPTACEL and for the next 24 hours. (5.4)
- Apnea following intramuscular vaccination has been observed in some infants born prematurely. The decision about when to administer an intramuscular vaccine, including DAPTACEL, to an infant born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination. (5.7)
- Syncope (fainting) has been reported following vaccination with DAPTACEL. Procedures should be in place to prevent falling injury and manage syncopal reactions. (5.8)

ADVERSE REACTIONS

- Rates of adverse reactions varied by dose number, with systemic reactions most frequent following doses 1-3 and injection site reactions most frequent following doses 4 and 5. Systemic reactions that occurred in >50% of subjects following any dose included fussiness/irritability, inconsolable crying, and decreased activity/lethargy. Fever ≥38.0°C occurred in 6-16% of US subjects, depending on dose number. Injection site reactions that occurred in >30% of subjects following any dose included tenderness, redness and increase in arm circumference. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi Pasteur Inc., at 1-800-822-2463 (1-800-VACCINE) or VAERS at 1-800-822-7967 and http://vaers.hhs.gov.

DRUG INTERACTIONS

- In cases where DAPTACEL and Menactra are to be administered to children 4 through 6 years of age, the two vaccines should be administered concomitantly or Menactra should be administered prior to DAPTACEL. Administration of Menactra one month after DAPTACEL has been shown to reduce meningococcal antibody responses to Menactra. (7.1)
- Do not mix with any other vaccine in the same syringe or vial. (7.1)
- Immunosuppressive therapies may reduce the immune response to DAPTACEL. (7.2)

See 17 for PATIENT COUNSELING INFORMATION.
Revised: [09/2016]

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION:

1 INDICATIONS AND USAGE

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and pertussis as a five-dose series in infants and children 6 weeks through 6 years of age (prior to seventh birthday).

2 DOSAGE AND ADMINISTRATION

2.1 Immunization Series

DAPTACEL is to be administered as a 5 dose series at 2, 4 and 6 months of age (at intervals of 6-8 weeks), at 15-20 months of age and at 4-6 years of age. The first dose may be given as early as 6 weeks of age. Four doses of DAPTACEL constitute a primary immunization course for pertussis. The fifth dose is a booster for pertussis immunization. Three doses of DAPTACEL constitute a primary immunization course for diphtheria and tetanus. The fourth and fifth doses are boosters for diphtheria and tetanus immunization. [See *Clinical Studies (14.1, 14.2, 14.3)*.]

DAPTACEL should be used as the fifth dose of the DTaP series in children who initially received 4 doses of Pentacel® [(Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) vaccine, Sanofi Pasteur Limited]. Pentacel and DAPTACEL contain the same pertussis antigens, manufactured by the same process, although Pentacel contains twice the amount of detoxified pertussis toxin (PT) and four times the amount of filamentous hemagglutinin (FHA) as DAPTACEL.

Data are not available on the safety and effectiveness of using mixed sequences of DAPTACEL and DTaP vaccines from different manufacturers for successive doses of the DTaP vaccination series. DAPTACEL may be used to complete the immunization series in infants who have received 1 or more doses of whole-cell pertussis DTP. However, the safety and efficacy of DAPTACEL in such infants have not been fully demonstrated.

If a decision is made to withhold any recommended dose of pertussis vaccine, [see *Contraindications (4.2), (4.3)* and *Warnings and Precautions (5.2)*], Diphtheria and Tetanus Toxoids Adsorbed For Pediatric Use (DT) should be administered.

2.2 Administration

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exist, the product should not be administered.

After removing the "flip-off" cap, cleanse the vaccine vial stopper with a suitable germicide. Do not remove either the rubber stopper or the metal seal holding it in place. Just before use, shake the vial well, until a uniform, white, cloudy suspension results.

Using a sterile needle and syringe and aseptic technique, withdraw and administer a single 0.5 mL dose of DAPTACEL intramuscularly. Use a separate sterile needle and syringe for each injection. Changing needles between withdrawing the vaccine from the vial and injecting it into a recipient is not necessary unless the needle has been damaged or contaminated. In infants younger than 1 year, the anterolateral aspect of the thigh provides the largest muscle and is the preferred site of injection. In older children, the deltoid muscle is usually large enough for injection. The vaccine should not be injected into the gluteal area or areas where there may be a major nerve trunk.

Do not administer this product intravenously or subcutaneously.

DAPTACEL should not be combined through reconstitution or mixed with any other vaccine.

3 DOSAGE FORMS AND STRENGTHS

DAPTACEL is a suspension for injection in 0.5 mL single dose vials. See *Description (11)* for a complete listing of ingredients.

4 CONTRAINDICATIONS

4.1 Hypersensitivity

A severe allergic reaction (eg, anaphylaxis) after a previous dose of DAPTACEL or any other tetanus toxoid, diphtheria toxoid, or pertussis-containing vaccine, or any other component of this vaccine is a contraindication to administration of DAPTACEL. [See *Description (11)*.] Because of uncertainty as to which component of the vaccine may be responsible, none of the components should be administered. Alternatively, such individuals may be referred to an allergist for evaluation if further immunizations are to be considered.

4.2 Encephalopathy

Encephalopathy (eg, coma, decreased level of consciousness, prolonged seizures) within 7 days of a previous dose of a pertussis containing vaccine that is not attributable to another identifiable cause is a contraindication to administration of any pertussis-containing vaccine, including DAPTACEL.

4.3 Progressive Neurologic Disorder

Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy is a contraindication to administration of any pertussis-containing vaccine, including DAPTACEL. Pertussis vaccine should not be administered to individuals with such conditions until a treatment regimen has been established and the condition has stabilized.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs.

5.2 Adverse Reactions Following Prior Pertussis Vaccination

If any of the following events occur within the specified period after administration of a whole-cell pertussis vaccine or a vaccine containing an acellular pertussis component, the decision to administer DAPTACEL should be based on careful consideration of potential benefits and possible risks. [See *Dosage and Administration (2.1)*.]

- Temperature of ≥40.5°C (105°F) within 48 hours, not attributable to another identifiable cause.
- Collapse or shock-like state (hypotonic-hyporesponsive episode (HHE)) within 48 hours.
- Persistent, inconsolable crying lasting ≥3 hours within 48 hours.
- Seizures with or without fever within 3 days.

5.3 Guillain-Barré Syndrome and Brachial Neuritis

A review by the Institute of Medicine found evidence for a causal relation between tetanus toxoid and both brachial neuritis and Guillain-Barré syndrome. (1) If Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following DAPTACEL.

5.4 Infants and Children with a History of Previous Seizures

For infants or children with a history of previous seizures, an appropriate antipyretic may be administered (in the dosage recommended in its prescribing information) at the time of vaccination with a vaccine containing an acellular pertussis component (including DAPTACEL) and for the following 24 hours, to reduce the possibility of post-vaccination fever.

5.5 Limitations of Vaccine Effectiveness

Vaccination with DAPTACEL may not protect all individuals.

5.6 Altered Immunocompetence

If DAPTACEL is administered to immunocompromised persons, including persons receiving immunosuppressive therapy, the expected immune response may not be obtained. [See *Immunosuppressive Treatments (7.2)*.]

5.7 Apnea in Premature Infants

Apnea following intramuscular vaccination has been observed in some infants born prematurely. The decision about when to administer an intramuscular vaccine, including DAPTACEL, to an infant born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination.

5.8 Syncope

Syncope (fainting) has been reported following vaccination with DAPTACEL. Procedures should be in place to prevent falling injury and manage syncopal reactions.

6 ADVERSE REACTIONS

6.1 Data from Clinical Studies

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to vaccine use and for approximating rates of those events.

Approximately 18,000 doses of DAPTACEL have been administered to infants and children in 9 clinical studies. Of these, 3 doses of DAPTACEL were administered to 4,998 children, 4 doses of DAPTACEL were administered to 1,725 children, and 5 doses of DAPTACEL were administered to 485 children. A total of 989 children received 1 dose of DAPTACEL following 4 prior doses of Pentacel.

In a randomized, double-blinded pertussis vaccine efficacy trial, the Sweden I Efficacy Trial, conducted in Sweden during 1992-1995, the safety of DAPTACEL was compared with DT and a whole-cell pertussis DTP vaccine. A standard diary card was kept for 14 days after each dose and follow-up telephone calls were made 1 and 14 days after each injection. Telephone calls were made monthly to monitor the occurrence of severe events and/or hospitalizations for the 2 months after the last injection. There were fewer of the solicited common local and systemic reactions following DAPTACEL than following the whole-cell pertussis DTP vaccine. As shown in Table 1, the 2,587 infants who received DAPTACEL at 2, 4 and 6 months of age had similar rates of reactions within 24 hours as recipients of DT and significantly lower rates than infants receiving whole-cell pertussis DTP.

Table 1: Percentage of Infants from Sweden I Efficacy Trial with Local or Systemic Reactions within 24 Hours Post-Dose 1, 2 and 3 of DAPTACEL compared with DT and Whole-Cell Pertussis DTP Vaccines

EVENT	Dose 1 (2 MONTHS)			Dose 2 (4 MONTHS)			Dose 3 (6 MONTHS)		
	DAPTACEL N = 2,587	DT N = 2,574	DTP N = 2,102	DAPTACEL N = 2,563	DT N = 2,555	DTP N = 2,040	DAPTACEL N = 2,549	DT N = 2,538	DTP N = 2,001
Local									
Tenderness (Any)	8.0*	8.4	59.5	10.1*	10.3	60.2	10.8*	10.0	50.0
Redness ≥2 cm	0.3*	0.3	6.0	1.0*	0.8	5.1	3.7*	2.4	6.4
Swelling ≥2 cm	0.9*	0.7	10.6	1.6*	2.0	10.0	6.3*†	3.9	10.5
Systemic									
Fever‡ ≥38°C (100.4°F)	7.8*	7.6	72.3	19.1*	18.4	74.3	23.6*	22.1	65.1
Fretfulness§	32.3	33.0	82.1	39.6	39.8	85.4	35.9	37.7	73.0
Anorexia	11.2*	10.3	39.2	9.1*	8.1	25.6	8.4*	7.7	17.5
Drowsiness	32.7*	32.0	56.9	25.9*	25.6	50.6	18.9*	20.6	37.6
Crying ≥1 hour	1.7*	1.6	11.8	2.5*	2.7	9.3	1.2*	1.0	3.3
Vomiting	6.9*	6.3	9.5	5.2**	5.8	7.4	4.3	5.2	5.5

DT: Swedish National Biologics Laboratories
DTP: whole-cell pertussis DTP, Sanofi Pasteur Inc.
N = Number of evaluable subjects

* p<0.001: DAPTACEL versus whole-cell pertussis DTP
† p<0.0001: DAPTACEL versus DT
‡ Rectal temperature
§ Statistical comparisons were not made for this variable
** p<0.003: DAPTACEL versus whole-cell pertussis DTP

The incidence of serious and less common selected systemic events in the Sweden I Efficacy Trial is summarized in Table 2.

Table 2: Selected Systemic Events: Rates Per 1,000 Doses after Vaccination at 2, 4 and 6 Months of Age in Sweden I Efficacy Trial

EVENT	Dose 1 (2 MONTHS)			Dose 2 (4 MONTHS)			Dose 3 (6 MONTHS)		
	DAPTACEL N = 2,587	DT N = 2,574	DTP N = 2,102	DAPTACEL N = 2,565	DT N = 2,556	DTP N = 2,040	DAPTACEL N = 2,551	DT N = 2,539	DTP N = 2,002
Rectal temperature ≥40°C (104°F) within 48 hours of vaccination	0.39	0.78	3.33	0	0.78	3.43	0.39	1.18	6.99
Hypotonic-hyporesponsive episode within 24 hours of vaccination	0	0	1.9	0	0	0.49	0.39	0	0
Persistent crying ≥3 hours within 24 hours of vaccination	1.16	0	8.09	0.39	0.39	1.96	0	0	1.0
Seizures within 72 hours of vaccination	0	0.39	0	0	0.39	0.49	0	0.39	0

DT: Swedish National Biologics Laboratories
DTP: whole-cell pertussis DTP, Sanofi Pasteur Inc.
N = Number of evaluable subjects

In the Sweden I Efficacy Trial, one case of whole limb swelling and generalized symptoms, with resolution within 24 hours, was observed following dose 2 of DAPTACEL. No episodes of anaphylaxis or encephalopathy were observed. No seizures were reported within 3 days of vaccination with DAPTACEL. Over the entire study period, 6 seizures were reported in the DAPTACEL group, 9 in the DT group and 3 in the whole-cell pertussis DTP group, for overall rates of 2.3, 3.5 and 1.4 per 1,000 vaccinees, respectively. One case of infantile spasms was reported in the DAPTACEL group. There were no instances of invasive bacterial infection or death.

In a US study, children received 4 doses of DAPTACEL at 2, 4, 6 and 15-17 months of age. A total of 1,454 children received DAPTACEL and were included in the safety analyses. Of these, 51.7% were female, 77.2% Caucasian, 6.3% Black, 6.5% Hispanic, 0.9% Asian and 9.1% other races. The use of DAPTACEL as a fifth dose of DTaP vaccine was evaluated in 2 subsequent US clinical studies. In one study, a total of 485 children received DAPTACEL at 4-6 years of age following 4 prior doses of DAPTACEL in infancy (DAPTACEL-primed). In a separate study, a total of 989 children received DAPTACEL at 4-6 years of age following 4 prior doses of Pentacel in infancy (Pentacel-primed). The children included in these fifth dose studies were non-random subsets of participants from previous DAPTACEL or Pentacel studies. The subsets were representative of all children who received 4 doses of DAPTACEL or Pentacel in the earlier studies with regard to frequencies of solicited local and systemic adverse events following the fourth dose.

In the US 4-dose DAPTACEL study, at 2, 4, and 6 months of age, DAPTACEL was administered concomitantly with *Haemophilus in luenzae* type b (Hib) conjugate vaccine (tetanus toxoid conjugate) (Sanofi Pasteur SA), inactivated poliovirus vaccine (IPV) (Sanofi Pasteur SA), and 7-valent pneumococcal conjugate vaccine (Wyeth Pharmaceuticals Inc.). Infants had received the first dose of hepatitis B vaccine at 0 months of age. At 2 and 6 months of age, hepatitis B vaccine (recombinant) (Merck & Co., Inc.) was also administered concomitantly with DAPTACEL. Based on random assignment, the fourth dose of DAPTACEL was administered either alone; concomitantly with Hib conjugate (tetanus toxoid conjugate) vaccine; or concomitantly with Hib conjugate (tetanus toxoid conjugate) vaccine, 7-valent pneumococcal conjugate vaccine, measles, mumps, rubella (MMR) vaccine (Merck & Co., Inc.), and varicella vaccine (Merck & Co., Inc.). In the fifth dose studies, DAPTACEL was administered concomitantly with IPV (all DAPTACEL-primed subjects and 47% of Pentacel-primed subjects) and MMR vaccine.

In the US studies, the occurrence of solicited local and systemic adverse events listed in Table 3 was recorded daily by parents or guardians for Days 0-7 following vaccination. For Days 0 and 1 following the first three doses of DAPTACEL, signs and symptoms of HHE also were solicited. Periodic telephone calls were made to inquire about adverse events. Serious adverse events were monitored during the three studies, through 6 months following the last dose of DAPTACEL.

The incidence and severity of selected solicited local and systemic adverse events that occurred within 3 days following each dose of DAPTACEL are shown in Table 3. The incidence of redness, tenderness and swelling at the DAPTACEL injection site increased with the fourth and fifth doses, with the highest rates reported after the fifth dose. The incidence of redness, tenderness and swelling at the DAPTACEL injection site was similarly increased when DAPTACEL was given as a fifth dose of DTaP vaccine in Pentacel-primed children.

Table 3: Number (Percentage) of Children from US Studies with Selected Solicited Local and Systemic Adverse Events by Severity Occurring Between 0 to 3 Days after Each Dose of DAPTACEL

	Dose 1*	Dose 2*	Dose 3*	Dose 4*	Dose 5	
					DAPTACEL-primed*	Pentacel-primed*
	N = 1390-1406 %	N = 1346-1360 %	N = 1301-1312 %	N = 1118-1144 %	N = 473-481 %	N = 936-981 %
Injection Site Reactions (DAPTACEL injection site)						
Redness						
>5 mm	6.2	7.1	9.6	17.3	35.8	20.2
25 - 50 mm	0.6	0.5	1.9	6.3	10.4	6.8
>50 mm	0.4	0.1	0.0	3.1	15.8	6.6
Swelling						
>5 mm	4.0	4.0	6.5	11.7	23.9	12.0
25 - 50 mm	1.2	0.6	1.0	3.2	5.8	4.1
>50 mm	0.4	0.1	0.1	1.6	7.7	2.9
Tenderness†						
Any	48.8	38.2	40.9	49.5	61.5	50.0
Moderate	16.5	9.9	10.6	12.3	11.2	7.4
Severe	4.1	2.3	1.7	2.2	1.7	0.3
Increase in Arm Circumference‡						
>5 mm	–	–	–	30.1	38.3	28.6
20 - 40 mm				7.0	14.0	7.6
>40 mm				0.4	1.5	1.2
Interference with Normal Activity of the Arm§						
Any	–	–	–	–	20.4	8.8
Moderate					5.6	1.7
Severe					0.4	0.0
Systemic Reactions						
Fever**						
≥38.0°C	9.3	16.1	15.8	10.5	6.1	4.6
>38.5-39.5°C	1.5	3.9	4.8	2.7	2.1	2.0
>39.5°C	0.1	0.4	0.3	0.7	0.2	0.2
Decreased Activity/ Lethargy††						
Any	51.1	37.4	33.2	25.3	21.0	12.6
Moderate	23.0	14.4	12.1	8.2	5.8	3.6
Severe	1.2	1.4	0.6	1.0	0.8	0.4
Inconsolable Crying‡‡						
Any	58.5	51.4	47.9	37.1	14.1	7.2
Moderate	14.2	12.6	10.8	7.7	3.5	1.9
Severe	2.2	3.4	1.4	1.5	0.4	0.3
Fussiness/Irritability§§						
Any	75.8	70.7	67.1	54.4	34.9	22.9
Moderate	27.7	25.0	22.0	16.3	7.5	5.3
Severe	5.6	5.5	4.3	3.9	0.4	0.5

* In one U.S. study, children received four doses of DAPTACEL. A non-random subset of these children received a fifth dose of DAPTACEL in a subsequent study. A non-random subset of children previously vaccinated with 4 doses of Pentacel in previous clinical studies received a dose of DAPTACEL at 4-6 years of age as the fifth dose of DTaP vaccine in another clinical study.

† Doses 1-4 - Moderate: subject cries when site is touched; Severe: subject cries when leg or arm is moved.
Dose 5 - Moderate: interfered with activities, but did not require medical care or absenteeism; Severe: incapacitating, unable to perform usual activities, may have/or required medical care or absenteeism.

‡ The circumference of the DAPTACEL-injected arm at the level of the axilla was monitored following the fourth and fifth doses only. Increase in arm circumference was calculated by subtracting the baseline circumference pre-vaccination (Day 0) from the circumference post-vaccination.

§ Moderate: decreased use of arm, but did not require medical care or absenteeism; Severe: incapacitating, refusal to move arm, may have/or required medical care or absenteeism.

** For Doses 1-3, 53.7% of temperatures were measured rectally, 45.1% were measured axillary, 1.0% were measured orally, and 0.1% were measured by an unspecified route. For Dose 4, 35.7% of temperatures were measured rectally, 62.3% were measured axillary, 1.5% were measured orally, and 0.5% were measured by an unspecified route. For Dose 5 in DAPTACEL-primed children, 0.2% of temperatures were measured rectally, 11.3% were measured axillary, and 88.4% were measured orally. For Dose 5 in Pentacel-primed children, 0.2% of temperatures were measured rectally, 0.5% were measured tympanically, 17% were measured axillary, and 81.7% were measured orally. Fever is based upon actual temperatures recorded with no adjustments to the measurement for route.

†† Dose 1-4 - Moderate: interferes with and limits daily activity, less interactive; Severe: disabling (not interested in usual daily activity, subject cannot be coaxed to interact with caregiver).
Dose 5 - Moderate: interfered with activities, but did not require medical care or

absenteeism; Severe: incapacitating, unable to perform usual activities, may have/or required medical care or absenteeism.

‡‡ Doses 1-4 - Moderate: 1 to 3 hours inconsolable crying; Severe: >3 hours inconsolable crying. Dose 5 - Moderate: interfered with activities, but did not require medical care or absenteeism; Severe: incapacitating, unable to perform usual activities, may have/or required medical care or absenteeism.

§§ Doses 1-4 - Moderate: Irritability for 1 to 3 hours; Severe: irritability for >3 hours. Dose 5 - Moderate: interfered with activities, but did not require medical care or absenteeism; Severe: incapacitating, unable to perform usual activities, may have/or required medical care or absenteeism.

In the US study in which children received 4 doses of DAPTACEL, of 1,454 subjects who received DAPTACEL, 5 (0.3%) subjects experienced a seizure within 60 days following any dose of DAPTACEL. One seizure occurred within 7 days post-vaccination: an infant who experienced an afebrile seizure with apnea on the day of the first vaccination. Three other cases of seizures occurred between 8 and 30 days post-vaccination. Of the seizures that occurred within 60 days post-vaccination, 3 were associated with fever. In this study, there were no reported cases of HHE following DAPTACEL. There was one death due to aspiration 222 days post-vaccination in a subject with ependymoma. Within 30 days following any dose of DAPTACEL, 57 (3.9%) subjects reported at least one serious adverse event. During this period, the most frequently reported serious adverse event was bronchiolitis, reported in 28 (1.9%) subjects. Other serious adverse events that occurred within 30 days following DAPTACEL include three cases of pneumonia, two cases of meningitis and one case each of sepsis, pertussis (post-dose 1), irritability and unresponsiveness.

In the US study in which DAPTACEL was administered as a fifth DTaP dose in DAPTACEL-primed subjects, within 30 days following the fifth consecutive dose of DAPTACEL, 1 (0.2%) subject reported 2 serious adverse events (bronchospasm and hypoxia). In the US study in which DAPTACEL was administered as a fifth DTaP dose in Pentacel-primed subjects, within 30 days following DAPTACEL, 4 (0.4%) subjects reported one or more serious adverse events (asthma and pneumonia; idiopathic thrombocytopenic purpura; vomiting; cellulitis not at the injection site). In these two studies, there were no reports of seizures within 30 days following DAPTACEL in either the DAPTACEL-primed subjects or Pentacel-primed subjects.

In another study (Sweden II Efficacy Trial), 3 DTaP vaccines and a whole-cell pertussis DTP vaccine, none of which are licensed in the US, were evaluated to assess relative safety and efficacy. This study included HCPDT, a vaccine made of the same components as DAPTACEL but containing twice the amount of detoxified PT and four times the amount of FHA (20 mcg detoxified PT and 20 mcg FHA). HHE was observed following 29 (0.047%) of 61,220 doses of HCPDT; 16 (0.026%) of 61,219 doses of an acellular pertussis vaccine made by another manufacturer; and 34 (0.056%) of 60,792 doses of a whole-cell pertussis DTP vaccine. There were 4 additional cases of HHE in other studies using HCPDT vaccine for an overall rate of 33 (0.047%) in 69,525 doses.

In a randomized, parallel-group, US multi-center clinical trial conducted in children 4 through 6 years of age, DAPTACEL was administered as follows: concomitantly with IPV (Sanofi Pasteur SA) followed 30 days later by Menactra® [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate vaccine, Sanofi Pasteur Inc.] [Group A]; concomitantly with Menactra followed 30 days later by IPV [Group B]; or 30 days after concomitant administration of Menactra and IPV [Group C]. Solicited injection site and systemic reactions were recorded in a diary card for 7 consecutive days after each vaccination. For all study groups, the most frequently reported solicited local reaction at the DAPTACEL injection site was pain: 71.7%, 69.4% and 52.1% of subjects in Groups A, B and C, respectively. For all study groups, the most frequently reported systemic reaction after DAPTACEL vaccination was myalgia: 46.2%, 37.3% and 25.8% of subjects in Groups A, B and C, respectively. Fever >39.5°C occurred at <1.0% in all groups.

6.2 Data from Post-Marketing Experience

The following adverse events have been spontaneously reported during the post-marketing use of DAPTACEL in the US and other countries. Because these events are reported voluntarily from a population of uncertain size, it may not be possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

The following adverse events were included based on one or more of the following factors: severity, frequency of reporting, or strength of evidence for a causal relationship to DAPTACEL.

Blood and lymphatic disorders
Lymphadenopathy
Cardiac disorders
Cyanosis
Gastro-intestinal disorders
Nausea, diarrhea
General disorders and administration site conditions
Local reactions: injection site pain, injection site rash, injection site nodule, injection site mass, extensive swelling of injected limb (including swelling that involves adjacent joints).
Infections and infestations
Injection site cellulitis, cellulitis, injection site abscess
Immune system disorders
Hypersensitivity, allergic reaction, anaphylactic reaction (edema, face edema, swelling face, pruritus, rash generalized) and other types of rash (erythematous, macular, maculo-papular)
Nervous system disorders
Convulsions: febrile convulsion, grand mal convulsion, partial seizures
HHE, hypotonia, somnolence, syncope
Psychiatric disorders
Screaming

7 DRUG INTERACTIONS

7.1 Concomitant Administration with Other Vaccines

In clinical trials, DAPTACEL was administered concomitantly with one or more of the following US licensed vaccines: Hib conjugate vaccine, IPV, hepatitis B vaccine, pneumococcal conjugate vaccine, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate vaccine, MMR vaccine, and varicella vaccine. [See *Adverse Reactions (6.1)* and *Clinical Studies (14.4)*.] When DAPTACEL is given at the same time as another injectable vaccine(s), the vaccines should be administered with different syringes and at different injection sites.

In cases where DAPTACEL and Menactra are to be administered to children 4 through 6 years of age, the two vaccines should be administered concomitantly or Menactra should be administered prior to DAPTACEL. Administration of Menactra one month after DAPTACEL has been shown to reduce meningococcal antibody responses to Menactra. [See *Adverse Reactions (6.1)* and *Clinical Studies (14.4)*.]

7.2 Immunosuppressive Treatments

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids (used in greater than physiologic doses), may reduce the immune response to DAPTACEL.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

DAPTACEL is not approved for use in individuals 7 years of age and older. Human or animal data are not available to assess vaccine-associated risks in pregnancy.

8.2 Lactation

DAPTACEL is not approved for use in individuals 7 years of age and older. Human or animal data are not available to assess the impact of DAPTACEL on milk production, its presence in breast milk, or its effects on the breastfed infant.

8.4 Pediatric Use

DAPTACEL is not indicated for use in infants below 6 weeks of age or children 7 years of age or older. Safety and effectiveness of DAPTACEL in these age groups have not been established.

11 DESCRIPTION

DAPTACEL is a sterile isotonic suspension of pertussis antigens and diphtheria and tetanus toxoids adsorbed on aluminum phosphate, for intramuscular injection.

Each 0.5 mL dose contains 15 Lf diphtheria toxoid, 5 Lf tetanus toxoid and acellular pertussis antigens [10 mcg detoxified pertussis toxin (PT), 5 mcg filamentous hemagglutinin (FHA), 3 mcg pertactin (PRN), and 5 mcg fimbriae types 2 and 3 (FIM)].

Other ingredients per 0.5 mL dose include 1.5 mg aluminum phosphate (0.33 mg of aluminum) as the adjuvant, ≤5 mcg residual formaldehyde, <50 ng residual glutaraldehyde and 3.3 mg (0.6% v/v) 2-phenoxyethanol (not as a preservative).

The acellular pertussis vaccine components are produced from *Bordetella pertussis* cultures grown in Stainer-Scholte medium (2) modified by the addition of casamino acids and dimethyl-beta-cyclodextrin. PT, FHA and PRN are isolated separately from the supernatant culture medium. The FIM components are extracted and co-purified from the bacterial cells. The pertussis antigens are purified by sequential filtration, salt-precipitation, ultrafiltration and chromatography. PT is detoxified with glutaraldehyde. FHA is treated with formaldehyde, and the residual aldehydes are removed by ultrafiltration. The individual antigens are adsorbed separately onto aluminum phosphate.

Corynebacterium diphtheriae is grown in modified Mueller's growth medium. (3) After purification by ammonium sulfate fractionation, diphtheria toxin is detoxified with formaldehyde and diafiltered. *Clostridium tetani* is grown in modified Mueller-Miller casamino acid medium without beef heart infusion. (4) Tetanus toxin is detoxified with formaldehyde and purified by ammonium sulfate fractionation and diafiltration. Diphtheria and tetanus toxoids are individually adsorbed onto aluminum phosphate.

The adsorbed diphtheria, tetanus and acellular pertussis components are combined with aluminum phosphate (as adjuvant), 2-phenoxyethanol (not as a preservative) and water for injection.

Both diphtheria and tetanus toxoids induce at least 2 units of antitoxin per mL in the guinea pig potency test. The potency of the acellular pertussis vaccine components is determined by the antibody response of immunized mice to detoxified PT, FHA, PRN and FIM as measured by enzyme-linked immunosorbent assay (ELISA).

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Diphtheria

Diphtheria is an acute toxin-mediated disease caused by toxigenic strains of *C diphtheriae*. Protection against disease is due to the development of neutralizing antibodies to diphtheria toxin. A serum diphtheria antitoxin level of 0.01 IU/mL is the lowest level giving some degree of protection. Antitoxin levels of at least 0.1 IU/mL are generally regarded as protective. (5) Levels of 1.0 IU/mL have been associated with long-term protection. (6)

Tetanus

Tetanus is an acute disease caused by an extremely potent neurotoxin produced by *C tetani*. Protection against disease is due to the development of neutralizing antibodies to tetanus toxin. A serum tetanus antitoxin level of at least 0.01 IU/mL, measured by neutralization assay is considered the minimum protective level. (5) (7) A tetanus antitoxin level ≥0.1 IU/mL as measured by the ELISA used in clinical studies of DAPTACEL is considered protective.

Pertussis

Pertussis (whooping cough) is a respiratory disease caused by *B pertussis*. This Gram-negative coccobacillus produces a variety of biologically active components, though their role in either the pathogenesis of, or immunity to, pertussis has not been clearly defined.

13 NON-CLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

DAPTACEL has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.

14 CLINICAL STUDIES

14.1 Diphtheria

In a US study in which children received 4 doses of DAPTACEL at 2, 4, 6 and 15-17 months of age, after the third dose, 100% (N = 1,099) achieved diphtheria antitoxin levels of ≥0.01 IU/mL and 98.5% achieved diphtheria antitoxin levels of ≥0.10 IU/mL. Among a random subset of children who received the fourth dose of DAPTACEL at 15-16 months of age, 96.5% (N = 659) achieved diphtheria antitoxin levels of ≥1.0 IU/mL after the fourth dose.

14.2 Tetanus

In a US study in which children received 4 doses of DAPTACEL at 2, 4, 6 and 15 17 months of age, after the third dose, 100% (N = 1,037) achieved tetanus antitoxin levels of ≥0.10 IU/mL. Among a random subset of children who received the fourth dose of DAPTACEL at 15-16 months of age, 98.8% (N = 681) achieved tetanus antitoxin levels of ≥1.0 IU/mL after the fourth dose.

14.3 Pertussis

A randomized, double-blinded, placebo-controlled efficacy and safety study was conducted in Sweden during 1992-1995 (Sweden I Efficacy Trial) under the sponsorship of the National Institute of Allergy and Infectious Diseases. A total of 9,829 infants received 1 of 4 vaccines: DAPTACEL (N = 2,587); another investigational acellular pertussis vaccine (N = 2,566); whole-cell pertussis DTP vaccine (N = 2,102); or DT vaccine as placebo (Swedish National Bacteriological Laboratory, N = 2,574). Infants were immunized at 2, 4 and 6 months of age. The mean length of follow-up was 2 years after the third dose of vaccine. The protective efficacy of DAPTACEL against pertussis after 3 doses using the World Health Organization (WHO) case definition (≥21 consecutive days of paroxysmal cough with culture or serologic confirmation or epidemiologic link to a confirmed case) was 84.9% (95% confidence interval [CI] 80.1 to 88.6). The protective efficacy of DAPTACEL against mild pertussis (≥1 day of cough with laboratory confirmation) was 77.9% (95% CI 72.6 to 82.2). Protection against pertussis by DAPTACEL was sustained for the 2-year follow-up period.

In order to assess the antibody response to the pertussis antigens of DAPTACEL in the US population, 2 lots of DAPTACEL, including the lot used in the Sweden I Efficacy Trial, were administered to US infants in the US Bridging Study. In this study, antibody responses following 3 doses of DAPTACEL given to US children at 2, 4 and 6 months of age were compared to those from a subset of the infants enrolled in the Sweden I Efficacy Trial. Assays were performed in parallel on the available sera from the US and Swedish infants. Antibody responses to all the antigens were similar except for those to the PRN component. For both lots of DAPTACEL, the geometric mean concentration (GMC) and percent response to PRN in US infants (Lot 006, N = 107; Lot 009, N = 108) were significantly lower after 3 doses of vaccine than in Swedish infants (N = 83). In separate US and Canadian studies in which children received DAPTACEL at 2, 4 and 6 months of age, with a fourth dose at either 17-20 months (Canadian study) or 15-16 months (random subset from US study) of age, antibody responses to each pertussis antigen following the fourth dose (Canadian study N = 275; US study N = 237-347) were at least as high as those seen in the Swedish infants after 3 doses. While a serologic correlate of protection for pertussis has not been established, the antibody response to all antigens in North American infants after 4 doses of DAPTACEL at 2, 4, 6 and 15-20 months of age was comparable to that achieved in Swedish infants in whom efficacy was demonstrated after 3 doses of DAPTACEL at 2, 4 and 6 months of age.

14.4 Concomitantly Administered Vaccines

In the US Bridging study, DAPTACEL was given concomitantly with Hib conjugate vaccine (Sanofi Pasteur SA) according to local practices. Anti-PRP immune response was evaluated in 261 infants who received 3 doses of Hib conjugate vaccine. One month after the third dose, 96.9% achieved anti-PRP antibody levels of at least 0.15 mcg/mL and 82.7% achieved antibody levels of at least 1.0 mcg/mL.

In the US study in which infants received DAPTACEL concomitantly with Hib conjugate (tetanus toxoid conjugate) vaccine, IPV, 7-valent pneumococcal conjugate vaccine, and hepatitis B vaccine [see *Adverse Reactions (6.1)*], at 7 months of age, 100.0% of subjects (N = 1,050-1,097) had protective neutralizing antibody levels (≥1:8 1/dil) for poliovirus types 1, 2 and 3; and 92.4% (N = 998) achieved anti-hepatitis B surface antigen levels ≥10.0 mIU/mL. Although there is no established serologic correlate of protection for any of the pneumococcal serotypes, at 7 months of age 91.3%-98.9% (N = 1,027-1,029) achieved anti-pneumococcal polysaccharide levels ≥0.5 mcg/mL for serotypes 4, 9V, 14, 18C, 19F and 23F and 80.7% (N = 1,027) achieved an anti-pneumococcal polysaccharide level ≥0.5 mcg/mL for serotype 6B. The mumps seroresponse rate was lower when DAPTACEL was administered concomitantly (86.6%; N = 307) vs. non-concomitantly (90.1%; N = 312) with the first dose of MMR vaccine [upper limit of 90% confidence interval for difference in rates (non-concomitant minus concomitant) >5%]. There was no evidence for interference in the immune response to the measles, rubella, and varicella antigens or to the fourth dose of the 7-valent pneumococcal conjugate vaccine with concomitant administration of DAPTACEL.

In a randomized, parallel-group, US multi-center clinical trial conducted in children 4 through 6 years of age, DAPTACEL was administered as follows: concomitantly with IPV (Sanofi Pasteur SA) followed 30 days later by Menactra [Group A]; concomitantly with Menactra followed 30 days later by IPV [Group B]; or 30 days after concomitant administration of Menactra and IPV [Group C]. Sera were obtained approximately 30 days after each respective vaccination. When DAPTACEL was administered concomitantly with Menactra [Group B], antibody responses to PT, FHA and PRN (GMC), tetanus (% participants with antibody concentrations ≥1.0 IU/mL), and diphtheria (%participants with antibody concentrations ≥1.0 IU/mL) were non-inferior to those observed when DAPTACEL (and IPV) were administered [Group A]. The anti-FIM GMCs were marginally lower when DAPTACEL and Menactra were administered concomitantly but the clinical significance is unknown because there are no established serological correlates of protection for pertussis. When DAPTACEL (and IPV) were administered 30 days prior to Menactra [Group A], significantly lower serum-bactericidal assay-human complement (SBA-H) GMTs to all 4 meningococcal serogroups were observed compared to when Menactra (and IPV) were administered 30 days prior to DAPTACEL [Group C]. When DAPTACEL was administered concomitantly with Menactra [Group B], SBA-H GMTs to meningococcal serogroups A, C, and W-135 were non-inferior to those observed when Menactra (and IPV) were administered [Group C]. The non-inferiority criterion was marginally missed for meningococcal serogroup Y. [See *Drug Interactions (7.1)*.]

15 REFERENCES

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16 HOW SUPPLIED/STORAGE AND HANDLING

The vial stopper for this product is not made with natural rubber latex.
DAPTACEL is supplied in a single dose vial (NDC No. 49281-286-58):
in packages of 1 vial: NDC No. 49281-286-01;
in packages of 5 vials: NDC No. 49281-286-05;
in packages of 10 vials: NDC No. 49281-286-10.
DAPTACEL should be stored at 2° to 8°C (35° to 46°F). DO NOT FREEZE. Product which has been exposed to freezing should not be used. Do not use after expiration date shown on the label.

17 PATIENT COUNSELING INFORMATION

Inform the parent or guardian of the following:

- The potential benefits and risks of immunization with DAPTACEL.
- The common adverse reactions that have occurred following administration of DAPTACEL or other vaccines containing similar components.
- Other adverse reactions can occur. Call healthcare provider with any adverse reactions of concern.

Provide the Vaccine Information Statements (VIS), which are required by the National Childhood Vaccine Injury Act of 1986.

Manufactured by:
Sanofi Pasteur Limited
Toronto Ontario Canada

Distributed by:
Sanofi Pasteur Inc.
Swiftwater PA 18370 USA

US Patents: 4500639, 4687738, 4784589, 4997915, 5444159, 5667787, 5877298.

Testimony in Opposition
HB 1468
Human Services Committee
January 25, 2021

Good afternoon Chair Weisz, Vice Chair Rohr, and members of the Committee,

My name is Dr Ana Tobiasz, MD and I am a Maternal Fetal Medicine physician at Sanford Health in Bismarck. Thank you for the opportunity to testify in opposition to HB 1468. I am asking the committee to give this bill a Do Not Pass recommendation.

My medical training and expertise is in caring for women during high risk pregnancies. I was born and raised in Munich, ND and completed my undergraduate and medical school training at the University of North Dakota. After medical school I completed a 4 year residency training in Obstetrics and Gynecology in Grand Rapids, MI, followed by a 3 year fellowship training in Maternal Fetal Medicine at the University of Tennessee. I have worked as a maternal fetal medicine specialist at Sanford Bismarck since July 2017. I am the first and only MFM in Bismarck and one of only three within the entire state. I care for women who have underlying health conditions, as well as diagnose and manage fetal health conditions, and have a unique understanding of the interaction between the mother, placenta, and unborn fetus.

I strongly oppose this bill because the decision model for administering vaccines in pregnancy is not any different than any other medication I discuss with my patients, many of which have significant effects on their unborn child. We have never required a pregnant patient to sign a consent form or have a witness present for the discussion about medication use in pregnancy. This bill would harm the physician/patient relationship and will cause an unnecessary burden on the healthcare system with additional unnecessary documentation. We already have a method of documenting our counseling and discussion with patients in the electronic medical record.

Treating health conditions during pregnancy is challenging and unique due to the relationship between the mother and fetus. Many pregnant women have health conditions that are more harmful to both the mother and fetus if left untreated than if treated with a medication that may have adverse effects on one or both of them. Decisions regarding medication use in pregnancy are always made on a risk/benefit scale. I spend a great deal of time discussing this with my patients, and then documenting this discussion and the patient's decision in the medical record. Unfortunately due to the ethical limitations of studying medications during pregnancy, pregnant women are routinely excluded from research trials with new medications. This includes new vaccines. The average pregnant woman takes 2-3 prescription medications over the course of their pregnancy—none of which were likely studied during a randomized trial on the specific effects in pregnancy. We do generally have the benefit of animal studies on pregnant animals and extrapolate this data to human pregnancies. Information about the effects of the medications during pregnancy are obtained retrospectively after women are either incidentally or intentionally exposed to the medication during pregnancy. Many new medications and vaccines have drug registries where we have our patients register and the individual patient and their exposed fetus/child are then followed over time to see what the effects were after the exposure. At this time, we have years of data and retrospective studies on commonly administered vaccines in pregnancy.

There are two vaccines that are routinely given and recommended to be given during each and every pregnancy. This includes the influenza vaccine and the Tdap vaccine (tetanus, diphtheria, and pertussis vaccine). I have a very high uptake (85-90%) of these vaccines in my practice, with almost no women declining after discussing the risks and benefits of vaccination. I have had no serious adverse reactions as a result of vaccination for my patients. The time frame of vaccination is generally not at the time of admission for delivery, therefore women are not generally being offered vaccines under duress. I have had extensive training in counseling patients on medical treatments and procedures during labor—vaccinations are no different.

We give the influenza vaccine to protect the mother, as pregnant women are at a significantly higher risk of complications if they become ill with influenza as compared to a non-pregnant individual. I have cared for many pregnant women who were ill from influenza. I vividly remember one of my patients in my last year of fellowship training—one who nearly lost her life and the life of her unborn child. She had made the decision to not receive the influenza vaccine as was recommended, and ended up in the intensive care unit and required specialized medical treatments such as prone positioning, ventilator support and had to receive ECMO. ECMO is a medical treatment that is used to bypass the lungs for oxygenation and return the blood back to the body. This would have been avoidable with administration of the influenza vaccine.

The Tdap vaccine is given during each pregnancy to protect the infant after birth. When the vaccine is given during the third trimester, the antibodies produced by the mother will pass through the placenta and gives the infant protection in the first months of life, during which time they cannot receive the Tdap vaccine. This was all determined by retrospective studies.

There are many other vaccines that are acceptable to be given during pregnancy. In fact, the only vaccines which are not recommended in pregnancy are those that are considered live virus vaccines. This is due to the fact that if a person receives a live vaccine, they have a chance of becoming ill from the virus. The viral illnesses which are prevented with live vaccines, such as varicella, are unfortunately teratogenic to the fetus, therefore we do not give these vaccines during pregnancy.

The covid-19 vaccine is a new topic that I am discussing daily with my patients. This is not a live virus vaccine. The technology used for the currently available covid-19 vaccines is new, however based on the mechanism of these vaccines, there is unlikely to be harm to the fetus. The mother cannot become ill from receiving the covid-19 vaccine as it is not a live virus vaccine. The majority of the side effects that commonly occur would not be detrimental to the growing fetus and are short-lived. Despite our limitations of studying medications and vaccines directly in pregnancy during randomized trials, we do have evidence that pregnant women who become ill from covid-19 are at a substantially higher risk of severe complications. When weighing the risks of covid-19 infection versus the vaccine, the benefits of vaccine administration are clearly favored. These are the types of discussions and decisions I make on a daily basis with my patients.

In summary, I strongly oppose this bill, which proposes to add additional unnecessary intrusions into the patient/physician relationship and adds unnecessary and burdensome documentation to our healthcare system.

I strongly urge a Do Not Pass recommendation on HB 1468.

Dr Ana Tobiasz, MD
Maternal Fetal Medicine Physician
Sanford Health Bismarck
Phone: 218-779-8497

House Bill 1468- In Opposition
Human Services Committee
67th Legislative Assembly of North Dakota
January 25, 2021

Good afternoon Chairman Weisz, Vice Chair Rohr, and Human Services Committee Members,

My name is Joan Connell. As a pediatrician, I am asking for a Do-Not-Pass decision on House Bill 1468. I am opposed to this piece of legislative, which mandates the conversation shared in the sanctity of the patient-physician relationship for the following reasons:

1. Legislatively mandating that providers give patients a package insert for each vaccine they are receiving will cost human and office resources, unnecessarily and wastefully. The Vaccine Information Statement (VIS) is a document prepared by the Advisory Committee on Childhood Vaccines, which includes two parents of children sustaining injury from vaccines, that contains the most relevant information for a given vaccine, and through federal law, must be provided to each patient/guardian prior to receiving the suggested vaccine. In my office, my nurse will provide this paperwork when the patient family initially is roomed for their visit, providing parents/guardians a chance to look at these statements and ask questions during their appointment. Patients/guardians who have questions and would like additional information are then able to have a discussion with their provider. While I have had a handful of patients' guardians request the vaccine package insert (which I am happy to provide to those who request), the majority of my patients' guardians want and expect me as their provider to cut through the scientific jargon to address their concern. Patients/guardians still uncomfortable with a particular vaccine simply do not agree to its administration. This is one of many discussions that are held during this sanctified period of time during the physician-patient appointment. A package insert is several pages long- the copying and provision of this to each patient/guardian for each vaccine is wasteful, particularly since the patient/guardian already receives a Vaccine Information Statement for each vaccine. Assuming a copy cost of 10 cents/page, and an average package insert length of 10 pages (some are over 40 pages), providing package inserts to the North Dakotans receiving the 689,890 vaccine doses administered in 2020 would cost $689,890- that means $1,380,000 spent on this mandated paperwork per biennium! Here are links to the Measles Mumps and Rubella Vaccine Information Statement https://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.pdf and package insert https://www.fda.gov/media/75191/download, with a copy of each found at the bottom of this testimony.
2. Legislatures mandating what providers discuss with their patients/guardians during this very intimate time results in elimination of discussions that may have been more pertinent for that patient during that particular visit. The end result is that both patient and provider are short-changed as neither has accomplished all of the goals of the visit. Here is a link https://brightfutures.aap.org/Bright%20Futures%20Documents/BF4_EarlyChildhoodVisits.pdf to a Bright Futures document that outlines what is to be accomplished during a well check for a 12 month old, covered on pages 503-523, with recommendations for

what is to be covered regarding anticipatory guidance beginning on page 510. As you can see, this is already overwhelming. Mandating additional discussion on vaccine exemption will shortchange patients and providers.

3. The National Vaccine Injury Compensation Program (VICP) https://www.hrsa.gov/vaccine-compensation/index.html is a federal program that has been in place since the 1980s to assure that rare patients who have experienced a serious adverse reaction to immunization are financially compensated. HB 1468's section 1-4's statement about continued liability for manufacturers of immunizations is misleading as patients experiencing adverse events from vaccination would actually pursue compensation through VICP.
4. Mandating provision of information regarding vaccine exemption will potentially undermine confidence in vaccine safety, resulting in decreasing percentages of vaccinated individuals. This compromises everyone's health, particularly the patients who are unable to be vaccinated due to medical conditions or those with history of significant adverse reactions to vaccines, who were unable to complete their vaccine series. Ultimately, this legislation may hurt those you are intending to protect by increasing their risk for infection from the illnesses that result from insufficient vaccination of the rest of the population.

In summary, vaccination saves lives. Patient information about each vaccine is readily available and legally must be provided to patients prior to vaccination. Programs that compensate the rare individual who has a serious reaction to vaccination are already in place and are being utilized. I urge a Do-Not-Pass vote on HB 1468, which adds unnecessary mandates that compromises the patient-physician relationship, increases unnecessary costly paperwork for providers, misleads the rare patient who experiences a vaccine-related adverse event, and has the potential to increase risk of infection from vaccine-preventable diseases for all of us.

Vaccine Information Statement

MMR Vaccine (Measles, Mumps, and Rubella): 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?**

MMR vaccine can prevent **measles**, **mumps**, and **rubella.**

- • **MEASLES (M)** can cause fever, cough, runny nose, and red, watery eyes, commonly followed by a rash that covers the whole body. It can lead to seizures (often associated with fever), ear infections, diarrhea, and pneumonia. Rarely, measles can cause brain damage or death.
- • **MUMPS (M)** can cause fever, headache, muscle aches, tiredness, loss of appetite, and swollen and tender salivary glands under the ears. It can lead to deafness, swelling of the brain and/or spinal cord covering, painful swelling of the testicles or ovaries, and, very rarely, death.

- • **RUBELLA (R)** can cause fever, sore throat, rash, headache, and eye irritation. It can cause arthritis in up to half of teenage and adult women. If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

Most people who are vaccinated with MMR will be protected for life. Vaccines and high rates of vaccination have made these diseases much less common in the United States.

2. MMR vaccine

Children need 2 doses of MMR vaccine, usually:
- • First dose at 12 through 15 months of age
- • Second dose at 4 through 6 years of age

Infants who will be traveling outside the United States when they are between 6 and 11 months of age should get a dose of MMR vaccine before travel. The child should still get 2 doses at the recommended ages for long-lasting protection.

Older children, **adolescents**, and **adults** also need 1 or 2 doses of MMR vaccine if they are not already immune to measles, mumps, and rubella. Your health care provider can help you determine how many doses you need.

A third dose of MMR might be recommended in certain mumps outbreak situations.

MMR vaccine may be given at the same time as other vaccines. Children 12 months through 12 years of age might receive MMR vaccine together with varicella vaccine in a single shot, known as MMRV. Your health care provider can give you more information.

3. Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:
- • Has had an **allergic reaction after a previous dose of MMR or MMRV vaccine**, or has any **severe, life-threatening allergies.**
- • Is **pregnant**, or thinks she might be pregnant.
- • Has a **weakened immune system**, or has a **parent, brother, or sister with a history of hereditary or congenital immune system problems.**
- • Has ever had a **condition that makes him or her bruise or bleed easily.**
- • Has recently **had a blood transfusion or received other blood products**.
- • Has **tuberculosis.**
- • Has **gotten any other vaccines in the past 4 weeks.**

In some cases, your health care provider may decide to postpone MMR vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting MMR vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- • Soreness, redness, or rash where the shot is given and rash all over the body can happen after MMR vaccine.
- • Fever or swelling of the glands in the cheeks or neck sometimes occur after MMR vaccine.
- • More serious reactions happen rarely. These can include seizures (often associated with fever), temporary pain and stiffness in the joints (mostly in teenage or adult women), pneumonia, swelling of the brain and/or spinal cord covering, or temporary low platelet count which can cause unusual bleeding or bruising.
- • In people with serious immune system problems, this vaccine may cause an infection which may be life-threatening. People with serious immune system problems should not get MMR vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do 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. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

7. How can I learn more?

- • Ask your health care provider.
- • 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/vaccines**

Vaccine Information Statement (Interim)
MMR Vaccine
8/15/2019
42 U.S.C. § 300aa-26

Department of Health and Human Services
Centers for Disease Control and Prevention
Vaccine Package Insert

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use M-M-R II safely and effectively. See full prescribing information for M-M-R II.

M-M-R® II (Measles, Mumps, and Rubella Virus Vaccine Live) Suspension for subcutaneous injection
Initial U.S. Approval: 1978

----------INDICATIONS AND USAGE----------

M-M-RII is a vaccine indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older. (1)

---------- DOSAGE AND ADMINISTRATION ----------

Administer a 0.5-mL dose of M-M-R II subcutaneously. (2.1)

- The first dose is administered at 12 to 15 months of age. (2.1)
- The second dose is administered at 4 to 6 years of age. (2.1)

---------- DOSAGE FORMS AND STRENGTHS ----------

Suspension for injection (0.5-mL dose) supplied as a lyophilized vaccine to be reconstituted using accompanying sterile diluent. (3)

----------CONTRAINDICATIONS ----------

- Hypersensitivity to any component of the vaccine. (4.1)
- Immunosuppression. (4.2)
- Moderate or severe febrile illness. (4.3)
- Active untreated tuberculosis. (4.4)
- Pregnancy. (4.5, 8.1)

---------- WARNINGS AND PRECAUTIONS----------

• Use caution when administering M-M-R II to individuals with a history of febrile seizures. (5.1)

FULL PRESCRIBING INFORMATION: CONTENTS*

• Use caution when administering M-M-R II to individuals with anaphylaxis or immediate hypersensitivity following egg ingestion. (5.2)

• Use caution when administering M-M-R II to individuals with a history of thrombocytopenia. (5.3)

• Evaluate individuals for immune competence prior to administration of M-M-R II if there is a family history of congenital or hereditary immunodeficiency. (5.4)

• Immune Globulins (IG) and other blood products should not be given concurrently with M-M-R II. (5.5, 7.2)

---------- ADVERSE REACTIONS ----------

See full prescribing information for adverse reactions occurring during clinical trials or the post-marketing period. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877- 888-4231 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

----------DRUG INTERACTIONS----------

• Administration of immune globulins and other blood products concurrently with M-M-RII vaccine may interfere with the expected immune response. (7.2)

• M-M-R II vaccination may result in a temporary depression of purified protein derivative (PPD) tuberculin skin sensitivity. (7.3)

---------- USE IN SPECIFIC POPULATIONS ----------

• Pregnancy: Do not administer M-M-R II to females who are pregnant. Pregnancy should be avoided for 1 month following vaccination with M-M-R II. (4.5, 8.1, 17)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: XX/20XX

*****Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION 1 INDICATIONS AND USAGE

M-M-R□ II is a vaccine indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older.

2 DOSAGE AND ADMINISTRATION For subcutaneous use only.

2.1 Dose and Schedule

Each 0.5 mL dose is administered subcutaneously.

The first dose is administered at 12 to 15 months of age. A second dose is administered at 4 to 6 years of age.

The second dose may be administered prior to 4 years of age, provided that there is a minimum interval of one month between the doses of measles, mumps and rubella virus vaccine, live {1-2}.

Children who received an initial dose of measles, mumps and rubella vaccine prior to their first birthday should receive additional doses of vaccine at 12-15 months of age and at 4-6 years of age to complete the vaccination series *[see Clinical Studies (14.2)]*.

For post-exposure prophylaxis for measles, administer a dose of M-M-R II vaccine within 72 hours after exposure.

2.2 Preparation and Administration

Use a sterile syringe free of preservatives, antiseptics, and detergents for each injection and/or reconstitution of the vaccine because these substances may inactivate the live virus vaccine. To reconstitute, use only the diluent supplied with the vaccine since it is free of preservatives or other antiviral substances which might inactivate the vaccine.

Withdraw the entire volume of the supplied diluent from its vial and inject into lyophilized vaccine vial. Agitate to dissolve completely. Discard if the lyophilized vaccine cannot be dissolved.

Withdraw the entire volume of the reconstituted vaccine and inject subcutaneously into the outer aspect of the upper arm (deltoid region) or into the higher anterolateral area of the thigh.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Visually inspect the vaccine before and after reconstitution prior to administration. Before reconstitution, the lyophilized vaccine is a light yellow compact crystalline plug, when reconstituted, is a clear yellow liquid. Discard if particulate matter or discoloration are observed in the reconstituted vaccine.

To minimize loss of potency, administer M-M-R II as soon as possible after reconstitution. If not used immediately, the reconstituted vaccine may be stored between 36°F to 46°F (2°C to 8°C), protected from light, for up to 8 hours. Discard reconstituted vaccine if it is not used within 8 hours.

3 DOSAGE FORMS AND STRENGTHS

M-M-R II vaccine is a suspension for injection supplied as a single dose vial of lyophilized vaccine to be reconstituted using the accompanying sterile diluent *[see Dosage and Administration (2.2) and How Supplied/Storage and Handling (16)]*. A single dose after reconstitution is 0.5 mL.

4 CONTRAINDICATIONS

4.1 Hypersensitivity

Do not administer M-M-R II vaccine to individuals with a history of hypersensitivity to any component of the vaccine (including gelatin) {3} or who have experienced a hypersensitivity reaction following administration of a previous dose of M-M-R II vaccine or any other measles, mumps and rubella-containing vaccine. Do not administer M-M-R II vaccine to individuals with a history of anaphylaxis to neomycin *[see Description (11)].*

4.2 Immunosuppression

Do not administer M-M-R II vaccine to individuals who are immunodeficient or immunosuppressed due to disease or medical therapy. Measles inclusion body encephalitis {4} (MIBE), pneumonitis {5} and death as a direct consequence of disseminated measles vaccine virus infection have been reported in immunocompromised individuals inadvertently vaccinated with measles-containing vaccine. In this population, disseminated mumps and rubella vaccine virus infection have also been reported.

4.3 Moderate or Severe Febrile Illness

Do not administer M-M-R II vaccine to individuals with an active febrile illness with fever >101.3°F (>38.5°C).

4.4 Active Untreated Tuberculosis

Do not administer M-M-R II vaccine to individuals with active untreated tuberculosis (TB). **4.5 Pregnancy**

Do not administer M-M-R II to individuals who are pregnant or who are planning on becoming pregnant within the next month *[see Use in Specific Populations (8.1) and Patient Counseling Information (17)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Febrile Seizure

There is a risk of fever and associated febrile seizure in the first 2 weeks following immunization with M-M-R II vaccine. For children who have experienced a previous febrile seizure (from any cause) and those with a family history of febrile seizures there is a small increase in risk of febrile seizure following receipt of M-M-R II vaccine *[see Adverse Reactions (6)]*.

5.2 Hypersensitivity to Eggs

Individuals with a history of anaphylactic, anaphylactoid, or other immediate reactions (e.g., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) subsequent to egg ingestion may be at an enhanced risk of immediate-type hypersensitivity reactions after receiving M-M-R II vaccine. The potential risks and known benefits should be evaluated before considering vaccination in these individuals.

5.3 Thrombocytopenia

Transient thrombocytopenia has been reported within 4-6 weeks following vaccination with measles, mumps and rubella vaccine. Carefully evaluate the potential risk and benefit of vaccination in children with thrombocytopenia or in those who experienced thrombocytopenia after vaccination with a previous dose of measles, mumps, and rubella vaccine {6-8} *[see Adverse Reactions (6)]*.

5.4 Family History of Immunodeficiency

Vaccination should be deferred in individuals with a family history of congenital or hereditary immunodeficiency until the individual's immune status has been evaluated and the individual has been found to be immunocompetent.

5.5 Immune Globulins and Transfusions

Immune Globulins (IG) and other blood products should not be given concurrently with M-M-R II *[see Drug Interactions (7.2)]*. These products may contain antibodies that interfere with vaccine virus replication and decrease the expected immune response.

The Advisory Committee on Immunization Practices (ACIP) has specific recommendations for intervals between administration of antibody containing products and live virus vaccines.

6 ADVERSE REACTIONS

The following adverse reactions include those identified during clinical trials or reported during post-approval use of M-M-R II vaccine or its individual components.

Body as a Whole

Panniculitis; atypical measles; fever; syncope; headache; dizziness; malaise; irritability.

Cardiovascular System

Vasculitis.

Digestive System

Pancreatitis; diarrhea; vomiting; parotitis; nausea.

Hematologic and Lymphatic Systems

Thrombocytopenia; purpura; regional lymphadenopathy; leukocytosis.

Immune System

Anaphylaxis, anaphylactoid reactions, angioedema (including peripheral or facial edema) and bronchial spasm.
Musculoskeletal System

Arthritis; arthralgia; myalgia.

3

Nervous System

Encephalitis; encephalopathy; measles inclusion body encephalitis (MIBE) subacute sclerosing panencephalitis (SSPE); Guillain-Barré Syndrome (GBS); acute disseminated encephalomyelitis (ADEM); transverse myelitis; febrile convulsions; afebrile convulsions or seizures; ataxia; polyneuritis; polyneuropathy; ocular palsies; paresthesia.

Respiratory System

Pneumonia; pneumonitis; sore throat; cough; rhinitis.

Skin

Stevens-Johnson syndrome; acute hemorrhagic edema of infancy; Henoch-Schönlein purpura; erythema multiforme; urticaria; rash; measles-like rash; pruritus; injection site reactions (pain, erythema, swelling and vesiculation).
Special Senses — Ear

Nerve deafness; otitis media.

Special Senses — Eye

Retinitis; optic neuritis; papillitis; conjunctivitis.

Urogenital System

Epididymitis; orchitis.

7 DRUG INTERACTIONS

7.1 Corticosteroids and Immunosuppressive Drugs

M-M-R II vaccine should not be administered to individuals receiving immunosuppressive therapy, including high dose corticosteroids. Vaccination with M-M-R II vaccine can result in disseminated disease due to measles vaccine in individuals on immunosuppressive drugs *[see Contraindications (4.2)].*

7.2 Immune Globulins and Transfusions

Administration of immune globulins and other blood products concurrently with M-M-R II vaccine may interfere with the expected immune response {9-11} *[see Warnings and Precautions (5.5)].* The ACIP has specific recommendations for intervals between administration of antibody containing products and live virus vaccines.

7.3 Tuberculin Skin Testing

It has been reported that live attenuated measles, mumps and rubella virus vaccines given individually may result in a temporary depression of tuberculin skin sensitivity. Therefore, if a tuberculin skin test with tuberculin purified protein derivative (PPD) is to be done, it should be administered before, simultaneously with, or at least 4 to 6 weeks after vaccination with M-M-R II vaccine.

7.4 Use with Other Live Viral Vaccines

M-M-R II vaccine can be administered concurrently with other live viral vaccines. If not given concurrently, M-M-R II vaccine should be given one month before or one month after administration of other live viral vaccines to avoid potential for immune interference.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary
M-M-R II vaccine is contraindicated for use in pregnant women because infection during pregnancy

with the wild-type viruses has been associated with maternal and fetal adverse outcomes.
Increased rates of spontaneous abortion, stillbirth, premature delivery and congenital defects have been observed following infection with wild-type measles during pregnancy. {12,13} Wild-type mumps

infection during the first trimester of pregnancy may increase the rate of spontaneous abortion.
Infection with wild-type rubella during pregnancy can lead to miscarriage or stillbirth. If rubella infection occurs during the first trimester of pregnancy, it can result in severe congenital defects, Congenital Rubella Syndrome (CRS). Congenital Rubella Syndrome in the infant includes but is not limited to eye manifestations (cataracts, glaucoma, retinitis), congenital heart defects, hearing loss, microcephaly, and intellectual disabilities. M-M-R II vaccine contains live attenuated measles, mumps and rubella viruses. It is not known whether M-M-R II vaccine can cause fetal harm when administered to pregnant woman. There are no adequate and well-controlled studies of M-M-R II vaccine administration to pregnant

women.

All pregnancies have a risk of birth defect, loss or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Available data suggest the rates of major birth defects and miscarriage in women who received M-M-R II vaccine within 30 days prior to pregnancy or during pregnancy are consistent with estimated background rates *(see Data)*.
Data

Human Data

A cumulative assessment of post-marketing reports for M-M-R II vaccine from licensure 01 April 1978 through 31 December 2018, identified 796 reports of inadvertent administration of M-M-R II vaccine occurring 30 days before or at any time during pregnancy with known pregnancy outcomes. Of the prospectively followed pregnancies for whom the timing of M-M-R II vaccination was known, 425 women received M-M-R II vaccine during the 30 days prior to conception through the second trimester. The outcomes for these 425 prospectively followed pregnancies included 16 infants with major birth defects, 4 cases of fetal death and 50 cases of miscarriage. No abnormalities compatible with congenital rubella syndrome have been identified in patients who received M-M-R II vaccine. Rubella vaccine virus can cross the placenta, leading to asymptomatic infection of the fetus. Mumps vaccine virus has also been shown to infect the placenta {14}, but there is no evidence that it causes congenital malformations or disease in the fetus or infant.

The CDC established the Vaccine in Pregnancy registry (1971-1989) of women who had received rubella vaccines within 3 months before or after conception. Data on 1221 inadvertently vaccinated pregnant women demonstrated no evidence of an increase in fetal abnormalities or cases of Congenital Rubella Syndrome (CRS) in the enrolled women {15}.

8.2 Lactation

Risk Summary
It is not known whether measles or mumps vaccine virus is secreted in human milk. Studies have

shown that lactating postpartum women vaccinated with live attenuated rubella vaccine may secrete the virus in breast milk and transmit it to breast-fed infants. {16,17} In the breast-fed infants with serological evidence of rubella virus vaccine strain antibodies, none exhibited severe disease; however, one exhibited mild clinical illness typical of acquired rubella. {18,19}

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for M-M-R II, and any potential adverse effects on the breastfed child from M-M-R II or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

M-M-R II vaccine is not approved for individuals less than 12 months of age. Safety and effectiveness of measles vaccine in infants below the age of 6 months have not been established *[see Clinical Studies (14)]*. Safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established.

8.5 Geriatric Use

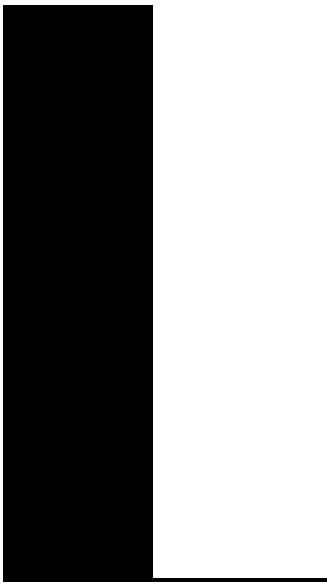
Clinical studies of M-M-R II did not include sufficient numbers of seronegative subjects aged 65 and over to determine whether they respond differently from younger subjects.

11 DESCRIPTION

M-M-R II vaccine is a sterile lyophilized preparation of (1) Measles Virus Vaccine Live, an attenuated line of measles virus, derived from Enders' attenuated Edmonston strain and propagated in chick embryo cell culture; (2) Mumps Virus Vaccine Live, the Jeryl LynnTM (B level) strain of mumps virus propagated in chick embryo cell culture; and (3) Rubella Virus Vaccine Live, the Wistar RA 27/3 strain of live attenuated rubella virus propagated in WI-38 human diploid lung fibroblasts. {20,21} The cells, virus pools, recombinant human serum albumin and fetal bovine serum used in manufacturing are tested and determined to be free of adventitious agents.

After reconstitution, each 0.5 mL dose contains not less than 3.0 $\log_{10}$ $TCID_{50}$ (tissue culture infectious doses) of measles virus; 4.1 $\log_{10}$ $TCID_{50}$ of mumps virus; and 3.0 $\log_{10}$ $TCID_{50}$ of rubella virus.

Each dose is calculated to contain sorbitol (14.5 mg), sucrose (1.9 mg), hydrolyzed gelatin (14.5 mg), recombinant human albumin (≤0.3 mg), fetal bovine serum (<1 ppm), approximately 25 mcg of neomycin and other buffer and media ingredients. The product contains no preservative.



12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

M-M-R II vaccination induces antibodies to measles, mumps, and rubella associated with protection which can be measured by neutralization assays, hemagglutination-inhibition (HI) assays, or enzyme linked immunosorbent assay (ELISA) tests. Results from efficacy studies or effectiveness studies that were previously conducted for the component vaccines of M-M-R II were used to define levels of serum antibodies that correlated with protection against measles, mumps, and rubella *[see Clinical Studies (14)].*

12.6 Persistence of Antibody Responses After Vaccination

Neutralizing and ELISA antibodies to measles, mumps, and rubella viruses are still detectable in 95-100%, 74-91%, and 90-100% of individuals respectively, 11 to 13 years after primary vaccination. {22-28}

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

M-M-R II vaccine has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.

14 CLINICAL STUDIES

14.1 Clinical Efficacy

Efficacy of measles, mumps, and rubella vaccines was established in a series of double-blind controlled trials. {29-34} These studies also established that seroconversion in response to vaccination against measles, mumps and rubella paralleled protection. {35-38}

14.2 Immunogenicity

Clinical studies enrolling 284 triple seronegative children, 11 months to 7 years of age, demonstrated that M-M-R II vaccine is immunogenic. In these studies, a single injection of the vaccine induced measles HI antibodies in 95%, mumps neutralizing antibodies in 96%, and rubella HI antibodies in 99% of susceptible individuals.

A study of 6-month-old and 15-month-old infants born to mothers vaccinated with a measles vaccine in childhood, demonstrated that, following infant and toddler vaccination with Measles Virus Vaccine, Live (previously US-licensed, manufactured by Merck), 74% of the 6-month-old infants developed detectable neutralizing antibody titers while 100% of the 15-month-old infants vaccinated with Measles Virus Vaccine, Live or M-M-R II vaccine developed neutralizing antibodies {39}. When the 6-month-old infants of immunized mothers were revaccinated at 15 months with M-M-R II vaccine, they developed antibody titers similar to those of toddlers who were vaccinated previously at 15-months of age.

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16 HOW SUPPLIED/STORAGE AND HANDLING

No. 4681 – M-M-R II vaccine is supplied as follows:
(1) a box of 10 single-dose vials of lyophilized vaccine (package A), NDC 0006-4681-00
(2) a box of 10 vials of diluent (package B)
Exposure to light may inactivate the vaccine viruses.
To maintain potency, M-M-R II must be stored between -58°F and +46°F (-50°C to +8°C). Use of

dry ice may subject M-M-R II to temperatures colder than -58°F (-50°C).
Before reconstitution, refrigerate the lyophilized vaccine at 36°F to 46°F (2°C to 8°C).
Store accompanying diluent in the refrigerator (36°F to 46°F, 2°C to 8°C) or at room temperature (68°F

to 77°F, 20°C to 25°C). **Do not freeze the diluent**.
Administer M-M-R II vaccine as soon as possible after reconstitution. If not administered immediately,

reconstituted vaccine may be stored between 36°F to 46°F (2°C to 8°C), protected from light, for up to 8 hours. Discard reconstituted vaccine if it is not used within 8 hours.

For information regarding the product or questions regarding storage conditions, call 1-800-MERCK-90 (1-800-637-2590).

17

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Package Insert).

Discuss the following with the patient:

- Provide the required vaccine information to the patient, parent, or guardian.
- Inform the patient, parent, or guardian of the benefits and risks associated with vaccination.
- Question the patient, parent, or guardian about reactions to a previous dose of M-M-R II vaccine or other measles-, mumps-, or rubella-containing vaccines.
- Question females of reproductive potential regarding the possibility of pregnancy. Inform female patients to avoid pregnancy for 1 month following vaccination *[see Contraindications (4.5) and Use in Specific Populations (8.1)]*.
- Inform the patient, parent, or guardian that vaccination with M-M-R II may not offer 100% protection from measles, mumps, and rubella infection.
- Instruct patients, parents, or guardians to report any adverse reactions to their health-care provider. The U.S. Department of Health and Human Services has established a Vaccine Adverse Event Reporting System (VAERS) to accept all reports of suspected adverse events after the administration of any vaccine, including but not limited to the reporting of events required by the National Childhood Vaccine Injury Act of 1986. For information or a copy of the vaccine reporting form, call the VAERS toll-free number at 1-800-822-7967, or report online at https://www.vaers.hhs.gov.

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NDMA
Est.1887 NORTH DAKOTA MEDICAL ASSOCIATION

House Human Services Committee
HB 1468
January 25, 2021

Chair Weisz and Committee Members, I am Misty Anderson, president of the ND Medical Association. The North Dakota Medical Association is the professional membership organization for North Dakota physicians, residents, and medical students. I am also an Internal Medicine physician at Sanford Health in Valley City.

NDMA stands in opposition to HB 1468 and I am here today to outline our reasons for opposing this bill.

I provide care to adults who still need and want various vaccinations depending on their age, underlying health conditions, planned travel, and desire to prevent disease. Vaccines are routinely given in my clinic, at local pharmacies, and at county health offices without a physician even present. At some visit's adults may receive 2-3 vaccinations and we already have a process for providing up to date vaccine information to patients.

Informed consent is very important for vaccines. Health care providers already provide extensive information for informed consent through Vaccine Information Statements (VIS). I also provide patients with information about the benefits and risks of vaccinations; therefore, providing additional and redundant information takes time away from the patient's other health concerns.

Actions proposed in HB 1468 have the potential to mitigate statewide vaccine progress by placing undue burden on health care professionals while instilling unfounded fear of the vaccine process. Regarding the package insert requirement, it is important to know that this information is not regularly updated, which can be problematic as new and evolving information may not be added, in addition to package inserts being very lengthy and confusing to the patient.

Federal law already mandates that providers give patients a Vaccine Information Statement (VIS) before vaccination and is handed out for each vaccine received. The VISs distributed to patients are straight forward and easy to understand.

HB 1468 places the onus to educate solely on health care providers through enforcement of a mandate that highly penalizes health care providers.

Thank you for the opportunity to testify today. I would be happy to answer any questions.

House Bill 1468 - In Opposition
Human Services Committee
67th Legislative Assembly in North Dakota
January 25, 2021

Good Afternoon Chairman Weisz, Vice Chair Rohr, and Human Services Committee Members,

My name is Kathy Anderson. I am President of the North Dakota American Academy of Pediatrics. I have been a general pediatrician in Bismarck for over 10 years, having served as chair of pediatrics at both CHI and Mid Dakota Clinic during that time. I am speaking in opposition to House Bill 1468.

I am a board certified general pediatrician and a board certified integrative medicine physician. My wholistic training provides me with a perspective that may be helpful in this discussion. I have spent additional time learning about nutrition, Ayurvedic Medicine, Traditional Chinese Medicine, osteopathic and chiropractic medicine. And, like most Americans, I do believe that there is a place for considering what is "outside the box" and how this can help augment care, quality of life, and outcomes. I think that the polarized environment within which much vaccine discussion occurs is narrow, uninformed, and not helpful to the individuals in our community that we are all trying to care for. I do not understand why we cannot both optimize our immune systems through ensuring all families access to sufficient high quality foods, toxin free water and air, while also providing vaccines to prevent infectious diseases that cause disability and death to children.

During a 15-30 minute appointment with a patient, providers are discussing parent and child concerns, discussing immunizations, assessing growth and development, assessing child and caregiver mental health, food insecurity, family stressors, counseling on preventing disease and injury, supporting healthy relationships, optimizing development and learning, and examining the child. Based on the discussion, assessment and exam, we are then developing a plan that prioritizes the needs of that patient and family, which may include close follow up for growth, referral for developmental concerns, or referral for physical exam findings, connection with resources or community support for food insecurity. Today's parents have a wealth of information from a variety of sources at their fingertips and come in with questions about various topics including vaccines. We take time providing information and answering questions. A bill like this will have may take away from valuable time needed to address other family stressors like mental health concerns or food insecurity.

Just like in any ecosystem, in our state, there is a delicate balance that exists which allows us to live the way that we are accustomed to. Especially in a year like this one, we can appreciate how much of a ripple effect occurs when one thing goes out of balance. Like COVID-19, many of the diseases for which we immunize children (and adults) are infectious and can easily spread around communities like ours, overwhelming our medical system and devastating our families.

If you refer to the handout on vaccine preventable diseases and North Dakota, these were made to illustrate state vaccine rates by disease, and % immunization required to prevent infection spread within the community. Different diseases have different thresholds required to prevent disease spread (based on how infectious the actual organism is and its mode of transmission). As you can see, we are above threshold for many diseases except pertussis, meaning we have about enough immunity within the community to prevent spread of disease amongst our population that is un-immunized, whether by personal choice, or because they are not yet eligible due to young age. IF we do not maintain immunity rates within the community, and we spread these infectious diseases, we will experience very similar quarantines and lock downs like we have had to implement for COVID-19.

As a first generation American with parents from developing countries, I can tell you that there are not groups like this discussing reducing vaccine rates, there are people lined up outside the hospitals and clinics and around the block ensuring that they get their children vaccinated because they have a neighbor, or cousin, or coworker, who has lost a child to diseases that vaccines prevent. We are lucky to be able to have philosophical discussions like these on the efficacy of vaccines when strong evidence already exists, and to craft roadblocks to vaccine delivery, because our privilege of having higher than threshold immunization rates, allows us to. But this will not be the case if we continue to support this discussion, discourage families from protecting their children from devastating diseases, and ultimately drive down our community rates of immunity, we will see a rise in disease, disability, and death in both the population that desires vaccine before children are eligible, and in the population that does not vaccinate. This could send us back to infant/child mortality rates in the 0-4 population closer to where we were in the 1950s, or where some developing countries sit now, almost 10 times higher than our current national infant/child mortality rates.

Bills like these were introduced in over 16 states in 2019 and none were passed or went very far in legislative committees. These bills are crafted to place an unrealistic emphasis on the negative effects of vaccines. And in many of the states, these bills are being pushed forward by a group of people that have never had the responsibility of caring for a child who has been devastated by one of these diseases. By groups who have never had to give chest compressions to a 12 lbs baby in the ER because they stopped breathing at home, and subsequently learned they tested positive for pertussis. Or had to meet with a family on a daily basis whose 4 month old was in the ICU recovering from HIB meningitis, and discuss the small improvements in ventilator settings and chest x rays, when imaging studies of the brain show how much of a toll the disease took before it was controlled, and there remained great uncertainty as to what recovery and capacity would look like for this child.

For the reasons previously stated, with the strong body of evidence supporting current practice, and for the families and communities across the state, I ask that you vote in opposition of moving this bill forward.

Kathy Anderson, MD, FAAP, IBCLC, CEIM
President, North Dakota American Academy of Pediatrics, NDAAP
District VI Champion, Diversity, Inclusion, Equity, AAP
Board Certified General Pediatrics and Integrative Medicine

The State of North Dakota's Child Vaccination Rates

How North Dakota Compares with National Rates

North Dakota USA

DTaP vaccine (≥4 doses) in children 19-35 months old

86.1%

83.2%

MMR vaccine (≥1 dose) in children 19-35 months old

95.7%

91.5%

Varicella vaccine (≥1 dose) in children 19-35 months old

95%

91%

HPV vaccine (≥1 dose) in adolescents 13-17 years old

74.7% North Dakota females

70.4% North Dakota males

68.6% USA females

62.6% USA males

Influenza vaccine, cumulative flu-season coverage in children 6 months-17 years old

62.4%

57.9%

Combined 7-vaccine series in children 19-35 months old

Includes ≥4 DTaP doses, ≥3 Polio doses, ≥1 MMR dose, Hib full series, ≥3 HepB doses, ≥1 Varicella dose, and ≥4 PCV doses

78.8%

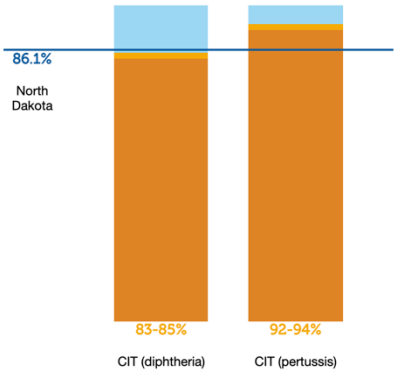
70.4%

Healthy People 2020 Target Goal: 80%

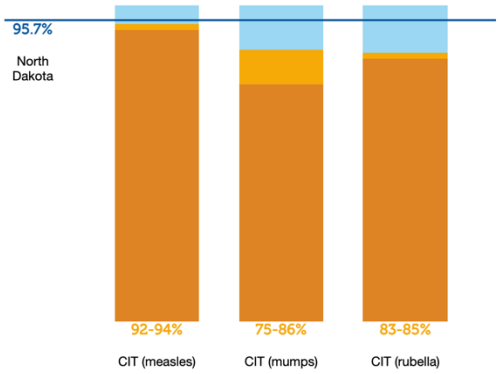
How North Dakota Compares with Community Immunity Thresholds (CIT)

Thresholds indicate the amount of vaccinated people needed to maintain community immunity—not all diseases have defined thresholds

DTaP vaccine (≥4 doses) in children 19-35 months old



MMR vaccine (≥1 dose) in children 19-35 months old



Exemptions from Vaccines Can Deter Meeting Community Immunity Thresholds

YES Religious exemptions allowed?

YES Philosophical exemptions allowed?

Testimony in Opposition
HB 1468
Human Services Committee January 25, 2021

Good afternoon Chair Weisz, Vice Chair Rohr, and members of the Committee,

My name is Dr Parag Kumar, MD, FAAP and I am a pediatrician at Sanford, Bismarck since last 20 years. I am also Clinical Professor, Clerkship director(Pediatrics), University of North Dakota School of Medicine and Health sciences Southwest campus Bismarck and Chairman of the North Dakota medical Association socioeconomic commission. Thank you for the opportunity to testify in **opposition** to HB 1468. I am asking the committee to give this bill a Do Not Pass recommendation.

Childhood vaccination rates in our community are 85 -95 %. 94 % of children entering Kindergarten are vaccinated against MMR. The requirement of providing the package insert will be burdensome to maintain such high immunization rates. Certainly, every parent who brings questions about vaccines to a pediatrician deserves support in a non-judgmental way. But then they deserve actual answers based on the science.

Package Inserts have very serious drawbacks as informed consent. First, and very importantly, inserts by design do not include a vaccine's benefits. They do not tell parents why they should get the vaccine, or the risks of not getting it. That makes the insert irredeemably flawed as an informed consent document. It simply does not include a major aspect of the information parents need to make a decision.

Most physicians feel that package inserts are not required and are also not useful for informed consent. Making this a law will hinder immunization and is government intrusion in to physician patient relationship. Is the package insert a helpful document to achieve informed consent? Imagine the following scenario. A child has been diagnosed with type I diabetes. The parent sits with the doctor and learns that the child will need to use insulin. The doctor pulls out a 24 page insert (pdf), gives to the parent, and says "here is a document I need to give you for informed consent." This is not only intimidating but will also hinder patient care.

Informed consent is important. For vaccines, as it is for all other medical treatments. But there appears to be some misunderstandings about what constitutes informed consent in this context. Informed consent is already provided in the form of **Vaccine information Statements (VIS)** . The Vaccine information Statements (VIS) are short, accessible, and accurate. They are made after a regulatory process that includes a notice and comment process as required in §553 of the Administrative Procedures Act: the government publishes notice, gives opportunity for comments, and then publishes an explanation for its final rule. Parents get an accessible, accurate document giving them the facts they need for informed consent – and additional facts, like information about what to do if there's an adverse reaction, including reporting to the Vaccine Adverse Events System and how to file a claim with the Vaccine Injury Compensation Program. All physicians go over this VIS, the patient gets this in time to peruse it, and has a chance to raise questions and complaints, thus meeting the requirements of informed consent.

The complications (autism, seizures, deaths) or events following vaccinations are spurious correlations and not causation. These reasonable observations have been looked at closely in multiple large studies which do **include a control group**. Hundreds of such huge studies, in many countries, with millions of dollars spent, have not found any association or causation.

Unpublished and anecdotal experience of witnessing children injured from vaccines by physicians are misleading. Many have conflict of interest in promoting their anti-vaccination books or agenda. It is important to understand the difference between correlation and causation. There is a very tight correlations with U.S. cell phone cells, or organic food sales and autism. Whenever sales of ice cream go up there is increase in drowning. These are some examples of correlation and not causation. Vaccines don't cause autism. Vaccines, instead, prevent disease. Vaccines have wiped out a score of formerly deadly childhood diseases. Vaccine skepticism has helped to bring some of those diseases back from near extinction. I fear this HB 1468 (requirement of package insert) will be burdensome, unnecessary and may bring back diseases from near extinction.

I strongly urge do not pass recommendation for the HB 1468.

Sincerely,
Parag Kumar, MD, FAAP.

NORTH Dakota | Health
Be Legendary.™

House Bill 1468
Human Services Committee
January 25, 2021, 2 p.m.

Good afternoon, Chairman Weisz and members of the Human Services Committee. My name is Molly Howell, and I am the Immunization Director at the North Dakota Department of Health (NDDoH). I am providing testimony in opposition to HB1468.

The NDDoH agrees that there should be informed consent for vaccination. In fact, there already is informed consent. Before each dose that is administered to children, health care providers are required by federal law to provide a vaccine information statement (VIS). Because COVID-19 vaccination is under emergency use authorization (EUA), an EUA fact sheet is required. The VIS and EUA factsheets provide information in plain language about the risks and benefits of vaccination. These factsheets inform the public about how to report vaccine adverse events. They explain who should and should not be vaccinated. VISs are approved by the Advisory Committee on Childhood Vaccines, which includes three members of the public (two of which are parents of vaccine-injured children) and three attorneys. Package inserts, on the other hand, are written in scientific language and intended for health care providers. They include information from clinical trials, even if unrelated to vaccination. For example, if a trial participant gets into a car accident and dies.

The NDDoH Division of Immunization conducts site visits at health care provider offices and assesses whether health care providers have up-to-date VISs on hand and that providers are routinely offering them. Each Vaccines For Children (VFC) Program enrolled provider site (195) receives at least one site visit every other year.

In 2020, 689,890 vaccine doses were administered in North Dakota according to the North Dakota Immunization Information System (NDIIS). If a package insert needs to be provided, in addition to a VIS, with each dose that will cost health care providers an estimated $1 per dose for about **$1.38 million** for the biennium. This is likely a low-cost estimate with a higher number of doses administered anticipated due to COVID-19 vaccination. This estimate is based on a package insert length of 10 pages and $0.10 per page, double-sided and stapled. Some package inserts are as long as 43 pages.

I have attached an example of a VIS and an example of a package insert. Also attached is an informative fact sheet from Vaccinate Your Family that explains what a VIS is and why it is used instead of a package insert.

Exemption information for child care and school immunizations is already available on our website. Exemption information is available on the exact same document as information about requirements. The Certificate of Immunization also includes exemption information and is available on our website.

Pregnant women are recommended to be vaccinated against influenza and pertussis. A 2018 study showed that getting a flu shot reduced a pregnant woman's risk of being hospitalized with flu by an average of 40%. Pregnant women who get a flu vaccine also are helping to protect their babies from flu illness for the first several months after their birth, when they are too young to get vaccinated. Protection against pertussis (whooping cough) is included in the tetanus, diphtheria, and acellular pertussis vaccine (Tdap). Getting a Tdap vaccine between 27 through 36 weeks of pregnancy lowers the risk of whooping cough in babies younger than 2 months old by 78%. They also receive a VIS informing them of the risks and benefits. There are numerous studies for both Tdap and influenza vaccines that show the safety and benefits of vaccination for pregnant women. The requirement for a "witness" to be present when vaccinating a pregnant woman creates an additional burden for already limited health care providers in North Dakota.

For the reasons I have outlined today, the NDDoH asks you to oppose HB1468. This concludes my testimony. I am happy to answer any questions you may have.

Vaccine Information Statements (VISs) Provide Informed Consent on Vaccines

For meaningful informed consent about vaccinations, you need materials that:

- Are accurate
- Cover necessary information in a way that is understandable to most people
- Link to more detailed information for those who want it

Vaccine Information Statements (VIS) provide informed consent about the risks and benefits of vaccinations. Materials that are too technical, lengthy, unclear or provide confusing information can undermine informed consent.

What is a VIS?

- VISs are important sources of vaccine information for the public. They are written in easy-to-understand language to help vaccine-recipients (or their parents/caregivers) better understand the risks and benefits of vaccines.
- Each VIS includes the benefits and risks of each vaccine, and clearly outlines the process for reporting to the Vaccine Adverse Event Reporting System (VAERS) as well as filing a claim with the National Vaccine Injury Compensation Program (VICP), if necessary.
- Federal law requires that a VIS be provided to patients or parents/caregivers *before* each and every vaccine is administered. It must be given regardless of the age of the vaccine recipient.
- Healthcare providers must also record specific information in the patient's medical record or permanent office log, including the edition date of the VIS, the date the VIS was given, the vaccine administration date, the office address and name and title of the person who administers the vaccine, and the vaccine manufacturer and lot number.

Who writes a VIS?

- Each VIS is written by the Centers for Disease Control and Prevention (CDC), and the content is informed by a group of independent experts and parents, including representatives from Vaccinate Your Family and the National Vaccine Information Center – two organizations with divergent views of vaccinations.
- The wording of each VIS is carefully crafted to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of *The Patient Protection and Affordable Care Act of 2010*.
- Each VIS is reviewed and approved by the Advisory Committee on Childhood Vaccines (ACCV), which includes:
    - Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury.

- Three members who are attorneys, including at least one who represents individuals who may have been vaccine-injured.

Why are VISs given to patients instead of the vaccine package insert?

- Vaccine manufacturers are required by the FDA to report all events during a clinical trial. For example, if a child is involved in a car accident during the clinical trial and reports to the hospital with a broken arm, the manufacturer must report a broken arm as an adverse event of the vaccine even though we know they are not related.
- Sometimes, a VIS does not exactly match a manufacturer's product insert. That's because VISs follow the Advisory Committee for Immunization Practices' (ACIP's) recommendations. ACIP carefully considers whether adverse events reported during clinical trials could be causally linked to the vaccination.
- ACIP has the ability to remove non-related injuries for the sake of clarity on a VIS. However, it is important to note that the final section of each VIS - *How can I learn more?* - states that parents and patients can ask their healthcare providers for the package insert.

Where can I find more information about Vaccine Information Statements?

- The CDC has all of the English-language VISs on their website: www.cdc.gov/vaccines/hcp/vis/index.html
- The CDC has a page on Frequently-Asked Questions on VISs: www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html
- VISs have been translated into about 40 languages. These can be found on the Immunization Action Coalition's website: www.immunize.org/vis/

Vaccine Information Statements ensure patients and parents have enough information to make a truly informed decision whether to vaccinate themselves or their children.

Source

National Center for Immunization and Respiratory Diseases. "Vaccine Information Statements (VISs)." *Centers for Disease Control and Prevention.* www.cdc.gov/vaccines/hcp/vis/index.html. Last Accessed: October 3, 2018.

Recombinant Zoster (Shingles) Vaccine: *What You Need to Know*

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

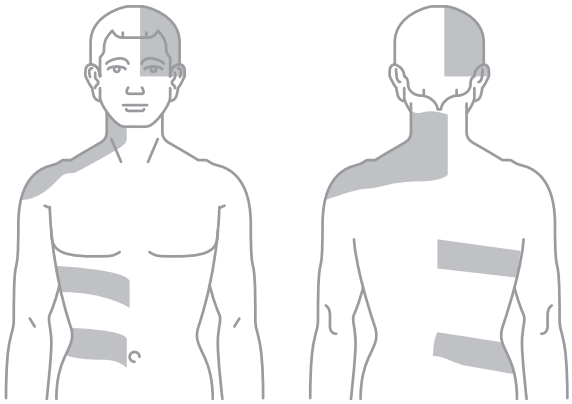
Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Recombinant zoster (shingles) vaccine can prevent **shingles**.

Shingles (also called herpes zoster, or just zoster) is a painful skin rash, usually with blisters. In addition to the rash, shingles can cause fever, headache, chills, or upset stomach. More rarely, shingles can lead to pneumonia, hearing problems, blindness, brain inflammation (encephalitis), or death.

The most common complication of shingles is long-term nerve pain called postherpetic neuralgia (PHN). PHN occurs in the areas where the shingles rash was, even after the rash clears up. It can last for months or years after the rash goes away. The pain from PHN can be severe and debilitating.



About 10 to 18% of people who get shingles will experience PHN. The risk of PHN increases with age. An older adult with shingles is more likely to develop PHN and have longer lasting and more severe pain than a younger person with shingles.

Shingles is caused by the varicella zoster virus, the same virus that causes chickenpox. After you have chickenpox, the virus stays in your body and can cause shingles later in life. Shingles cannot be passed from one person to another, but the virus that causes shingles can spread and cause chickenpox in someone who had never had chickenpox or received chickenpox vaccine.

2 Recombinant shingles vaccine

Recombinant shingles vaccine provides strong protection against shingles. By preventing shingles, recombinant shingles vaccine also protects against PHN.

Recombinant shingles vaccine is the preferred vaccine for the prevention of shingles. However, a different vaccine, live shingles vaccine, may be used in some circumstances.

The recombinant shingles vaccine is recommended for **adults 50 years and older** without serious immune problems. It is given as a two-dose series.

This vaccine is also recommended for people who have already gotten another type of shingles vaccine, the live shingles vaccine. There is no live virus in this vaccine.

Shingles vaccine may be given at the same time as other vaccines.

3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of recombinant shingles vaccine**, or has any **severe, life-threatening allergies**.
- Is **pregnant or breastfeeding**.
- Is **currently experiencing an episode of shingles**.

In some cases, your health care provider may decide to postpone shingles vaccination to a future visit.

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

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting recombinant shingles vaccine.

Your health care provider can give you more information.

4 Risks of a vaccine reaction

- A sore arm with mild or moderate pain is very common after recombinant shingles vaccine, affecting about 80% of vaccinated people. Redness and swelling can also happen at the site of the injection.
- Tiredness, muscle pain, headache, shivering, fever, stomach pain, and nausea happen after vaccination in more than half of people who receive recombinant shingles vaccine.

In clinical trials, about 1 out of 6 people who got recombinant zoster vaccine experienced side effects that prevented them from doing regular activities. Symptoms usually went away on their own in 2 to 3 days.

You should still get the second dose of recombinant zoster vaccine even if you had one of these reactions after the first dose.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do not give medical advice.*

6 How can I learn more?

- Ask your health care provider.
- 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/vaccines**

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SHINGRIX safely and effectively. See full prescribing information for SHINGRIX.

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted), suspension for intramuscular injection
Initial U.S. Approval: 2017

---------- INDICATIONS AND USAGE----------
SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.
Limitations of Use (1):
- SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

----------DOSAGE AND ADMINISTRATION----------
For intramuscular administration only.
Administer 2 doses (0.5 mL each) at 0 and 2 to 6 months. (2.2, 2.3)

---------- DOSAGE FORMS AND STRENGTHS----------
Suspension for injection supplied as a single-dose vial of lyophilized varicella zoster virus glycoprotein E (gE) antigen component to be reconstituted with the accompanying vial of $AS01_B$ adjuvant suspension component. After reconstitution, a single dose of SHINGRIX is 0.5 mL. (3)

---------- CONTRAINDICATIONS ----------
History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX. (4)

---------- ADVERSE REACTIONS ----------
- Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%). (6.1)
- Solicited general adverse reactions in subjects aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 10/2019

FULL PRESCRIBING INFORMATION: CONTENTS*

***Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.

Limitations of Use:

- SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Reconstitution

SHINGRIX is supplied in 2 vials that must be combined prior to administration. Prepare SHINGRIX by reconstituting the lyophilized varicella zoster virus glycoprotein E (gE) antigen

component (powder) with the accompanying $AS01_B$ adjuvant suspension component (liquid). Use only the supplied adjuvant suspension component (liquid) for reconstitution. The reconstituted vaccine should be an opalescent, colorless to pale brownish liquid. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

Figure 1. Cleanse both vial stoppers. Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the adjuvant suspension component (liquid) by slightly tilting the vial. Vial 1 of 2.

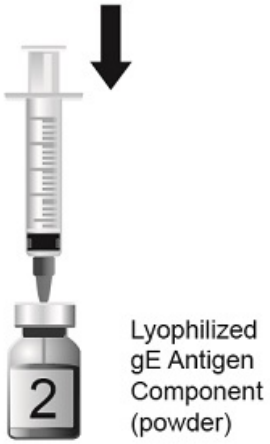


Figure 2. Slowly transfer entire contents of syringe into the lyophilized gE antigen component vial (powder). Vial 2 of 2.

Figure 3. Gently shake the vial to thoroughly mix contents until powder is completely dissolved.

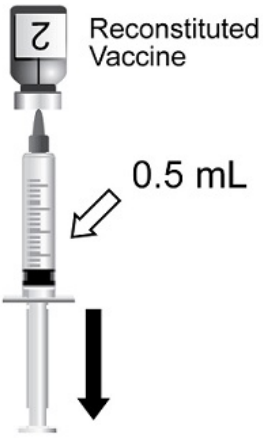


Figure 4. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine and administer **intramuscularly**.

2.2 Administration Instructions

For intramuscular injection only.

After reconstitution, administer SHINGRIX immediately or store refrigerated between 2° and 8°C (36° and 46°F) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours.

Use a separate sterile needle and sterile syringe for each individual. The preferred site for intramuscular injection is the deltoid region of the upper arm.

2.3 Dose and Schedule

Two doses (0.5 mL each) administered intramuscularly according to the following schedule: A

first dose at Month 0 followed by a second dose administered anytime between 2 and 6 months later.

3 DOSAGE FORMS AND STRENGTHS

SHINGRIX is a suspension for injection supplied as a single-dose vial of lyophilized gE antigen component to be reconstituted with the accompanying vial of $AS01_B$ adjuvant suspension component. A single dose after reconstitution is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer SHINGRIX to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX *[see Description (11)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. There is the possibility that broad use of SHINGRIX could reveal adverse reactions not observed in clinical trials.

Overall, 17,041 adults aged 50 years and older received at least 1 dose of SHINGRIX in 17 clinical studies.

The safety of SHINGRIX was evaluated by pooling data from 2 placebo-controlled clinical studies (Studies 1 and 2) involving 29,305 subjects aged 50 years and older who received at least 1 dose of SHINGRIX (n = 14,645) or saline placebo (n = 14,660) administered according to a 0- and 2-month schedule. At the time of vaccination, the mean age of the population was 69 years; 7,286 (24.9%) subjects were aged 50 to 59 years, 4,488 (15.3%) subjects were aged 60 to 69 years, and 17,531 (59.8%) subjects were aged 70 years and older. Both studies were conducted in North America, Latin America, Europe, Asia, and Australia. In the overall population, the majority of subjects were white (74.3%), followed by Asian (18.3%), black (1.4%), and other racial/ethnic groups (6.0%); 58% were female.

Solicited Adverse Events

In Studies 1 and 2, data on solicited local and general adverse events were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX, n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local adverse reaction and each solicited general adverse event following administration of SHINGRIX (both doses combined) were pain (78.0%), redness (38.1%), and swelling (25.9%); and myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%), respectively.

The reported frequencies of specific solicited local adverse reactions and general adverse events (overall per subject), by age group, from the 2 studies are presented in Table 1.

Table 1. Percentage of Subjects with Solicited Local Adverse Reactions and General Adverse Events within 7 Days[a] of Vaccination in Adults Aged 50 to 59 Years, 60 to 69 Years, and 70 Years and Older[b] (Total Vaccinated Cohort with 7-Day Diary Card)

	Aged 50 - 59 Years		Aged 60 - 69 Years		Aged ≥70 Years	
	SHINGRIX %	Placebo[c] %	SHINGRIX %	Placebo[c] %	SHINGRIX %	Placebo[c] %
Local Adverse Reactions	**n = 1,315**	**n = 1,312**	**n = 1,311**	**n = 1,305**	**n = 2,258**	**n = 2,263**
Pain	88.4	14.4	82.8	11.1	69.2	8.8
Pain, Grade 3[d]	10.3	0.5	6.9	0.5	4.0	0.2
Redness	38.7	1.2	38.4	1.6	37.7	1.2
Redness, >100 mm	2.8	0.0	2.6	0.0	3.1	0.0
Swelling	30.5	0.8	26.5	1.0	23.0	1.1
Swelling, >100 mm	1.1	0.0	0.5	0.0	1.3	0.0
General Adverse Events	**n = 1,315**	**n = 1,312**	**n = 1,309**	**n = 1,305**	**n =2,252**	**n = 2,264**
Myalgia	56.9	15.2	49.0	11.2	35.1	9.9
Myalgia, Grade 3[e]	8.9	0.9	5.3	0.8	2.8	0.4
Fatigue	57.0	19.8	45.7	16.8	36.6	14.4
Fatigue, Grade 3[e]	8.5	1.8	5.0	0.8	3.5	0.8
Headache	50.6	21.6	39.6	15.6	29.0	11.8
Headache, Grade 3[e]	6.0	1.7	3.7	0.2	1.5	0.4
Shivering	35.8	7.4	30.3	5.7	19.5	4.9
Shivering, Grade 3[e]	6.8	0.2	4.5	0.3	2.2	0.3
Fever	27.8	3.0	23.9	3.4	14.3	2.7
Fever, Grade 3[f]	0.4	0.2	0.5	0.2	0.1	0.1
GI[g]	24.3	10.7	16.7	8.7	13.5	7.6
GI, Grade 3[e]	2.1	0.7	0.9	0.6	1.2	0.4

Total vaccinated cohort for safety included all subjects with at least 1 documented dose (n).

[a] 7 days included day of vaccination and the subsequent 6 days.

[b] Data for subjects aged 50 to 59 years and 60 to 69 years are based on Study 1. Data for subjects 70 years and older are based on pooled data from Study 1: NCT01165177 and Study 2: NCT01165229.

[c] Placebo was a saline solution.

[d] Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.

[e] Grade 3 myalgia, fatigue, headache, shivering, GI: Defined as preventing normal activity.

[f] Fever defined as ≥37.5°C/99.5°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route; Grade 3 fever defined as >39.0°C/102.2°F.

[g] GI = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

The incidence of solicited local and general symptoms was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

The majority of solicited local adverse reactions and general adverse events seen with SHINGRIX had a median duration of 2 to 3 days.

There were no differences in the proportions of subjects reporting any or Grade 3 solicited local reactions between Dose 1 and Dose 2. Headache and shivering were reported more frequently by subjects after Dose 2 (28.2% and 21.4%, respectively) compared with Dose 1 (24.4% and 13.8%, respectively). Grade 3 solicited general adverse events (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3.1%, 3.6%, and 3.5%, respectively) compared with Dose 1 (1.4%, 1.4%, 2.3%, and 2.4%, respectively).

Unsolicited Adverse Events

Unsolicited adverse events that occurred within 30 days following each vaccination (Day 0 to 29) were recorded on a diary card by all subjects. In the 2 studies, unsolicited adverse events occurring within 30 days of vaccination were reported in 50.5% and 32.0% of subjects who received SHINGRIX (n = 14,645) and placebo (n = 14,660), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in ≥1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (3.5% versus 0.2%), injection site pruritus (2.2% versus 0.2%), malaise (1.7% versus 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

Gout (including gouty arthritis) was reported by 0.18% (n = 27) versus 0.05% (n = 8) of subjects who received SHINGRIX and placebo, respectively, within 30 days of vaccination; available information is insufficient to determine a causal relationship with SHINGRIX.

Serious Adverse Events (SAEs)

In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3%) and placebo (2.2%) from the first administered dose up to 30 days post last vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and for 10.4% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. One subject (<0.01%) reported lymphadenitis and 1 subject (<0.01%) reported fever greater than 39°C; there was a basis for a causal relationship with SHINGRIX.

Optic ischemic neuropathy was reported in 3 subjects (0.02%) who received SHINGRIX (all within 50 days after vaccination) and 0 subjects who received placebo; available information is insufficient to determine a causal relationship with SHINGRIX.

Deaths

From the first administered dose up to 30 days post last vaccination, deaths were reported for 0.04% of subjects who received SHINGRIX and 0.05% of subjects who received placebo in the 2 studies. From the first administered dose up to 1 year post last vaccination, deaths were

reported for 0.8% of subjects who received SHINGRIX and for 0.9% of subjects who received placebo. Causes of death among subjects were consistent with those generally reported in adult and elderly populations.

Potential Immune-Mediated Diseases

In the 2 studies, new onset potential immune-mediated diseases (pIMDs) or exacerbation of existing pIMDs were reported for 0.6% of subjects who received SHINGRIX and 0.7% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. The most frequently reported pIMDs occurred with comparable frequencies in the group receiving SHINGRIX and the placebo group.

Dosing Schedule

In an open-label clinical study, 238 subjects 50 years and older received SHINGRIX as a 0- and 2-month or 0- and 6-month schedule. The safety profile of SHINGRIX was similar when administered according to a 0- and 2-month or 0- and 6-month schedule and was consistent with that observed in Studies 1 and 2.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of SHINGRIX. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

General Disorders and Administration Site Conditions

Decreased mobility of the injected arm which may persist for 1 or more weeks.

Immune System Disorders

Hypersensitivity reactions, including angioedema, rash, and urticaria.

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration

For concomitant administration of SHINGRIX with inactivated influenza vaccine *[see Clinical Studies (14.5)]*.

7.2 Immunosuppressive Therapies

Immunosuppressive therapies may reduce the effectiveness of SHINGRIX.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. There are no available human data to establish whether there is vaccine-associated risk with SHINGRIX in pregnant women.

A reproductive and developmental toxicity study was performed in female rats administered SHINGRIX or the $AS01_B$ adjuvant alone prior to mating, during gestation, and during lactation. The total dose was 0.2 mL on each occasion (a single human dose of SHINGRIX is 0.5 mL). This study revealed no adverse effects on fetal or pre-weaning development due to SHINGRIX *(see Data)*.

Data

Animal Data: In a reproductive and developmental toxicity study, female rats were administered SHINGRIX or the $AS01_B$ adjuvant alone by intramuscular injection 28 and 14 days prior to mating, on gestation Days 3, 8, 11, and 15, and on lactation Day 7. The total dose was 0.2 mL on each occasion (a single human dose of SHINGRIX is 0.5 mL). No adverse effects on pre-weaning development up to post-natal Day 25 were observed. There were no vaccine-related fetal malformations or variations.

8.2 Lactation

Risk Summary

It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for SHINGRIX and any potential adverse effects on the breastfed child from SHINGRIX or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

Safety and effectiveness in individuals younger than 18 years have not been established. SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

8.5 Geriatric Use

Of the total number of subjects who received at least 1 dose of SHINGRIX in the 2 efficacy trials (n = 14,645), 2,243 (15.3%) were aged 60 to 69 years, 6,837 (46.7%) were aged 70 to 79 years, and 1,921 (13.1%) were 80 years and older. There were no clinically meaningful differences in

efficacy across the age groups or between these subjects and younger subjects. *[See Clinical Studies (14.1, 14.2, 14.3).]*

The frequencies of solicited local and general adverse events in subjects aged 70 years and older were lower than in younger adults (aged 50 through 69 years). *[See Adverse Reactions (6.1).]*

11 DESCRIPTION

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted) is a sterile suspension for intramuscular injection. The vaccine is supplied as a vial of lyophilized recombinant varicella zoster virus surface glycoprotein E (gE) antigen component, which must be reconstituted at the time of use with the accompanying vial of $AS01_B$ adjuvant suspension component. The lyophilized gE antigen component is presented in the form of a sterile white powder. The $AS01_B$ adjuvant suspension component is an opalescent, colorless to pale brownish liquid supplied in vials.

The gE antigen is obtained by culturing genetically engineered Chinese Hamster Ovary cells, which carry a truncated gE gene, in media containing amino acids, with no albumin, antibiotics, or animal-derived proteins. The gE protein is purified by several chromatographic steps, formulated with excipients, filled into vials, and lyophilized.

The adjuvant suspension component is $AS01_B$ which is composed of 3-*O*-desacyl-4'-monophosphoryl lipid A (MPL) from *Salmonella minnesota* and QS-21, a saponin purified from plant extract *Quillaja saponaria* Molina, combined in a liposomal formulation. The liposomes are composed of dioleoyl phosphatidylcholine (DOPC) and cholesterol in phosphate-buffered saline solution containing disodium phosphate anhydrous, potassium dihydrogen phosphate, sodium chloride, and water for injection.

After reconstitution, each 0.5-mL dose is formulated to contain 50 mcg of the recombinant gE antigen, 50 mcg of MPL, and 50 mcg of QS-21. Each dose also contains 20 mg of sucrose (as stabilizer), 4.385 mg of sodium chloride, 1 mg of DOPC, 0.54 mg of potassium dihydrogen phosphate, 0.25 mg of cholesterol, 0.160 mg of sodium dihydrogen phosphate dihydrate, 0.15 mg of disodium phosphate anhydrous, 0.116 mg of dipotassium phosphate, and 0.08 mg of polysorbate 80. After reconstitution, SHINGRIX is a sterile, opalescent, colorless to pale brownish liquid.

SHINGRIX does not contain preservatives. Each dose may also contain residual amounts of host cell proteins (≤3.0%) and DNA (≤2.1 picograms) from the manufacturing process.

The vial stoppers are not made with natural rubber latex.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The risk of developing herpes zoster (HZ) increases with age and appears to be related to a decline in VZV-specific immunity. SHINGRIX was shown to boost VZV-specific immune

response, which is thought to be the mechanism by which it protects against zoster disease *[see Clinical Studies (14)]*.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

SHINGRIX has not been evaluated for its carcinogenic or mutagenic potential. Vaccination of female rats with SHINGRIX had no effect on fertility *[see Use in Specific Populations (8.1)]*. In a male fertility study, rats were vaccinated with 0.1 mL of SHINGRIX (a single human dose is 0.5 mL) on 42, 28, and 14 days prior to mating. There were no effects on male fertility.

14 CLINICAL STUDIES

14.1 Efficacy in Subjects 50 Years and Older

Study 1 was a randomized, placebo-controlled, observer-blind clinical study conducted in 18 countries. Randomization was stratified (8:5:3:1) by age: 50 to 59 years, 60 to 69 years, 70 to 79 years, and ≥80 years. The study excluded, among others, subjects who were immunocompromised, had a history of previous HZ, were vaccinated against varicella or HZ, and patients whose survival was not expected to be at least 4 years or with conditions that might interfere with study evaluations. Subjects were followed for the development of HZ and postherpetic neuralgia (PHN) for a median of 3.1 years (range: 0 to 3.7 years). Suspected HZ cases were followed prospectively for the development of PHN, an HZ-related complication defined as HZ-associated pain (rated as 3 or greater on a 0- to 10-point scale by the study subject) occurring or persisting at least 90 days following the onset of rash in confirmed cases of HZ.

The primary efficacy analysis population (referred to as the modified Total Vaccinated Cohort [mTVC]) included 14,759 subjects aged 50 years and older who received 2 doses (0 and 2 months) of either SHINGRIX (n = 7,344) or placebo (n = 7,415) and did not develop a confirmed case of HZ within 1 month after the second dose. In the mTVC population, 61.2% were female; 72.3% were white, 18.9% were Asian, 1.7% were black, and 7.0% were of other racial/ethnic groups. The mean age of subjects was 62.3 years.

Confirmed HZ cases were determined by either Polymerase Chain Reaction (PCR) (89.4%) or by a Clinical Evaluation Committee (10.6%).

Efficacy against Herpes Zoster

Compared with placebo, SHINGRIX significantly reduced the risk of developing HZ by 97.2% (95% CI: 93.7, 99.0) in subjects 50 years and older (Table 2).

Table 2. Efficacy of SHINGRIX on Incidence of Herpes Zoster Compared with Placebo in Study 1[a] (mTVC[b])

Age Group (Years)	SHINGRIX			Placebo			% Efficacy (95% CI)
	N	n	Incidence Rate of HZ per 1,000 Person-Years	N	n	Incidence Rate of HZ per 1,000 Person-Years	
Overall (≥50)[c]	7,344	6	0.3	7,415	210	9.1	97.2 (93.7, 99.0)
50 - 59	3,492	3	0.3	3,525	87	7.8	96.6 (89.6, 99.3)
60 - 69	2,141	2	0.3	2,166	75	10.8	97.4 (90.1, 99.7)
≥70	1,711	1	0.2	1,724	48	9.4	97.9 (87.9, 100.0)

N = Number of subjects included in each group; n = Number of subjects having at least 1 confirmed HZ episode; HZ = Herpes zoster; CI = Confidence Interval.

[a] Study 1: NCT01165177.

[b] mTVC = Modified Total Vaccinated Cohort defined as subjects who received 2 doses (0 and 2 months) of either SHINGRIX or placebo and did not develop a confirmed case of HZ within 1 month after the second dose.

[c] Primary study endpoint was based on confirmed HZ cases in subjects aged 50 years and older.

In a descriptive analysis, vaccine efficacy against HZ in subjects aged 50 years and older was 93.1% (95% CI: 81.3, 98.2) in the fourth year post-vaccination.

Occurrence of PHN

Among all subjects aged 50 years or older in the mTVC, no cases of PHN were reported in the vaccine group compared with 18 cases reported in the placebo group.

14.2 Efficacy in Subjects 70 Years and Older

Study 2 was a randomized, placebo-controlled, observer-blind clinical study conducted in 18 countries. Randomization was stratified (3:1) by age: 70 to 79 years and ≥80 years. With the exception of age, the study exclusion criteria were the same as for Study 1. Subjects were followed for the development of HZ and PHN for a median of 3.9 years (range: 0 to 4.5 years). Suspected HZ cases were followed prospectively for the development of PHN as for Study 1.

The primary efficacy analysis population (mTVC) included 13,163 subjects aged 70 years and older who received 2 doses (0 and 2 months) of either SHINGRIX (n = 6,541) or placebo (n = 6,622) and did not develop a confirmed case of HZ within 1 month after the second dose. In the mTVC population, 54.7% were female; 77.6% were white, 17.1% were Asian, 1.0% were black, and 4.2% were of other racial/ethnic groups. The mean age of subjects was 75.5 years.

Confirmed HZ cases were determined by either PCR (92.3%) or by a Clinical Evaluation

Committee (7.7%).

Efficacy against Herpes Zoster

Vaccine efficacy results against HZ in subjects 70 years and older are shown in Table 3.

Table 3. Efficacy of SHINGRIX on Incidence of Herpes Zoster Compared with Placebo in Study 2[a] (mTVC[b])

Age Group (Years)	SHINGRIX			Placebo			% Efficacy (95% CI)
	N	n	Incidence Rate of HZ per 1,000 Person-Years	N	n	Incidence Rate of HZ per 1,000 Person-Years	
Overall (≥70)[c]	6,541	23	0.9	6,622	223	9.2	89.8 (84.3, 93.7)
70 - 79	5,114	17	0.9	5,189	169	8.8	90.0 (83.5, 94.3)
≥80	1,427	6	1.2	1,433	54	11.0	89.1 (74.7, 96.2)

N = Number of subjects included in each group; n = Number of subjects having at least 1 confirmed HZ episode; HZ = Herpes zoster; CI = Confidence Interval.

[a] Study 2: NCT01165229.

[b] mTVC = Modified Total Vaccinated Cohort defined as subjects who received 2 doses (0 and 2 months) of either SHINGRIX or placebo and did not develop a confirmed case of HZ within 1 month after the second dose.

[c] Primary study endpoint was based on confirmed HZ cases in subjects aged 70 years and older.

In a descriptive analysis, vaccine efficacy against HZ in subjects 70 years and older was 85.1% (95% CI: 64.5, 94.8) in the fourth year after vaccination.

Efficacy against PHN

Among all subjects aged 70 years or older in the mTVC, 4 cases of PHN were reported in the vaccine group compared with 28 cases reported in the placebo group. Vaccine efficacy against PHN was 85.5% (95% CI: [58.5; 96.3]). The benefit of SHINGRIX in the prevention of PHN can be attributed to the effect of the vaccine on the prevention of HZ.

Reduction of Use of Pain Medication

Among subjects with confirmed HZ, the use of HZ-associated pain medications was reported for 10 of 23 subjects (43.5%) who received SHINGRIX and for 160 of 223 subjects (71.7%) who received placebo.

14.3 Pooled Efficacy Analyses across Studies 1 and 2

The efficacy of SHINGRIX to prevent HZ and PHN in subjects 70 years and older was evaluated by combining the results from Studies 1 and 2 through a pre-specified pooled analysis in the

mTVC. A total of 8,250 and 8,346 subjects who received SHINGRIX and placebo, respectively, were included in the pooled mTVC analysis.

Efficacy against Herpes Zoster

Compared with placebo, SHINGRIX significantly reduced the risk of developing HZ by 91.3% (95% CI: 86.9, 94.5) in subjects 70 years and older (Table 4).

Table 4. Efficacy of SHINGRIX on Incidence of Herpes Zoster Compared with Placebo in Studies 1 and 2 (Pooled Data[a]) (mTVC[b])

Age Group (Years)	SHINGRIX			Placebo			% Efficacy (95% CI)
	N	n	Incidence Rate of HZ per 1,000 Person-Years	N	n	Incidence Rate of HZ per 1,000 Person-Years	
Overall (≥70)[c]	8,250	25	0.8	8,346	284	9.3	91.3 (86.9, 94.5)
70 - 79	6,468	19	0.8	6,554	216	8.9	91.3 (86.0, 94.9)
≥80	1,782	6	1.0	1,792	68	11.1	91.4 (80.2, 96.9)

N = Number of subjects included in each group; n = Number of subjects having at least 1 confirmed HZ episode; HZ = Herpes zoster; CI = Confidence Interval.

[a] Pooled data from Study 1: NCT01165177 (subjects ≥50 years) and Study 2: NCT01165229 (subjects ≥70 years).

[b] mTVC = Modified Total Vaccinated Cohort defined as subjects who received 2 doses (0 and 2 months) of either SHINGRIX or placebo and did not develop a confirmed case of HZ within 1 month after the second dose.

[c] Primary endpoint of pooled analysis was based on confirmed HZ cases in subjects 70 years and older.

Efficacy against PHN

Table 5 compares the overall rates of PHN in the vaccine and placebo groups across both studies.

Table 5. Efficacy of SHINGRIX on Overall Incidence of Postherpetic Neuralgia Compared with Placebo in Studies 1 and 2 (Pooled Data[a]) (mTVC[b])

Age Group (Years)	SHINGRIX			Placebo			% Efficacy (95% CI)
	N	n	Incidence Rate of PHN[c] per 1,000 Person-Years	N	n	Incidence Rate of PHN per 1,000 Person-Years	
Overall (≥70)	8,250	4	0.1	8,346	36	1.2	88.8 (68.7, 97.1)
70 - 79	6,468	2	0.1	6,554	29	1.2	93.0 (72.5, 99.2)
≥80	1,782	2	0.3	1,792	7	1.1	71.2 (-51.5, 97.1)

N = Number of subjects included in each group; n = Number of subjects having at least 1 PHN; CI = Confidence Interval.

[a] Pooled data from Study 1: NCT01165177 (subjects ≥50 years) and Study 2: NCT01165229 (subjects ≥70 years).

[b] mTVC = Modified Total Vaccinated Cohort defined as subjects who received 2 doses (0 and 2 months) of either SHINGRIX or placebo and did not develop a confirmed case of HZ within 1 month after the second dose.

[c] PHN = Postherpetic neuralgia defined as HZ-associated pain rated as 3 or greater (on a 0- to 10-point scale) occurring or persisting at least 90 days following the onset of rash using Zoster Brief Pain Inventory questionnaire.

The benefit of SHINGRIX in the prevention of PHN can be attributed to the effect of the vaccine on the prevention of HZ. The efficacy of SHINGRIX in the prevention of PHN in subjects with confirmed HZ could not be demonstrated.

14.4 Immunological Evaluation to Support Dosing Schedule

A measure of the immune response that confers protection against HZ is unknown. Anti-gE antibody levels were measured by anti-gE enzyme-linked immunosorbent assay (gE ELISA) and were used to support the dosing schedule.

In an open-label clinical study, 238 subjects 50 years and older received SHINGRIX on either a 0- and 2-month or 0- and 6-month schedule. Non-inferiority of the 0- and 6-month schedule compared with the 0- and 2-month schedule based on anti-gE ELISA GMCs 1 month after the second dose was demonstrated.

14.5 Concomitant Administration with Influenza Vaccine

In an open-label clinical study, subjects 50 years and older received 1 dose each of SHINGRIX and FLUARIX QUADRIVALENT (QIV) at Month 0 and 1 dose of SHINGRIX at Month 2 (n = 413), or 1 dose of QIV at Month 0 and 1 dose of SHINGRIX at Months 2 and 4 (n = 415). There was no evidence for interference in the immune response to any of the antigens contained in SHINGRIX or the coadministered vaccine.

16 HOW SUPPLIED/STORAGE AND HANDLING

SHINGRIX is supplied as 2 components: A single-dose vial of lyophilized gE antigen component (powder) and a single-dose vial of adjuvant suspension component (liquid) (packaged without syringes or needles).

Table 6: Product Presentations for SHINGRIX

Presentation	Carton NDC Number	Components	
		Adjuvant Suspension Component (liquid)	Lyophilized gE Antigen Component (powder)
An outer carton of 1 dose	58160-819-12	Vial 1 of 2 NDC 58160-829-01	Vial 2 of 2 NDC 58160-828-01
An outer carton of 10 doses	58160-823-11	10 vials NDC 58160-829-03	10 vials NDC 58160-828-03

16.1 Storage before Reconstitution

Adjuvant suspension component vials: Store refrigerated between 2° and 8°C (36° and 46°F). Protect vials from light. Do not freeze. Discard if the adjuvant suspension has been frozen.

Lyophilized gE antigen component vials: Store refrigerated between 2° and 8°C (36° and 46°F). Protect vials from light. Do not freeze. Discard if the antigen component has been frozen.

16.2 Storage after Reconstitution

- Administer immediately or store refrigerated between 2° and 8°C (36° and 46°F) for up to 6 hours prior to use.
- Discard reconstituted vaccine if not used within 6 hours.
- Do not freeze. Discard if the vaccine has been frozen.

17 PATIENT COUNSELING INFORMATION

- Inform patients of the potential benefits and risks of immunization with SHINGRIX and of the importance of completing the 2-dose immunization series according to the schedule.
- Inform patients about the potential for adverse reactions that have been temporally associated

with administration of SHINGRIX.

- Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

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Research Triangle Park, NC 27709

SHX:4PI

My name is Stephanie Hager, and I am a resident of Mandan, North Dakota. I am testifying in **support** of HB 1468. It is known that **all** pharmaceutical drugs/vaccines carry some sort of risk and/or side effect. It is up to the patient to make an informed decision on whether to accept that drug/vaccine, however it should also be the job of the individual administering the vaccine to **provide** ALL information- benefits and dangers- to the patient before administering it. Most doctors will tell you that a vaccine is safe and effective without stating the risks associated with the vaccine. It is of utmost importance to give patients true informed consent to the risks associated with vaccines and not to just state the "normal" reactions such an injection site soreness, fever etc. There are/can be enormous risks associated with vaccines and it is a major role in the person administering said vaccine to inform the patient of such risks and there should absolutely be a penalty if a patient isn't provided this information BEFORE administering a vaccine. Again, I support this bill.

January 25, 2021
Written Testimony of Salesha Olson in Support of HB 1468 relating to informed consent and notice of risks associated with vaccines; and to provide a penalty

Chairman Weisz and members of the House Human Services Committee, I am writing with great concern and strong support of HB 1468.

I became a mother almost 19 years ago and have spent the last 14 years educating myself about vaccines for the sake of my, now 7, children. It should not be difficult to find information regarding the benefits vs. risks of vaccination, the contraindications, the alternative vaccination schedules, and any other information that will help parents make a fully informed choice.

I know that with my first child, I was blindly following a vaccination schedule without respect to my child's individuality, without knowledge of the risks, without questioning anything that our medical provider said. I'm fully aware now that our children and grandchildren deserve better.

No medical advice should be followed without first knowing the possible risks. Any surgery, prescription, or recommendation from a medical professional comes with clear information about the risks involved, EXCEPT vaccines. It is also highly important that pregnant women be given accurate information about vaccines, including the fact that no vaccine trials are done with pregnant women (because it would be unethical) yet many providers recommend an influenza shot during pregnancy without knowing the possible risks to the unborn child.

The 1 page colored sheet that a doctor/nurse gives to a parent right before a vaccine injection is NOT informed consent. As a matter of fact, I have compared the information sheet of a particular vaccine to the vaccine package insert and found that they contradict each other. Informed consent must include the right to read the manufacturer's package insert and the vaccination risks contained therein.

Lastly, if any person or parent, decides against receiving a vaccine, they should be given the right to an exemption and that option should be well-known and easily accessible.

I sincerely ask that you recommend a DO PASS on HB 1468 as originally written with no amendments.

Salesha Olson

Salesha Olson
Larimore, ND

OPPOSITION TO **HB 1468**

I oppose the State of North Dakota requiring homeschool parents to go through an educational module about disease causes and transmission. We parents are fully capable of discussing this issue with our children on our own. Our families do not live in a bubble, isolated and insulated from society. We just think we can do better than the instruction provided at public institutions. Statistics, concerning academic success or crime, etc. , without question, prove that case over and over. The single biggest predictor of student success is teacher:student ratio. No public school can match what I and other homeschool parents are providing.

We all know the endless litany of nonsense human resources videos employees everywhere must endure that remind us to be “nice” to one another. While this module alone is not onerous, it will no doubt give license for the development and requirement of other modules, making our decision to homeschool very burdensome. Basically, we are doing a great job and a great public service, so just leave us alone.

Please reject bill HB 1468 and let us continue providing strong educational experience for our families.

01/23/2021

Dear legislative team,

This letter is to express concern for HB 1468. This BILL relates to informed consent and notice of risks associated with vaccines; and to provide a penalty for those who fail to do so. I am a practicing pediatrician with 16 years of experience caring for children and adolescents in the states of North Dakota and Minnesota.. Please review my concerns, discussion and information on why HB 1468 should not be passed.

The Bill has four parts: 1) Informed Consent and Vaccine Information Statements, 2) Exemptions to Vaccines, 3) Pregnancy and Vaccination and 4) Infractions to providers.

.

1) Informed Consent and Vaccine Information Statements (VIS)

We all want informed consent for vaccines. It is the right thing to do. It is a easy process and valuable to both the provider and the patient.

In 1986, the National Childhood Vaccine Injury Act (NCVIA) passed and created the National Vaccine Injury Compensation Program (NVICP) and the Vaccine Adverse Events Reporting System (VAERS). NCVIA mandated the development and distribution of written information on vaccines. In the 1990s and 2000s, Vaccine Information Statements (VIS) were developed and refined. VISs provide written informed consent on vaccines.

Vaccine information statements have the following characteristics:

• Are accurate and updated regularly

• Are produced in multiple languages

• Cover necessary information in a way that is understandable to most people (ex. risks and benefits of vaccination, how to submit a report to VAERS)

• Provide links to more detailed information for those who want it

• Are typically 1-2 pages in length

Federal law mandates that providers give a patient a VIS BEFORE vaccination. VIS should be handed out for each vaccine received and each time a dose of a vaccine is administered (not just for the first dose). VISs must be given regardless of the age of the vaccine recipient.

HB 1468 would like providers to give the full vaccination package insert instead of the VIS. Here are the reasons a VIS is superior to the package insert for patients:

Package inserts are very technical, lengthy (the average package insert is 21 pages long), and may provide unclear or confusing information that can undermine informed consent. They are also written in technical medical lingo that is very hard for the general public to understand,

Sometimes, a VIS does not exactly match a manufacturer's product insert. That's because VISs follow the Advisory Committee on Immunization Practices' (ACIP's) recommendations. ACIP carefully considers whether adverse events reported during clinical trials could be causally linked to the vaccination.

• For example, package inserts must include all adverse events reported during clinical trials, regardless of whether or not they are related to vaccination. The package insert for the measles, mumps and rubella (MMR) vaccine lists otitis media (ear infection) as an adverse reaction that occurred during clinical trials. This does not mean the vaccine caused an ear infection, only that an ear infection was reported in a clinical trial participant following vaccination. ACIP has determined that ear infection cannot be caused by MMR vaccine, and so it is not listed on the VIS.

Package inserts are not updated regularly. This is problematic, as new and evolving information may not be added. For example, the risk of anaphylaxis following COVID-19 vaccine approval is not listed in the package insert, but would be included on a VIS as they are updated regularly.

In 2020, 689,890 doses of vaccine were administered in North Dakota. The cost of printing vaccine package inserts is estimated to cost hundreds of thousands of dollars.

2) Exemptions

Under HB 1468, any provider recommending vaccination must also offer information on exemptions and make the exemption form available.

Because of the safety and efficacy of our vaccine programs, many medical organizations (AAFP, AAP, ACOG, ACP, AMA, ANA, IDSA, NAPNP, March of Dimes) do not support the use of non-medical exemptions. Vaccine exemption without a medical reason reduces herd immunity and puts the entire population at risk for unnecessary vaccine preventable illness. Giving patient exemption information goes against our knowledge of the safety that vaccines provide for our citizens. Therefore, discussing non-medical exemptions that would put both the patient and other citizens at risk for disease is against the Hippocratic Oath.

3) Pregnancy and Vaccination

All pregnant women should get vaccinated against whopping cough (TDaP vaccine) and influenza during each pregnancy to protect herself and her baby. A comprehensive review of the research, safety and efficacy of influenza vaccine during pregnancy and TDaP vaccine during pregnancy can be found at https://www.who.int/vaccine_safety/publications/safety_pregnancy_nov2014.pdf

Vaccines are not typically tested on pregnant women because it makes running the trials simpler as including them would require testing scientists to provide safety for both the woman and unborn child. However, we routinely give the above vaccines to pregnant women to assure the health of mother and baby. Live vaccinations are excluded during pregnancy because there is theoretical risk that the live virus could be passed on to the developing fetus and cause infection in the unborn child. Again, this is a well studied topic with significant research to back up the current recommendations.

4) Infractions:

HB 1468 states that “any provider who does not offer information on exemptions, make the exemption form available, or provide information on vaccine studies in pregnant women with a witness present is guilty of an infraction.

The above is unreasonable. As providers we obtain verbal informed consent from our patients regarding the vaccines that we prescribe. This is an open opportunity to discuss individual therapy and concerns that the patient has. Any patient can decline the vaccine based on the information given. When the patient declines the vaccination, it should be documented by the provider in the visit note. In so doing, the patient and provider have written documentation that the therapy was discussed, risks and benefits explained, and the patient chose to decline. At that time, the provider should have the patient sign a universal form called the “Refusal To Vaccinate” form. This is a process that is already in place giving both the patient and the provider the ability to provide or decline any service. The infraction statement places unnecessary burden on providers to define and explain all exemptions to vaccines. This burden is also redundant to the above informed consent process and unnecessary not to mention overwhelmingly time consuming and expensive especially if they are requiring an additional witness.

In addition to the above information, Federal government recognized that there was liability on the vaccine manufacturer for side effects related to vaccines. Yet, they wanted the manufacturers to continue to provide safe, effective vaccines. A series of laws has been put in place to assure that he public’s best interest is maintained in the development and production of vaccines. In so doing, these laws eliminate the liability of the vaccine producers with regard to adverse effects from the administration of the vaccine so long as the following are met: 1) the vaccine is correctly manufactured in accordance with regulatory standards and prudent manufacturing practices and 2) the manufacturer has taken reasonable steps to ensure that the recipient of the vaccine will be warned of possible side effects. Therefore, “if a vaccine manufacturer adequately warns physicians or recipients about a drugs’ foreseeable adverse effects, he will escape liability unless the plaintiff can show that his injury was caused by some impurity or resulted from an unreasonably dangerous design.” [Merrill, “Compensation for Prescription Drug Injuries, “ 59 Va. L. Rev. 1, 49 (1973)]. This allows another level of vaccine safety by encouraging precise vaccine development with the least amount of danger for the public with administration of the vaccine. It releases the manufacturer from unnecessary legal repercussion expense and allows them to focus on quality production.

Why HB 1468 should not be passed:

-Vaccine Information Statements provide informed consent for vaccination. They are readable, updated regularly, and translated for use in over 40 languages.

-Package inserts are too technical, very lengthy, and may be confusing to the average person.

-Multiple medical organizations do not support non-medical exemptions to vaccination.

-Vaccination for pregnant women is important and the best way to protect the mother and child

This bill dictates how healthcare providers practice and is not conducive to good medicine. Under the Hippocratic oath we are sworn to do no harm. The informed consent process is a well tuned tool that we use to discuss vaccine administration to ALL patients and fulfill that oath. Enacting a bill that states that providers MUST mention exemptions and offer the exemption form is unnecessary with the informed consent process that is currently in place. Informed consent given with the additional VIS forms provides further resources should the patient need. In addition, bringing a witness into this well tuned process and placing infractions on providers with regard to any process that is being done with good intention and the Hippocratic oath in mind is a dangerous move toward the integrity of a provider and the care that they provide.

Thank you for your consideration,

Jenifer Jones-Dees, MD, FAAP

Ima Healthcare, Department of Pediatrics

4450 31st Ave S, Suite 102

Fargo, ND 58104

(701) 280-2033

jeniferjd@imahealthcare,com

Re: Testimony in favor of HB 1468

Attn: Committee Members,

I, Todd Kjelland am writing in favor of a DO PASS on HB 1468

I am grateful to see legislative action which prohibit employers from mandating medical procedures as a requirement of employment. I believe by allowing this practice to continue, employers will have the precedent to force employees at will to become non-voluntary medical test subjects without future recourse. While I am in favor of HB 1468, however, I'd also like to make sure this law does not replace required Doctor-to-patient, face-to-face informed consent conversations, nor does it give authority to non-medically licensed government officials to obtain informed consent.

Please note: Any health facility which accepts Medicare/Medicaid, gains financially from forcing employees to be vaccinated or medically tested through CMS payment bonuses/penalties. This information is not freely disclosed to employees, thus violating Informed Consent laws for which forces employees to participate in medical procedures against their free will, inclusive of religious beliefs. This is Human Trafficking, a criminal action as defined by 18 U.S. Code Chapter 77, Title 18.
My second request regarding Medical Battery stems from North Dakota lacking in "Informed Consent" definitions and laws. I was told by Walsh County States Attorney Kellie Cole that North Dakota does not have a statute to address "Medical Battery."
Law states that patient "Informed Consent" must be applied or provided specifically by a "physician" to any "medical procedure". This includes administering vaccines and performing diagnostic medical tests.

In a review of North Dakota Century Code (NDCC), only a MD, DO or PA has the authority to acquire patient "Informed Consent" and this cannot be delegated. (See North Dakota Century Code § 43-17-01 and N.D. Cent. Code § 43-17-02.1.)

NDCC only gives MD, OD and PA licensees authority to obtain "Informed Consent." North Dakota has limited court cases to establish legal precedent of "Informed Consent delegation" so we must look to a State Supreme Court case in Pennsylvania…

https://www.pamedsoc.org/detail/article/Informed-Consent-Brief

The decision in Shinal v. Toms could have significant ramifications for Pennsylvania physicians. With this decision, the Pennsylvania Supreme Court holds that **physicians alone** have the duty to provide patients with the sufficient information required to obtain informed consent. Thus, Pennsylvania physicians can seemingly no longer rely upon the aid of their qualified staff in the informed consent process.

Shinal v. Toms, 162 A. 3d 429 - Pa: Supreme Court 2017

https://scholar.google.com/scholar_case?case=4383380347487734123&hl=en&as_sdt=6&as_vis=1&oi=scholarr

….. Because a physician's duty to provide information to a patient sufficient to obtain her informed consent is non-delegable, …

Why is "Informed Consent" important? Because if a "physician" doesn't answer all your questions, not only about the procedure, but all the risks and the financial disclosures of your inquiry (benefits to be

gained by the physician, the health facility he/she represents) voids any signed consent form you have been asked to sign as a waiver of liability. The physician (MD, OD or PA) is then held personally accountable and can be sued for the civil tort of battery.

Basic right to consent to medical care - Schoendorff v. Society of New York Hosp., 105 N.E. 92, 93 (N.Y. 1914)

In reference to HB 1468 (Section 5. A government official, medical provider, or employer that violates this section is guilty of an infraction.)

I would recommend also adding Medical Battery to the ND Criminal Code as North Dakota lacks this definition. Medical Battery is different from Medical Malpractice and thus needs specific laws and penalties which are currently absent from North Dakota Century Code.

https://www.paulsonandnace.com/difference-medical-malpractice-medical-battery/

While medical malpractice is usually unintentional and occurs out of some form of negligence, medical battery is intentional. The elements of medical battery include:

The act
Intent
Causation (actual and proximate)
Touching
Harmful or offensive

(UND School of Law)

Medical battery is intentional touching without permission. The plaintiff does not have to prove that the perpetrator intended any harm. Former U.S. Supreme Court Justice Cardozo, in his opinion in Schloendorff v. Society of New York Hospital said, “Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault for which he is liable in damages. This is true except in cases of emergency, where the patient is unconscious and where it is necessary to operate before consent can be obtained.” (Schloendorff v. Society of New York Hosp., 105 N.E. 92, 93 (N.Y. 1914))

As a pure legal issue, forcing treatment on an unwilling person is no different from attacking that person with a knife. The legal term for a harmful or offensive touching without permission is battery. Battery is a criminal offense, and it can also be the basis of a civil lawsuit. The key element of battery is that the touching be unauthorized, not that it be intended to harm the person. Thus forcing beneficial care on an unwilling patient would be battery. The classic statement of a physician’s duty to get the patient’s consent is Justice Cardozo’s opinion in Schoendorff v. Society of New York Hospital:

https://biotech.law.lsu.edu/cases/consent/Schoendorff.htm

North Dakota Century Code defines penalties for practicing medicine without a license, however a penalty specifically for Medical Battery is needed to make sure properly licensed medical personnel are fulfilling the informed consent requirement.

NDCC - 43-17-34. Practicing without a license - Violation of chapter - Penalty. Any person who practices medicine in this state without complying with the provisions of this chapter, and any person who violates any of the provisions of this chapter for which another penalty is not specified is guilty of a class B misdemeanor. In addition to the criminal penalties provided, the civil remedy of injunction is available to restrain and enjoin violations of any provisions of this chapter without proof of actual damages sustained by any person.

Below is an example of such a law in Oklahoma I would hope North Dakota would adopt:

2014 Oklahoma Statutes
Title 21. Crimes and Punishments
§21-650.11. Medical battery – Penalties - Definition.
Universal Citation: 21 OK Stat § 21-650.11 (2014)

A. Medical battery is a felony, upon conviction, punishable by imprisonment in the county jail for a term of not more than one (1) year, or imprisonment in the custody of the Department of Corrections for a term of not more than four (4) years, and a fine in an amount not more than Five Thousand Dollars ($5,000.00). In addition, the defendant shall be ordered to make restitution to the victim in an amount as determined by the court.

B. For purposes of this section, “medical battery” means:

1. The defendant has been found guilty of practicing dentistry, medicine, osteopathic medicine, or surgery, without a license or authority as prohibited by the provisions of the State Dental Act, the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act, or the Oklahoma Osteopathic Medicine Act;

2. The treatment, or course of treatment, practiced in violation of the provisions of the State Dental Act, the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act, or the Osteopathic Medicine Act resulted in the victim having permanent physical injury or disfigurement;

3. The victim consented to such treatment, or course of treatment, under a belief that the defendant was licensed and authorized to diagnose and perform the treatment; and

4. The defendant willfully performed the act knowing that such act was prohibited pursuant to law.

Added by Laws 2008, c. 358, § 6, eff. Nov. 1, 2008.

Summary:

Committee Members, I thank you for your time. In recap, my desire for change stems from unauthorized medical personnel performing complex injections for which people have many questions which go unanswered before medical procedures are performed.

In my own experience, I was terminated from my employer, Sanford Health (Good Samaritan Society) because they refused to provide answers to my many medical questions. I sent human resources a list of questions two months prior to them mandating Covid testing. They told me they were not responsible

and to send them to NDDoH. I received confirmation they received my questions, however they never attempted to answer any of them. On my last day, I asked the person who was doing the testing to answer my informed consent questions. The lady was unqualified because she only had an EMT license, however she told me that I was the patient of the company who hired her, which was Sandford Health. Because she could not satisfy my questions, I refused to participate and was suspended for 30 days before being later terminated.

I believe many employees' rights can be preserved by taking legislative action now to assure our basic right to refuse unwanted medical testing and accepting injectables as mandated by employers is forbidden.

Todd Kjelland
113 Everett Ave
Park River, ND 58270
701-331-2956

As a mother and American citizen I believe that it is of upmost importance that we pass this bill in order to promote the medical industry to be honest and forthcoming in its information regarding vaccination and their associated health risks. I believe that pharmaceutical companies should be held accountable for any lack in transparency regarding vaccinations or other drugs. Whether a citizen is for or against a vaccination, it is a God-given right to maintain the liberty to make medical treatment decisions for yourself and children. I oppose any legislation that inhibits this Constitutional right and believe that withholding any information that may prevent an individual from making a said sound medical treatment decision is an infringement on this right.

Morgan Wisness

Chairman Weisz and members of the House Human Services Committee,

I would like to submit this testimony in STRONG SUPPORT of HB1468. This bill is so important, and I believe it should be something we all want in regards to the health and safety of North Dakotans.

There has been much debate recently on the safety and efficacy of vaccinations in general, but also specifically related to the Covid-19 vaccine, which is still in experimental stages. I don't pretend to think I can convince you all one way or another, as we all have different life experiences, moral and religious convictions, and definitions of health and wellness. What I would like to do is provide a couple of examples as to why I believe this bill is absolutely necessary.

1) This is a handout specifically designed for children by the North Dakota Department of Health: https://www.health.nd.gov/sites/www/files/documents/Files/MSS/Immunizations/Providers/BeWiseImmunize.pdf?fbclid=IwAR0S4tWpwxvtKGSvJesf-eyyQXYN5-KBQQSrMLl02MlumlJE2bTrTvqRhJQ I will not address it in its entirety, but I will pick just one example to illustrate my position.

   Page 1 of this activity book reads, "Did you know? Tetanus is called 'lockjaw' because it causes stiffness of the jaw and neck." This is of course, true. However, nowhere in this activity book or in any other parent handout I saw on the NDDoH website, was there information about the DTaP vaccine and its associated risks, possible adverse reactions, contraindications, or even a link where a parent can find the package insert online. Here is the package insert for Infanrix (DTaP) directly from the FDA website: https://www.fda.gov/media/75157/download . While lockjaw does sound scary, parents don't receive any further information about tetanus, the likelihood of catching tetanus, the percentage of severe symptoms, or the possibility of treatment and recovery. We are just provided with one scary statement about the disease. All while avoiding giving us the full information on risks of the vaccine, which deserve careful consideration. Parents should be given the opportunity to make a fully informed decision about the health of their child. This is just one reason why I support HB1468. (A great example of a book that gives FULL information on vaccines and vaccine-preventable diseases is called "The Vaccine Book" by a pro-informed consent, pro-vaccine doctor, Dr. Bob Sears. It provides risks and benefits of all vaccines and describes the ingredients in each one: https://www.thevaccinebook.com/)

2) This leads to my next point. If we are supposed to trust the medical professionals, they need to be completely transparent with us. I often hear the words "misinformation" and "disinformation" tossed around by NDDoH, the CDC,

and other public health authorities. I looked up the definitions of these words and would like to share them with you:

Misinformation: false or inaccurate information that is communicated regardless of an intention to deceive.

Disinformation: false information which is intended to mislead, especially propaganda issued by a government organization to a rival power or the media.

I would just like to point out that from what I have seen on the NDDoH website, particularly in regards to parent/child handouts, including several links dedicated to training providers on how to convince parents to agree to vaccines, I saw a lot that fits into those two definitions. What this bill is asking for, is the polar opposite. It is looking for people to have TRUE information, regarding both the potential risks and benefits of vaccines, as well as the true risks associated with the illnesses the vaccines are supposed to prevent. It seems to me that anyone in the healthcare field would be violating their oath to "do no harm" if they were not amenable to this bill. HB1468 will eliminate the possibility of any misinformation or disinformation passing between a provider and a patient. It encourages and promotes full transparency and builds a relationship based on trust and mutual respect. I think that is something we can all agree is extremely important for the health and well being of all ND citizens.

3) I just want to share from personal experience before I close. Several years ago, I was about to travel out of the country and determined that I needed a tetanus booster. At the time, I had no awareness on vaccine safety and efficacy and had not yet begun to research the subject. And yet, I was still shocked and confused when the doctor came into the room with the needle already out, and stuck it into my arm without even so much as saying "Hello." I had never met this doctor before, and had not established any level of trust. The nurse told him why I was there, so he took it upon himself to absurdly "surprise" me (as he put it, which he felt would be better than discussing it first). He never gave me any information about the vaccine, and I was too startled to ask. I dismissed it as just a strange experience, but 3 years later when I was pregnant with my first child, my OB asked me if I had recently had the TDaP. I told her that I hadn't, and she then informed me that if I had recently had a tetanus booster, it is likely that it was the TDaP. That was the first I had ever heard that information! Why would they give me a shot of 3 things when I only needed one? And why did they never tell me about the risks of doing so? My OB then persisted to try to convince me to receive another TDaP. She talked about how scary pertussis can be for babies and sought to guilt me into getting the vaccine. She never informed me that the

TDaP (Adacel) has not been tested on pregnant women and they don't know what effects it could have on an unborn baby or the mother's reproductive health (https://www.fda.gov/files/vaccines%2C%20blood%20%26%20biologics/published/Package-Insert---Adacel.pdf (pg 15)). She also tried to get me to receive a flu shot, which also has never been tested on pregnant women (https://www.fda.gov/media/119856/download pg 19). I learned all these things by doing my own research, and realized for the first time that if I wanted to know the full truth about vaccines and vaccine-preventable diseases, I would have to learn on my own. My doctors cannot be trusted to tell me.

In conclusion, this bill, HB1468, seeks to change all of that. To strengthen the doctor/patient relationship by ensuring that good, accurate, complete information is provided to any person receiving a vaccine. Because of my life experiences, I was set on a course about 10 years ago to look into vaccine-preventable disease and vaccines, both risks and benefits. I know where to find the whole story. Most people, like myself when I received that tetanus vaccine, don't know any different than what the doctor tells them. They don't know where to look for the full truth. They are told to trust the professionals, and just do what they say. I believe people deserve to be treated better. They should be given all the information and trusted to make an informed decision that best suits their health needs for themselves or their children. I believe that exemptions should be clearly explained and made accessible, instead of the materials I viewed on the NDDoH website (including that activity book I linked earlier), that simply state children must have their immunizations in order to attend school. This is a half truth. Isn't that the kind of "disinformation" that public health authorities so often speak against? Why manipulate the public? Please, allow them to learn "the truth, the whole truth, and nothing but the truth." Anything less is detrimental to the well being of North Dakotans. Again, I wholeheartedly support HB1468, and ask that you vote for a "Do Pass" recommendation.

Thank you for your time in reading this! I would love to discuss this further with any of you who are willing and interested in doing so!

Melyssa Howry
District 4, New Town

My name is Sarah Lepp and I am in favor of HB 1468. I feel that every person has the right to information about immunizations that would include ingredients, risks/benefits, and effectiveness of the product being administered without the feeling of being pressured, persuaded, or guilted if chosen to not accept administration of any or all products. I was vaccine injured from the HPV vaccine as I was pressured into getting it “because my boyfriend may cheat on me.” I was not given any information on it other than “it may prevent cervical cancer.” There were no long term studies on it at that time and I was pressured into it. After receiving all 3 shots, I was having difficulty with my menses becoming more painful and irregular. I developed endometriosis, pcos and hypothyroidism due to this vaccine. I was infertile. I underwent hormone replacement, surgery and infertility treatments due to the vaccine. Infertility is not covered by insurance and my husband and I spend tens of thousands of dollars to become pregnant to no avail. I finally became pregnant on God’s grace and prayers as we were not able to afford infertility treatment any longer. No, this is not a genetic thing as I am the only one to have these issues and I am the only one who received this vaccine. All of this could have been prevented if proper information was given. I fully support this bill as everyone has the right to be informed and make their decision upon the information given instead of pressured. Now, as a parent, to have the knowledge of the exemptions is a very good thing. Many parents are unaware of exemptions and again are feeling pressured into getting their children vaccinated even though it may go against their religious or philosophical beliefs because they do not want their children to be excluded in school.

Information should always be given to women who are pregnant way in advance from delivery as most women are not in the right mindset to even comprehend what’s going on, let alone comprehend medical jargon that is being pushed upon them during delivery.

I am in Favor of this bill and I believe it needs to pass to allow more North Dakotans information of what is being put into their bodies or their children’s or loved ones bodies.

Vaccine Management Plan

North Dakota Department of Health

Scope

This plan represents a complete revision and consolidation of prior NDDoH plans related to vaccine management. Because a moderate or severe influenza pandemic puts the greatest stress on vaccine management, that will be the base scenario for development of this plan. Other scenarios to which this plan may apply are bioterrorism (anthrax, smallpox), community-based vaccination for a localized outbreak (e.g., meningitis) and seasonal influenza in which vaccine shortages are substantially impacting vaccine coverage of the population.

Response Goals for Pandemic Vaccination

- To maximize uptake of vaccine by the population;
- To ensure that those persons determined to be at highest priority for vaccination are vaccinated first;
- To ensure that specific population subgroups (e.g., age) receive the correct, FDA approved vaccine;
- To minimize the amount of time from receipt of vaccine in the state to administration;
- To maximize second dose administration as soon as possible after completion of the required interval after the first dose;
- To maintain the cold chain and security of the vaccine;
- To have vaccine allocation which is ethical and transparent;
- To ensure that adverse events associated with vaccine administration are captured and investigated as indicated;
- To minimize disease transmission which will arise from aggregating persons in vaccination clinics during a pandemic.

Assumptions For Pandemic Influenza Vaccination

- Vaccine for pandemic influenza will be administered to the entire population that accepts it.
- Vaccine which is specific to the pandemic strain will not be available until many months after the pandemic is identified, and once it becomes available, quantities will not be initially available to vaccinate all persons.
- Pandemic vaccine will be prioritized either to 1) high risk groups first, or 2) to high risk groups and critical infrastructure, depending on the nature of the pandemic.
- Receipt of vaccine into the state will be in proportion to the state population (about 0.2% of the US population), but may not take into account persons crossing over into North Dakota from other states.
- Initial vaccine dose will provide little, if any, protection against infection[1];
- Influenza is contagious during the 24 hours prior to symptom onset (making exclusion of all contagious individuals from vaccination clinics impossible) and vaccination clinics potentially have a strong anti-social distancing effect which, if not neutralized, may increase morbidity and mortality;
    - Anti-social distancing effect will be minimized by vaccination between waves.

[1] This assumption was not true for the H1N1 pandemic because the population already had some inherent immunity to H1N1, but it will remain as a planning assumption for most pandemics since it is likely to be true for many potential influenza pandemics (H5N1).

    - Some types of clinics (e.g., drive-through) are expected to minimize any anti-social distancing effect.
    - For indoor clinics, infection control procedures (screening for ill, cough hygiene, distancing between families) will be needed to minimize disease transmission.
- If vaccine for mass vaccination arrives during the first wave, rapid administration of the vaccine may not be possible in the face of high absenteeism among public health and health care staff.
- Second dose vaccination, if needed to secure immunity, will, in almost all circumstances, take precedence over first dose administration. That is, completion of immunity which is protective is more important than initiating immunity which is not protective. However, doses will not be held from a shipment to provide the second dose to persons who are not yet eligible to receive the second dose.
- Within NDDoH, the lead role for vaccine management policy will be taken by the Immunization Program of the Division of Disease Control. The Immunization Program will function as part of incident command under the Operations Section of the DOC, but will not be relocated to the DOC.
- The roles for the Immunization Program and the DOC in vaccination management will be different.
    - Immunization Program roles will include provider registration, vaccine ordering, allocation to registered sites, management and analysis of NDIIS, vaccine adverse events coordination, and communication with CDC Immunization Program.
    - DOC roles will be logistical management (including vaccine receipt, cold chain and distribution), public information and policy.
- In a moderate or severe pandemic for which vaccine is perceived as lifesaving, the vaccine may pose a security risk.

Refer to planning documents relevant to specific diseases (e.g., anthrax, smallpox) for assumptions for those conditions.

Background

Many factors that cannot be known prior to a major event will potentially affect vaccine management. These include the nature of the event (severity, public reaction to the pandemic and to the vaccine, impact on infrastructure), the characteristics of the vaccine (quantity available, timing, release rate, doses required, adjuvant required, toxicity, mode of administration, cold chain requirements and FDA approvals) and the response of the health care system. Each of these factors is discussed below.

<u>Nature of the Event</u>

In a pandemic setting, it is assumed that the entire population will be at risk and that the intent of the vaccine delivery process will be to reach every person with the vaccine. In an anthrax, smallpox or meningitis scenario, it is assumed that the vaccine will be targeted toward a much narrower part of the population actually at risk for illness; however, public and political pressure may result in broader use of the vaccine than is actually indicated (and broader adverse consequences). During a pandemic, the amount of public fear of the illness will likely be the strongest factor determining the extent of public uptake of the vaccine and the amount of political pressure.

In an influenza pandemic, it is expected that several months will elapse from the time the specific organism (clade) is typed to the time that vaccine becomes available, and all vaccine will not become available at the same time. This will result in prioritization of the vaccine. In the event of small impact on the national infrastructure, the vaccine will be targeted toward risk groups at highest risk of adverse outcome (e.g., pregnant women). If the pandemic is causing serious impacts on infrastructure, substantial portions of the vaccine will be directed toward persons responsible for maintaining the infrastructure. CDC plans call for this infrastructure allocation to extend to all critical sectors of the economy (e.g., transportation, energy production, communications) and not just the health care or emergency response sector. (See Attachment C.)

In a moderate or severe pandemic, timing of mass vaccine delivery would logically be impacted by concerns about the anti-social distancing effect of vaccination clinics. Mass vaccination during a pandemic wave, particularly for a vaccine which requires two doses to be protective, may actually increase the mortality rate. That is, providing the initial, non-protective dose in an anti-social distancing environment may increase illness rates while providing no protection. In some pandemic settings, waiting until after the wave is over to begin vaccination may be the best option for improving outcome, albeit an option of questionable political viability. Some regions of the state are prepared to deliver vaccine by drive-through clinics to minimize the anti-social distancing impact, but it is not clear that this could be done on a scale large enough for rapid vaccination of most of the population, and some regions have never exercised this approach[2].

Vaccine Characteristics

In an influenza pandemic, it is likely that two doses will be needed to achieve adequate protective antibodies. This might be altered by the use of an adjuvant. If a chemical (adjuvant) can be added to the vaccine when administered to increase the body's immunological reaction to the disease agent, less vaccine or fewer injections may be required. Mixing and matching of antigen and adjuvant at point of care may be required. Matching an antigen and adjuvant type from the first dose at the time the second dose is given may be needed. The exact combination of antigen and adjuvant administered for the first dose may also be needed for administration of the second dose. Introduction of adjuvants may cause public distrust of the vaccine since adjuvants have not previously been used in this country.

Influenza vaccine is currently being developed primarily using chicken embryos as the cell culture medium. This process is slow. During the H1N1 pandemic, the vaccine was released late and in a trickle. By the time substantial amounts of the vaccine were available, much of the public appeared to be "over it," particularly since the pandemic was mild and the initial wave was on the decline in many states. Cell culture-produced vaccine is now appearing

[2] It is not clear what the relative throughputs for drive through clinics and walk-in clinics are. However, an additional barrier is availability of venues for drive-through vaccination which are protected from the weather, have sufficient space and flow for many lanes and can safely handle vehicle exhaust.

which could decrease the wait time after the identification of a pandemic to vaccine availability, although it still may take several months to produce vaccine.

A transition to intradermal vaccination may result in improved vaccine coverage when quantities of the antigen are limited, since intradermal vaccination requires less antigen to achieve the same level of immune response now seen with intramuscular vaccination. Some vaccine for intradermal is now available but represents only a small fraction of the influenza vaccine in use.

If the influenza subtype is known in advance of the pandemic (e.g. H5N1), the U.S. government may have developed vaccine to the subtype which is not clade specific. That is, the vaccine would not offer substantial protection to the recipient, but may be quite adequate as a priming dose to improve response to the clade-specific vaccine. It is unlikely that generic subtype vaccine would be available to vaccinate a large percentage of the population, but may be sufficient to start the vaccination sequence for certain high risk subgroups or for infrastructure personnel.

Vaccines vary substantially in risk of adverse events. Influenza vaccine is very safe, but if given to millions of people, a few serious adverse events are inevitable. Some persons take this information and miscalculate their relative risk of receiving the vaccine versus not receiving the vaccine and refuse vaccination. Alternately, smallpox carries a higher risk of adverse events of the available vaccines. For this reason, and because smallpox spread can be quite effectively controlled using ring vaccination techniques, the preference of public health will be to avoid mass vaccination. However, fear of smallpox with political pressure to vaccinate everyone may make this impossible. People will tend to overestimate their risk of illness relative to the risk of the vaccine and demand vaccination[3]. This is not likely to be as big a problem with anthrax since the disease is not contagious, but a larger group than is actually exposed may demand prophylaxis. In the case of both smallpox and anthrax, unlike pandemic influenza, sufficient vaccine should be available immediately for all persons who need it.

Another characteristic of influenza vaccine that makes mass vaccination complicated is the number of different manufacturers and formulations with varying FDA approvals. Some products will be approved for infants, toddlers, pregnant women, immunocompromised persons, persons with egg allergy or persons over 65; however, a typical product will be approved for some of these categories but not for all. During H1N1, as vaccine trickled in, the specific products had to be allocated to specific providers according to the type and number of patients they expected to vaccinate who were eligible to be vaccinated with the vaccine that was available. This not only made allocation complicated, but was confusing to

[3] Just because people demand vaccination is not sufficient reason to provide it, any more than people demanding a narcotic should be given a prescription in the absence of a medical indication for treatment with a narcotic. Political mandates can alter public health action by taking the decision to vaccinate or withhold vaccination away from public health.

providers[4]. To the degree possible, Disease Control tried not to give many different vaccines to the same provider over time.

During H1N1, vaccine came in a variety of package formats including multi-dose vials, single dose pre-filled syringes and single dose nasal vaccine. The pharmaceutical industry has increasingly moved toward single dose formats due to higher safety. The primary impact of the dosage form on vaccine management is the amount of cold chain space required to store and transport the vaccine since single dose packaging is much bulkier. A marked increase in the amount of vaccine received in single dose containers could pose a storage problem at some local sites; however, the NDDoH warehouse is expected to have sufficient space to maintain the vaccine that it receives for re-distribution.

Health Care System Response

The health care system currently provides the vast majority of vaccinations; for influenza this is estimated at around 80%[5] of the doses given (exact number is pending). However, during seasonal influenza, a large percentage of the population does not request influenza vaccination. During the 2012 – 2013 flu season, only 48.9% of North Dakotans were vaccinated[6]. During a pandemic, more people will be requesting vaccine, more doses will be needed and the health care system may be overwhelmed by clinical care. Not only may the private health care system be unwilling to pick up the large number of extra vaccinations which need to be provided, they may not even have the resources to vaccinate the patients they would have vaccinated during a normal influenza season. What vaccine is not administered by the private health care sector will need to be administered by public health, pharmacies, long term care facilities or other non-traditional vaccine providers (e.g., contract vaccinators, employee-based clinics).

Physical Vaccine Management and Cold Chain

For a bioterrorism related outbreak, vaccine would likely come to the state via the SNS. For all other circumstances, NDDoH would request and receive vaccine through CDC's authorized contractor which in recent years has been [redacted] for North Dakota shipments). During H1N1, CDC authorized the direct shipment of full cases (100-dose increments) to providers authorized by the state to receive that much vaccine at one time. Because vaccine was released slowly, relatively few providers could be allocated full cases. Consequently, a high percentage of the vaccine had to be received by the NDDoH warehouse and re-apportioned into smaller quantities for shipment to specific sites. During the H1N1

[4] For example, a provider needing to vaccinate a seven year old child may have been able to do so with vaccine provided to his or her office one week but not with vaccine provided the following week with vaccine only approved for children eight and older. Keeping track of which vaccine can be given to which people and which vaccine the clinic has could be very difficult. During a normal influenza season the provider would have ordered only vaccine that he or she was familiar with.

[5] The percentage of H1N1 vaccine provided by various provider types has not been calculated, but it is believed that LPH provided a substantially larger percentage of the H1N1 vaccine than it normally provides of seasonal influenza vaccine.

[6] CDC Fluvax View: http://www.cdc.gov/flu/fluvaxview/reports/reporti1213/reporti/index.htm

pandemic, shipments of vaccine went to well over 100 public and private destinations, although not all these destinations would receive vaccine from every shipment.

Most vaccines, including influenza, are expected to be received as liquid that must be stored between 35º and 46º Fahrenheit (2º – 8º Celsius)[7]. Vaccines for some conditions (e.g.., smallpox) have traditionally shipped frozen and need to remain frozen. Mass shipment of influenza vaccine during winter months proved to be difficult due to the need to protect the vaccine from moderate warmth and severe cold[8]. The only methods proven to be reliable by trial and error were shipping in controlled temperature environments (i.e., portable refrigeration units in temperature controlled vehicles) and certified shippers, which had a small payload for the shipping weight making them an expensive and inefficient distribution option except in select circumstances (e.g., sites a long distance from Bismarck).

During H1N1, NDDoH had concern about the [redacted] shipments that it received. The shipments were packed in large Styrofoam containers which did not have thick walls. No temperature loggers were included in the shipments. NDDoH found that even containers with much thicker walls could not reliably prevent freezing during harsh winter conditions for the lengths of time which commercial shipping companies kept the vaccine containers out of doors[9]. In the event that forecasted temperatures dropped so low that [redacted] refused to ship, NDDoH developed plans for retrieval of vaccine from [redacted] directly using a temperature controlled aircraft. It never became necessary to implement this plan during H1N1. Substantial changes in federal shipment practices could occur for the next pandemic, but are not expected at this time.

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[7] Vaccine removed from refrigeration to a warm environment does not instantly reach ambient temperature and 46º is not a firm number above which the vaccine loses potency. Vaccine can likely tolerate periods (days to weeks) of moderate temperatures above 46º without substantial loss of potency (the warmer the temperature, the faster it will degrade), but this varies by vaccine and the temperature stabilizers added to the vaccine. At least one study found insignificant degradation of influenza vaccine after two weeks at room temperature (see abstract at http://www.ncbi.nlm.nih.gov/pubmed/16150515). Another study found no loss of influenza vaccine potency for live attenuated vaccine after three freeze-thaw cycles (see abstract at http://www.ncbi.nlm.nih.gov/pubmed/22341195). However, even if vaccine can stand freezing, it is typically packed with rubber stoppered bottles of diluent (e.g., sterile water). If the bottle diluent freezes, the stopper is forced part way or entirely out of the bottle so that it is no longer guaranteed to be sterile and must be discarded.

[8] Vaccine leaving the warehouse by commercial shipper during the winter would be packed in a warm room, be picked up by the commercial carrier where it might remain outside in an unheated truck overnight, be transferred to the cargo hold of a plane (variable temperature), again spend time on a truck, go to a warehouse belonging to the shipping agent, go back into a plane, go back on a truck and finally arrive at its destination where it may or may not be moved immediately to a refrigerator.

[9] It is not clear that this concern has been fully addressed at the federal level. Although NDDoH never proved that any Xxxxxxxx material froze, temperature monitoring was not present in the periphery of the containers near the walls.

Provider Recruitment

During H1N1

The first step in the vaccination process during H1N1 was provider recruitment. This was initiated upon CDC instructing to the states to begin; CDC also provided most of the language for enrollment documents. NDDoH held a series of video/webcast sessions to educate providers, including pharmacies, clinics, long term care facilities, hospitals and local public health. This was followed by a memo sent through multiple communication channels (e.g., email, HAN contacts, professional associations) providing information about the enrollment process. Since enrollment was the only means for providers to acquire the vaccine, it is thought that nearly all eligible vaccine providers chose to enroll. Enrollment occurred over a website; a paper enrollment option was not provided in order to eliminate data entry.

Enrollment was by vaccine delivery site. This meant for large health systems, which make up the bulk of health care providers in North Dakota, multiple enrollments would be necessary, one for each delivery point. Specific information required for shipping was collected at the time of enrollment and populated into a lookup table in the CDC vaccine ordering software. This information was used by both [redacted], to ship directly to providers, and by the warehouse for direct delivery. The registration site also provided a contact who could be called to ensure that someone would receive the vaccine when it arrived at the door.

Another action initiated by enrollment was ensuring providers where signed up and prepared to use NDIIS. Upon receipt of an enrollment request, the Immunization Program looked up the provider site in NDIIS to ensure that that site was using NDIIS. If not, the practice was contacted and required to enroll in NDIIS before they could become a vaccine recipient site.

The final action initiated by enrollment was a request to providers to estimate the number of each risk group that they believed they could vaccinate, so this information could be used as part of allocation. This is discussed below under allocation. To help providers make this estimate, they were provided with information from orders made during regular flu vaccination seasons.

No specific guidance was given to providers about accounting for out-of-state residents coming to North Dakota to get vaccinated. For Grand Forks, Fargo, Wahpeton and the western edge of North Dakota substantial numbers of people flow into the state for health care services. That is, the number of doses provided to out-of-state residents by North Dakota would substantially exceed the number of North Dakota residents who got their vaccination out of state. (No allocation adjustment was made by CDC for this during H1N1.)

The vaccine was provided free of charge, but vaccine providers were permitted to charge an administration fee up to a maximum set by CDC. The administration fee could be collected from insurance or out of pocket from the recipient, but providers were not allowed to turn anyone away for inability to pay[10]. Additional requirements set by CDC for vaccine eligibility

[10] No mechanisms were in place during H1N1 to ensure that non-pay patients weren't turned away, but anecdotal reports of this were not received by the state so attempting to monitor this is not needed unless a problem becomes evident.

included agreement to meet vaccine storage requirements (which may include continuous monitoring[11]), and agreement to abide by the prioritization of vaccine to the specified high risk groups CDC specified. The NDDoH required use of the NDIIS for vaccine administration documentation.

During H1N1 in two regions of the state, the local public health unit was allowed to become the local vaccine recipient and redistribution point for vaccine within that regional area. This was done at the request of those local public health units. While it had the advantage of decreasing the number of distribution points for NDDoH, it also created a substantial number of problems including provider complaints (e.g., unfair allocation, lack of transparency, excessive control, increased delay), primarily from one of the two areas. Having an additional drop-off and redistribution point, also created another opportunity for a break in cold chain.

Provider Recruitment for Future Pandemic

The process used for provider recruitment during H1N1 worked well. No substantial change is anticipated in the method unless changes imposed by CDC require it. It was not necessary during H1N1 to recruit additional providers after the initial enrollment due to the large percentage of providers who chose to enroll. In a future pandemic, if insufficient numbers of providers of specific types (e.g., pediatricians, obstetricians) are initially enrolled, these needed groups will be targeted specifically with enrollment messages. An enrollment cutoff date would be stated to try to get all providers on-board and trained before mass vaccination was needed, but in practice, enforcement of the cut-off date would be unlikely.

Non-traditional vaccinators (e.g., pharmacies, other private vaccination groups) received their allocations relatively late during H1N1. This was due to an incident command decision to preferentially direct vaccine toward providers providing longitudinal care of patients, and due to greater numbers of persons in clinics with influenza risk factors. If a future pandemic is more severe, the anticipated large gap in vaccination by clinic-based vaccination providers would have to be filled by public health and non-traditional vaccinators. Current law allows pharmacists to vaccinate against influenza down to age five. The greater need for vaccinators during a more severe pandemic may make an executive order allowing pharmacists to vaccinate young children advisable.

Future policy related to local redistribution will default to a strong no; however, it is possible that some compromise might have to be reached. If that becomes necessary it is proposed that LPH must:

- Obtain the consent of all provider recipients in the area; and,
- Develop and provide to NDDoH for approval a vaccine allocation and redistribution plan which addresses:
    - Communications;
    - Allocation algorithm including fairness and optimal use of vaccine;
    - Security;
    - Cold chain and storage;

[11] Many providers who have implemented continuous monitoring are finding substantial problems with vaccine storage which is necessitating replacing vaccine storage equipment.

- Timeliness;
- Transportation;
- Documentation (NDIIS); and,
- Transparency.

If these criteria could not be met, the vaccine would be distributed directly to providers by NDDoH.

Procedures for Vaccine Ordering by the State

During H1N1

A set amount of vaccine was allocated to the state by CDC as the vaccine became available; however, the state still had to order the vaccine. A computer program provided by CDC used for the ordering process during periods of non-pandemic was also used during H1N1. To complete the ordering process, the Immunization Program had to:

1) Populate the recipient lookup table which included the names and addresses of all registered vaccination sites eligible to receive vaccine (i.e., registered). This information was obtained from the data generated by the registration website, but had to be manually transferred into the ordering software.
2) Examine the specific vaccine (how supplied, manufacturer, quantity) which had been allocated to the state (provided daily by spreadsheet from CDC, even if no new vaccine was allocated during the previous 24 hours). From this information, the specific amounts of each vaccine to go to each provider were input into an excel spreadsheet.
3) Adjust quantities to try to reach full boxes for those destinations near that level, so that vaccine at least would not have to be repackaged and shipped from the NDDoH warehouse. This adjustment had to be done in a manner which was not unfair to smaller volume vaccinators who would never get enough vaccine at one time to make a full carton.
4) Orders were then entered into CDC's vaccine ordering system on behalf of providers. Orders had to be in 100-dose increments by vaccine type. Orders for providers receiving less than 100 doses by vaccine type were aggregated and ordered to be sent to the NDDoH warehouse for redistribution.
5) Update the allocation information into NDIIS (manual entry) and generate a packing slip for the warehouse in NDIIS which would describe the specific vaccine, quantity and destination. These packing slips were then sent to the warehouse by email or fax.
6) Populate a website where providers could look up how much of each vaccine they had been allocated.
7) For those sites which used a local regional health broker, the warehouse shipping point was ultimately different from the data in NDIIS (i.e., actual provider who administered the vaccine), so that information had to be corrected.

Vaccine Ordering for Future Pandemic

CDC is now using new vaccine ordering software, VTrcks, which should allow direct uploading of spreadsheets rather than manual entry. Additionally, NDIIS now has a vaccine ordering system where providers can enter orders for vaccine directly and then the orders are reviewed by Immunization Program staff, and if approved, electronically uploaded to VTrcks. The Immunization Program will be responsible for training providers as to how to use the NDIIS vaccine ordering system. During a pandemic, Immunization Program staff may have to

enter orders into the NDIIS on behalf of providers. A substantial burden of data entry would be expected, so Disease Control would work with the DOC to pre-plan additional assistance in the Immunization Program. Whether these needs would be filled by existing NDDoH staff redirected to emergency response or whether by temporary employees would be determined at the time.

One option for ordering in a pandemic would be to tell the local provider how much vaccine their site was allowed to order, but require the provider to go in and order the vaccine. The ordering system allows all vaccine orders from within the state to be reviewed and approved by NDDoH before the order goes to CDC for processing. The state would need to ensure that providers did not order a greater quantity of vaccine from the state allocation or order a different type of vaccine then they were told they could have. Vaccine orders in excess of the state allocation would mean that someone at the federal level would determine who would or would not receive vaccine in the state. To avoid this, the state will need to stay within its allocation limit.

An additional change that would streamline the ordering process would be a modification to NDIIS to improve its handling of spreadsheet data without manual re-entry of information. However, this would take a financial investment that is not available at this time.

The NDIIS ordering system does give providers a vaccine shipment tracking number, so they are able to track vaccine shipments, however, providers receiving vaccine from the NDDoH warehouse would not receive this tracking number. Also, if orders are directly entered into VTrcks, providers would not see this tracking number in NDIIS. A method would need to be developed to notify providers of vaccine shipments.

Vaccine Prioritization and Allocation

During H1N1

Prioritization of vaccine during H1N1 followed CDC guidelines; however, NDDoH did attempt to sub-prioritize CDC authorized risk groups to ensure that those at very highest risk were vaccinated first. This created some confusion on the part of the public re: who was eligible be vaccinated, and inconsistency between local sites with some vaccine providers moving on to vaccinate other sub-groups while others were still waiting for sufficient vaccine to reach the highest priority groups. Because the H1N1 pandemic did not threaten infrastructure, no infrastructure allocation was necessary other than the targeting of health care workers.

The allocation process during H1N1 was awkward and time consuming. Disease Control would determine number of vaccine doses of what type had been allocated to the state and assign each dose to a provider based on the best estimate of population need and provider ability to reach high risk groups. This would be input into the ordering system. When the vaccine arrived, Disease Control would use the NDIIS to generate a packing slip in NDIIS and transmit this to the warehouse by fax or email where it would be used to pack the right amounts and types of vaccine for each destination.

For allocation, Disease Control relied heavily on provider estimates of how many people in each risk group the site could vaccinate. After Disease Control received the vaccine quantity request, the amounts sometimes required adjustment. For instance, if the sum of providers serving a catchment area were ordering quantities believed to exceed likely ability to reach

persons needing vaccine, estimates were adjusted down. One local public health broker site that ordered enough vaccine for the entire population in their region had their allocation adjusted down, since this would not be achieved and was substantially out of line with estimates from other sites. (Sites estimating high tended to receive vaccine faster relative to the population size than sites which estimated low.)

As each provider was allocated vaccine, this was tracked on a cumulative basis with calculation of expected vaccine coverage in that area. Adjustments were made to the allocation of vaccine based on these estimates. Even with these adjustments, substantial unevenness in vaccine availability across the state appeared to exist. To some extent this was unavoidable, but better methods for determining how much vaccine to allocate to each provider were needed.

As vaccine come in which was suitable for specific risk groups, it was allocated to all providers who reporting being able to vaccinate that risk group. One problem with this was that it meant a provider might have to deal with many different vaccines with different approved indications rather than vaccines the provider was familiar with.

Priority Vaccination

The current plans for prioritization of vaccine are dependent on the severity of the pandemic and the potential for the pandemic to impact infrastructure. CDC has provided some planning guidance for covering critical infrastructure sectors including health care, transportation, energy production, community utility, community services (e.g., grocers) and others. The prioritization would not ignore high risk groups like pregnant women, but a substantial quantity of the early vaccine would be directed away from adverse outcome-based allocation to cover infrastructure. This would not happen in a milder pandemic in which damage to infrastructure was not expected to be substantial. DES has maintained lists of critical infrastructure which could be used to help make the allocation.

For the health care and public health sector, NDDoH has also planned for within sector prioritization. Hospitals especially would determine internally who received vaccine first in order to preserve its internal infrastructure. Generally ER and ICU personnel would be highest priority followed by other direct care providers, but portions of the support infrastructure (e.g., dietary, housekeeping, maintenance) would have be vaccinated reasonably early. For guidance on how within sector prioritization would occur and be documented, refer to the pandemic influenza plan re: prioritization and to attachments A and B.

Entities which received vaccine which required population prioritization (e.g., hospitals) would need to document how each dose was allocated. Since during a pandemic, people would be expected to become seriously ill or die due to vaccine shortage, the entities allocating vaccine within their system would need to be able to defend the appropriate use of the vaccine at a later date (e.g.., vaccine was not diverted away from high priority groups to lower priority group with more authority).

During priority vaccination only, a local vaccine broker may be used. A vaccine broker is a partner institution at the local level which has agreed to receive vaccine and administer it

according to state and federal guidance. Only local public health units (LPHU) and hospitals are designated as eligible vaccine brokers in current plans[12]. Only a vaccine broker would be designated as a ship-to site during priority vaccination.

The roles of the vaccine broker include:

- Receipt and storage of vaccine, including maintenance of cold chain;
- Security of the vaccine;
- Administration of the vaccine to those authorized to receive it;
- Maintaining documentation of administration and reason for vaccination priority, and providing that documentation on request;
- Ensuring that persons given their initial dose receive an appropriately timed second dose;
- Allocation of vaccine to end user organizations (duty of LPHU only);
- Establishing clinics or PODs for mass vaccination (duty of LPHU only), and;
- Splitting vials of vaccine among priority recipient groups (duty of LPHU only).

For additional details related to roles during priority vaccination, see Attachment C.

Vaccine Prioritization and Allocation during a Future Pandemic

The NDIIS can calculate where (provider) people routinely go to get vaccinated. This could provide a reasonable estimate of how much each destination should expect to receive, but would still have to be modified by provider input since the percentage of the vaccination burden that will be left to LPH or other vaccinators may vary from provider to provider. For instance, Hettinger Clinic would need to plan to vaccinate substantial portions of Bowman, Slope, Hettinger, Grant and Adams Counties, and could receive an allocation based on the percentage of people it normally vaccinated from each county in its catchment area. This might result in a substantially better algorithm than that based on provider estimates of coverage alone. An allocation module in the registry would have the potential to improve the allocation process, but creating it would likely be expensive and no funds have been identified for this at this time. Another possible resource is SAS code written in Tennessee intended to assist with the allocation process. This software has not been evaluated in North Dakota to date.

[12] One problem that has developed since the H1N1 vaccinations is the rapid population growth in Western North Dakota and shortfall in health and public health services for the population. In this area of the state at least, it may be necessary to encourage employers to register to receive and administer vaccination, if they have the capability to do that. Employer-based vaccination would still be required to follow risk-group prioritization requirements and would need to provide estimates of how many of each risk group they could vaccinate. Estimates from NDIIS would not be available to help allocate vaccine to employers.

To the extent possible, Disease Control would attempt to provide the same vaccine to a provider consistently rather than giving them whatever vaccine is available. If providers must track the indications of many different vaccines, they are likely to make errors and deliver vaccine to individuals for which the vaccine available is not approved. This effort to create some consistency for providers would have to be balanced with the need to fairly distribute vaccine to the entire population. That is, if no shipment of the vaccine which the provider previously received is expected soon, they would be allocated a different vaccine so that the patients served by that site could have access to vaccine.

The use of adjuvant would provide a new challenge to vaccine management. It will not be known whether one or more adjuvants will be used or how they will be managed or administered until the event. Some additional training will be required for providers, but that is not expected to pose a substantial problem. NDIIS is being setup to manage data related to adjuvant. This is discussed further in the section allocation of vaccine for second vaccination.

During H1N1, traditional vaccination providers (clinic-based) providing longitudinal care and local public health were given allocation priority over pharmacies or contract vaccine providers in the allocation process. Although this was felt to be advantageous at that time, it would be less likely to be advantageous in a situation in which outpatient care was being overwhelmed with sick patients. This would remain an incident command decision during a future pandemic. Allocation will also need to consider special destinations like state penitentiary and other custodial care institutions and cross border vaccinees in how vaccine will be allocated. Consideration may rest heavily on the epidemiology of the virus (e.g., susceptibility to serious disease outcomes). For instance, H1H1 has not had a propensity to cause epidemic illness in long term care facilities, so allocation to LTC was less urgent during the last pandemic. See section on vaccination of vulnerable population for additional discussion.

Example:
In county X with a population of 5,000 of which 1,000 are children, 50% of adults (2,500) and 50% of the child population (500) usually get an annual influenza vaccine, of which 30% of the vaccinations provided to children in the county are done by Clinic A (150), 50% by Clinic B (250), and 20% by LPH (100). For adults 50% are provided by Clinic B (1,250), 10% by Clinic C (250) and 40% by LPH (1,000). If Clinic A reports that it will attempt to vaccinate any children presenting for vaccination (guess maybe 40% of child population or 400 children) and Clinics B and C expect to only vaccinate the number of people they would normally vaccinate in a typical influenza season, that is B (250 + 1,250) and C (250 adults). If 90% of the population is expected to be vaccinated with pandemic vaccine, that leaves 250 children ((1,000*0.9) – 650=250) and 2,100 adults ((4,000*0.9)-2,500=2,100) that LPH or other non-traditional vaccinators would vaccinate in that county. If two doses are required, the total allocation to that provider for that county would be double the number of people that they would expect to vaccinate. Each provider would also receive an allocation for each of the other counties they served.

Communication to the Public and to Providers

During H1N1

On a single instance early in the vaccine delivery process, part of a shipment of vaccine was thought to have possibly frozen. The vaccine was administered before a determination was made that it should be discarded. NDDoH decided to report the vaccine loss in the media and ask that those who received the vaccine be re-vaccinated. Other states also froze some vaccine but NDDoH was the only one known to have reported it to the media. The NDDoH response was consistent with DOC policy of media transparency during a disaster.

Information about influenza and vaccination were communicated through the media by weekly press conferences, radio and TV ads. This was in addition to information which was coming from CDC through the media. The hotline was open and received calls, but many callers were looking for clinical information (e.g., about care of an individual) that the hotline was not able to provide.

Although the amount of information flowing to the public was large, misinformation remained a problem. For example, as the pandemic progressed it became increasingly difficult for the state to give a uniform message about who was eligible for vaccination. Initially all local providers were targeting the same high risk groups, and it was intended that local areas not progress to vaccinating new groups until the DOC notified them that the entire state would begin to vaccinate the same new groups. In part because vaccine availability and demand were uneven, some local areas began to run out of eligible and willing vaccinees before they ran out of vaccine, so they moved to new target groups without consulting the DOC. Rumors about low vaccine safety were also common nationwide although the extent to which that impacted vaccine uptake was not known.

Communicating local vaccine availability to the public during H1N1 was a challenge that was never fully solved. The vaccine delivered to a particular provider could be provided by NDDoH because NDDoH made the allocation decision, but local clinic-specific information which the public needed to know to seek out vaccination could not be updated by the state. This included eligibility, how many doses the clinic had for what age or risk groups and when vaccination clinics were being held. Although local providers (e.g., LPHU) may have used methods specific to their area, the primary method used by the state was the Flu-Finder website.

The intent was that each provider or clinic would update this information in Flu-Finder as the information changed, but this was not done consistently. The only incentive offered to providers was the ability to get information to their patients and to decrease the number of phone calls to the office. Substantial pressure was applied by the federal government to the states related to this issue, but that did nothing to alleviate the problem[13]. The website was adequate, but the updating was not, and NDDoH did not control the updating.

Communication during a Future Pandemic

[13] DHHS went so far as to call state governors to complain about problems with up-to-date vaccination information in Flu Finder without first consulting with state health agencies. This created a firestorm of protest.

The communication of general information about the pandemic and vaccine worked reasonably well, particularly with federal investments in nationwide education, and is unlikely to be greatly different in a future pandemic. However, communication about the specifics of vaccine availability at local sites needs to improve (see below).

During a moderate or severe pandemic, some issues will be difficult to communicate to the public such as declining quality of care and allocation of ventilators. Priority vaccination may be one of these issues since it may be viewed as inherently unfair by some persons. Priority vaccination is about valuing the protection of some people over others. This not likely to be as much a problem for vaccination of high risk group as it will be for vaccination of priority infrastructure, particularly those outside of health care. Since the recommendation for priority infrastructure vaccination will come from the federal level, the federal level is also likely to take the lead in justifying it to the public.

A couple of methods may be useful for getting provider offices to update the Flu-Finder website. A requirement to update Flu-Finder can be included in the initial registration agreement signed by the provider as a condition of receiving vaccine, as well as requiring contact information for one or more persons in each office who were assigned the responsibility for updating. Incentives may be helpful but have not been identified. Yet, as long as it is left to the providers' initiative to update this information, gaps will occur.

A more reliable approach would be for NDDoH to assume responsibility for updating the website. This would require incident command to collect this information from provider offices, probably by daily or every other day phone calls to all registered provider offices. This information would then be posted by NDDoH to the Flu-Finder website. Taking on this task would require additional personnel time, either by using additional NDDoH non-EPR staff in the response or by hiring temporary employees. In a moderate or severe pandemic, additional personnel time to make phone calls to provider offices may not be available due to high absentee rates.

Heavy dependence on a website to communicate the needed information may tend to limit access for some people to this information; however, the information is complex and changes often, so other easily accessible statewide alternatives are not apparent. Some alternatives include reverse 911, mass text messages through Amber Alert, large clinic reverse 911 systems or National Weather Service alerts. Problems with these systems include 1) triggering the use of several of these would require that the information had a substantially higher urgency than was the case in H1N1, and 2) complex information which is locally specific and changing frequently would be a barrier for these methods. Social media use may be successful but would have similar limitations to the Flu-Finder website. Local communications (newspaper, public access channels) can reach local populations with provider specific messages about availability and may be the best option, but one better employed by local public information providers. Local public health could be asked to be responsible for collecting and communicating vaccine availability within their jurisdiction, but many local public health units are small and may have very thin staff due absenteeism. Complete loss of public health services in some local jurisdictions is possible due to absenteeism since staff depth is so small.

No mechanism was in place to evaluate the success of communication systems in H1N1, but anecdotal information suggests a substantial problem. In a future pandemic, it would be helpful to determine if alternative communication strategies being employed were meeting the information need. Although not without bias, one simple approach would be the addition of a pop-up survey on the Flu-Finder website and questions asked of callers to the hotline. The BRFSS could be used with less bias, but is more difficult to alter and would have a substantial delay (e.g., one or more months until prior months data became available).

Warehouse Vaccine Processing

During H1N1

During H1N1, the warehouse received cases of vaccine which had to be split among multiple delivery points. These arrived in large Styrofoam containers delivered by commercial carrier. The vaccine was transferred into alarm-monitored, walk-in refrigerators. Allocation schedules were received as packing slips produced by NDIIS prior to actual receipt of the vaccine and faxed or emailed to the warehouse by Disease Control. All the designated sites were plotted on a map and eight cluster routes were defined for delivery[14]. The vaccine was sorted by provider and route and routing sheets were created. Vaccine for each route was put into a holding container (basket) in the refrigerator for loading at 6:00 am the next morning.

The next morning, all the vaccine in a single container was placed in a portable refrigerator, a glycerin thermometer with lead wire was placed among the vaccine and the lead wire was attached to the external temperature display of the thermometer. One route sheet was put on a clipboard with route instructions and another route sheet was attached to the top of the portable refrigerator. Each refrigerator was numbered and the number was added to the routing sheets.

The drivers would leave the warehouse in time to arrive at their first destination after the site had opened to receive it (usually 8:00am). The route driver called the recipient contact for each site a few minutes before arrival. If the contact could not be reached, the driver called the DOC and requested the DOC to make contact with the destination. On arrival at the site, all the vaccine for that site was removed from the refrigerator to a Styrofoam cooler and carried into the building, where it was transferred into the refrigerator. If the site had any coolers or shippers to return the warehouse, these were picked up by the driver. Routes were intended to be no longer than 12 hours. To keep the length of the routes down, far distant destinations (e.g., Divide County) received their allocation by certified shipper shipped by commercial carrier. The vaccine recipient shipped the certified shippers back to the warehouse once emptied.

It was not intended that the driver stay overnight with any vaccine, but return to the warehouse to report-in that same afternoon. If a driver had to stay overnight, the driver would take the vaccine refrigerator into the hotel room and plug it in. If the driver was unable to deliver all the vaccine (e.g., the recipient site refused the vaccine because they

[14] In large rural areas like North Dakota, cluster routing in which routes look like lollipops on a stick are more efficient that loop routes that look like a horseshoe.

had all they wanted), the vaccine was returned to the warehouse and reallocated for the next shipment.

Several problems had to be overcome (during and after the pandemic) until final procedures were established. These included:

- Non-certified shippers could not always maintain temperature during extreme weather. Shipping switched to controlled temperature refrigerators in temperature controlled vehicle cabins, and certified shippers.
- Refrigerators initially used were hard to set and did not reliably hold temperature. The refrigerator could be plugged into the cigarette lighter, but did not have battery backup. They were replaced with vaccine refrigerators with battery backup.
- Drivers were not initially instructed to carry vaccine into the destination building in coolers. This upset some recipients so procedures were changed.
- Attempts to use SNS software called TourSolver v. 2 were not successful. The faster way to route was by hand which proved to be quite adequate for this state. Many iterations of TourSolver have been released since then, but it may not be valuable for this purpose in this state.
- Disposable temperature monitors were not found to be reliable enough and could not be externally monitored. The disposable thermometers had a plus or minus two degree margin of error. Glycerin thermometers had a plus or minus one degree margin of error and could be externally monitored.
- DOT drivers "wore out" over the course the outbreak. The DOC switched to a contract service to transport the vaccine to its destination. This worked well.
- Certified shippers needed to be pre-cooled before loading to help them maintain the correct temperature. This resulted in a procedure change.
- Although no frozen vaccine was used during H1N1, it was used in other vaccination projects. Vaccine refrigerators can manage frozen vaccine. Packing frozen vaccine in shippers is problematic since there is no reliable source of dry ice in Bismarck.
- Two vaccine refrigerators can be run off the cigarette lighter of a truck, but not in a smaller vehicle due to insufficient amperage.
- If a refrigerator is unable to keep temperature and the time to route completion lengthy, the vaccine can be dropped off at a LPHU (if so directed by the DOC) until the problem is solved. I reality, the vaccine is not so sensitive to a modest temperature rise that that should be necessary, but the freeze-thaw threshold for that vaccine should not be crossed.

Communications between the warehouse, the DOC and Disease Control evolved over the course of the pandemic and seemed to work well during most of the course of the response. Communication from providers to the DOC or Disease Control did not always work as well. Often the first indication NDDoH got that a particular provider had all the vaccine that that clinic wanted was when the vaccine was refused at the door. Most clinics would make provisions to receive vaccine after hours if they were notified to expect it. After hour delivery was an occasional problem for private providers, but a bigger problem for some small local public health units. Communications from NDDoH to providers improved over the course of the H1N1 response. The next allocation of vaccine was posted on the FluFinder website for each provider including when to expect delivery. The only place substantial problems remained was in one of the areas which was managing vaccine allocation for its region. Substantial provider complaints were received from that region.

Warehouse Vaccine Processing during Future Pandemics

A future pandemic would follow the procedures outlined above except:

- Data loggers (with probe in glycol) which can be externally monitored and have an alarm (different from the refrigerator alarm) have replaced glycerin thermometers. These are periodically re-calibrated.
- Vaccine refrigerators do not need to be plugged in unless there is an overnight stay. They will hold temperature over the course of the delivery route. Batteries will re-charge overnight.
- During H1N1, NDDoH attempted to receive, route, pack and deliver vaccine it received within 24 hours of receiving it. Although the policy prevented vaccine from sitting in the warehouse when it was needed by vaccine providers, it placed considerable strain on resources both in Disease Control and the warehouse. Whether to continue this policy would be an incident command decisions. In a serious pandemic when personnel resources become stretched and tired, this may be unreasonable.
- Additional contacts other than the primary contact for each destination are held in NDIIS; this information needs to be transmitted to the DOC.
- For shipped vaccine, recipients have had a hard time learning how to read the temperature log. More training is required and is being undertaken by Disease Control. Recipients must look at the logger at the time of vaccine receipt to ensure the vaccine is still good.
- Transportation capacity may be impaired in a severe pandemic. This may result in less frequent shipments and possible use of a greater combination of transportation resources to move vaccine.
- Higher volume of vaccine may cause a problem for certified shippers, but portable vaccine refrigerator capacity should not be taxed.
- Having all vaccine for a single destination inside a single, breathable container (e.g., laundry mesh bag) inside the refrigerator would prevent driver errors in selecting vaccine for each destination. This was not perceived to be a serious problem during H1N1, but occasionally errors were made.
- Destination will sign for the vaccine when they receive it.
- Sites which may have difficulty having someone available after hours to receive the vaccine need to make arrangements with an alternate recipient such as hospital or LTC facility which would be able to store the vaccine until it could be picked up by the vaccine provider.

Vaccine Documentation

During H1N1

Data from the vaccine recipient (vaccinee) was collected at the clinic site on a form designed for that purpose. The form could be scanned using an appropriate fax machine which would upload it into NDIIS.

- Persons completing the form often made little effort to write into the designated scannable boxes on the form.
- The program reading the forms did not perform adequately. This lead to data being dropped or scanned in as gibberish, including some critical information.
- Information required before the data could go into NDIIS was often unreadable or unavailable. There was no way to ensure that all the information needed was collected

at the time of the encounter. Mandatory fields had to be removed in order for the data to go in.
- Form scanning was often delayed.
- It was not possible for the person scanning the form to know of the form had been successfully transmitted or not.
- Data going into the registry often duplicated individuals rather than merging with existing individuals, mostly due to the poor data quality from the scan.

Eventually data was redirected to the DOC where manual data correction occurred.

Vaccine Documentation during Future Pandemics

Collection of all vaccine administration data during a pandemic will be important, and data needs to be available as soon as possible to permit assessment of coverage and reminder recalls for second dose administration. Consequently, all providers must agree to submit the data into NDIIS if they wish to become vaccine providers. The Immunization Program will be responsible for training providers as to how to use the NDIIS.

With the adoption of electronic health records (EHRs) by many health systems, data from the EHR can automatically document the vaccine record in NDIIS in real time. As of the time of this writing, about 60% of records were going into NDIIS electronically by EHRs. One of the limitations of EHR is inflexibility of the systems that generate the data for NDIIS. That is, if a new field is wanted in NDIIS, the EHR cannot easily be altered to capture the information. Pharmacies and local public health account for most of the remaining vaccine that is not transferred by EHR. Few vaccinations given in LTC facilities are currently being entered into NDIIS so that data is being lost (a new grant has been received to bring LTC into NDIIS). Additionally, IHS is not yet electronically submitting immunization data to the NDIIS.

It is assumed that all or nearly all mass vaccination records will need to be collected on paper forms for later entry into NDIIS, and a very substantial portion of the vaccines given in a pandemic could take place in mass clinics. Those forms blanks would be created by Disease Control at the time of the pandemic with content adjusted to the specific pandemic situation. To encourage getting data into NDIIS, the proposed policy is not to ship additional vaccine to a site which does not account in NDIIS for administration of all the doses previously sent (that is, every dose is accounted for by administration to a specific individual). Failure to enter data into NDIIS would limit ability of that provider to receive more vaccine; the assumption will be if the data is not in NDIIS, the vaccine dose has not been delivered. This is already being done with Vaccines For Children (VFC) vaccine. (Whether this could actually be enforced during a pandemic would depend on the circumstances.) Another alternative to ensure timely entry of data into NDIIS would be for the paper records to be sent to NDDoH for entry here. Substantial numbers of temporary staff would be needed to accomplish this. Forms would be destroyed once the data is entered.

Entry of data into NDIIS from a paper record has not proven to be problematic; matching to the correct person for data updating appears to be quite good. Time requirements for data entry into NDDoH for persons without existing records is not expected to be a serious problem since about 80% of all North Dakotans already have a record in the system.

NDIIS can generate recall reminders for persons who received the initial dose of pandemic vaccine once the required time between doses had elapsed. The system can produce line lists to upload to an autodialer which could deliver a generic message to persons needing to return to the clinic[15]. A more specific message would be better, especially if it is determined that to be important that a person's second dose be exactly the same vaccine (e.g., type, manufacturer) as the first dose, or at least the same adjuvant. In that case, just because sufficient time had elapse for the person to receive the second dose would not mean the specific vaccine would be available in the community. It might prove difficult for the patient to show up at the right place and time to get the correct vaccine, even if they knew what vaccine and adjuvant they needed. A reminder letter could be generated when the vaccine the person needed was available to them locally, but this would be labor intensive and expensive, and likely impractical during a pandemic when hundreds of thousands of persons were receiving two doses of vaccine. Furthermore, by the time the letter was received, the vaccine the person needed might already have been used.

Adverse Event Reporting

Influenza vaccines are rarely associated with serious side effects, but any vaccine or drug given to enough people will cause serious adverse reactions in rare instances. The addition of adjuvant to the vaccine, even if very safe, will increase the risk of adverse reactions, although the risk profile of the vaccine will depend on specific adjuvant used with it. The NDDoH currently recommends that providers directly report adverse events using an on-line form to VAERS (www.vaers.org). Previously, providers reported adverse events using the NDIIS. Since these events are not able to be electronically submitted to VAERS, the immunization program changed this process. During a pandemic, VAERS reporting in NDIIS could be turned back on. During H1N1, CDC pushed states to receive adverse events and investigate those that were unexplained and serious. CDC is likely to do this again during the next pandemic. Not all vaccines are quite as safe as influenza vaccine, and some are substantially less safe.

Wasted and Recalled Vaccine

Some wastage of vaccine is inevitable. Currently this is reported to NDDoH through the NDIIS. The Immunization Program is responsible for training providers on how to use the NDIIS vaccine return/waste system. If vaccine is recalled, NDIIS will be able track who received the specific vaccine that was recalled in order to make contact with the provider to quit using the vaccine.

Security

In the event of a serious pandemic in which many otherwise healthy persons are dying because insufficient vaccine is available to protect them, vaccine security may become a substantial problem. In that event, security will be handled as outlined in the SNS for other types of materials distribution.

Mass Vaccination Clinics

Medical Waste

[15] Use of autodialers in North Dakota is currently against the law; however, this could be altered during a pandemic by executive order.

NDDoH has acquired the materials needed for safe containment of large amounts of medical waste. Individual public health units have their own local arrangements with providers of services for disposal or destruction of the waste material. During a pandemic it is expected that there will be some problems with managing large amounts of sharps generated by mass vaccination within the capacities of existing disposal companies. If necessary, LPHU will store the waste in sealed containers in locked rooms until the capacity of disposal companies is sufficient to receive and destroy the excess medical waste material.

Infection Control and Social Distancing

Public health workers routinely administer vaccines, including influenza, and are trained in universal and bloodborne pathogen precautions. It is possible that a public health worker shortage might lead to vaccine administration by some workers who are not normally allowed to administer vaccine, but could do so under circumstances of a Governor-declared disaster. Ensuring that these employees are adequately trained in infection control will be the responsibility of the vaccinating entity.

Prevention of transmission of influenza during a pandemic vaccination clinic is a serious concern, since presence in a pandemic vaccine clinic may increase the risk of exposure but receiving the vaccine will not provide immediate protection against disease. In other words, a vaccination clinic will have a potentially powerful anti-social distancing effect. There are several approaches that may be used to minimize the adverse social distancing:

- Universal covering of the nose and mouth – Masking appears to be at least somewhat effective a limiting the droplet spread of a person who is sneezing or coughing, even if its effectiveness at preventing another person from inhaling the droplets is less clear. Although sufficient surgical masks may not be available to put on every person, clinics may need to require every person to have their nose and mouth covered with a mask or a cloth at all times.
- Education – Continuous education of those who enter the clinic regarding respiratory etiquette, avoiding touching surfaces, frequent hand washing, not touching the face with one's hands, and maintaining a distance between families of at least three feet may be needed.
- Use of outdoor space or drive through clinics – Not all local sites have exercised drive through clinics which should more effectively limit spread between families, but many of the large jurisdictions in the state have exercised it. Throughput would likely be a problem for large scale vaccination is needed quickly.
- Clinic intensity – Lower clinic throughput may decrease the risk of transmission; if is not likely that if this will be known although if it permits greater distance between families coming in for vaccination, it should be partially effective. Lower than expected throughputs may also be necessary if an acute shortage of public health workers makes staffing large clinics impossible.

Logistics

Vaccination at the LPHU may be logistically easier than POD-based vaccination when the number of doses to be administered remains small. It will be the option of LPHU to determine when the number of doses is so large that transition to POD-based vaccination would be more efficient. The details of POD-based operations are contained within local POD planning documents which are part of the SNS documentation at the local level.

Local POD plans[16] encompass both drug distribution and mass vaccination. Initial plans were developed for antibiotic prophylaxis, but have been modified to address vaccine specific issues. Issues unique to vaccination, when compared to mass dispensing of oral medication include:

- Workforce vaccinators and person drawing up vaccine/adjuvant– Even though an executive order by the Governor made under the state disaster act would provide opportunity to use providers to give vaccines who don't normally give vaccinations, the availability of providers who will be capable of administering an injection will be limited. In addition the greater physical demand of the work compared to pill dispensing will place more limitation on the number of hours a vaccinator can work without rest.
- Cold chain – Mass vaccination sites may have limited refrigeration capacity which will require LPHU to transport the vaccine from the storage site to the mass vaccination site and maintain the vaccine within temperature at the clinic site. Requirement for cold chain maintenance may limit the amount of vaccine that can be brought to the vaccination site at any one time.
- Number of persons to be treated – Unlike antibiotic dispensing which provides multiple courses of medication to the head of household, vaccination clinic will have to reach all persons.

Vaccination of Special and Dependent Populations

The approach to vaccination of special and dependent populations will vary from one LPHU to another, but is similar to plans developed for SNS drug distribution.

- Homebound – Vaccination of homebound will take place after mass vaccination clinics have largely completed general population vaccination. This reflects the somewhat lower risk of infection of persons who are not mobile, but more especially the low efficiency of reaching the population compared to mass clinics. In most LPHU, this will involve home visits by public health personnel.
- Outreach to custodial institutions – Delivery of vaccine to institutions which have custodial responsibility for the health of their population, when health care personnel are not on-staff to provide the vaccine, will require a visit by public health vaccine providers. Generally, public health personnel will be dispatched to go on-site after mass vaccination is completed, but institutions may be prioritized for earlier vaccination based on risk assessment. Some institutions will be able to vaccinate their own residents. These would include hospitals and clinics, long term care, some schools (if operational at that time), state penitentiaries.
- Language barriers - North Dakota has a low percentage of non-English speaking persons generally, but substantially higher in some areas. Approaches vary depending on the percentage of the population which is not English speaking. In areas with relatively higher numbers of non-English speakers (e.g., Fargo area), interpreters will be available within clinics for common languages. For areas with low numbers of non-English speakers (as well as for languages which are spoken by few persons in all parts of the state) telephone-based interpretative services will be provided with the help of designated persons assigned to assist those with special needs in the clinic.

<u>Vaccination of Reservation Populations</u>

Some reservations have PODs which may be able to vaccinate. Otherwise, persons on reservation will need to seek vaccination at the nearest public venue off reservation. For both Spirit Lake and Turtle Mountain reservations, these venues are likely to be close. Fort

[16] Each of the 62 local POD plans includes an MOU and points of contact for both site command structure and building access including multiple access numbers. The plans are located in the secure document library of NDDoH.

Berthold is likely to be able to vaccinate locally since they have had the most stable POD structure. Standing Rock has not been able to sustain a POD in the past across changes in tribal leadership. Because of the large distance to the nearest substantial city (Mandan), and accessory transportation plan has been drafted and may need to be activated. Standing Rock is trying to re-establish a POD at this time. The NDIIS should provide the ability to track vaccine coverage among American Indians.

Emergency Use Authorization Vaccination

The provisions of an EUA requires that persons receiving the vaccine know that the vaccine has not completed full approval, but that it is being offered due to an emergency. Potential recipients would need to know the risks and benefits of receiving the vaccine or of refusing the vaccine, any alternatives that they have to the vaccine, and an assurance of their right to refuse the vaccine. In the event that NDDoH needed to administer vaccine under an EUA, the agency would expect to receive substantial information from DHHS detailing the following:

- Target recipients;
- FDA conditions for use;
- Information regarding risk and benefit of use;
- Additional information to be collected (in addition to contact information and information collected as part of the vaccination process for a non-EUA vaccine);
- Guidance regarding enhancements to adverse event reporting and case investigation which would need to implemented as additional safeguards.

NDDoH would provide training of all persons who would be administering vaccine under an EUA. Training would be provided using video conferencing over Stagenet and BTWAN (hospital network), as well as by web-casting if needed to reach additional entities not tied into the videoconferencing system.

Investigational New Drug Protocol

IND protocols require specific information collection, especially related to adverse events, a detailed consent signed by each recipient and patient follow-up. Because of its high burden of documentation, investigational new drug protocols would be impossible to implement on a mass scale; however, implementation within a narrowly targeted population could be feasible. Should IND vaccine use be necessary, NDDoH will look for additional guidance specific to the vaccine being used under IND including vaccine recipients to be targeted, additional documentation requirements and reporting. The NDDoH IRB would be prepared to review the protocol on a priority basis. Prior to use of the IND protocol, NDDoH would ensure that it had:

- FDA site approval for administration;
- IRB approval by the NDDoH IRB (or a CDC IRB which NDDoH has recognized as a substitute IRB);
- A designated principal investigator. Since the vaccine would be administered under the authority of NDDoH, the State Health Officer would likely be the PI.
- A research protocol which incorporated FDA requirements for data collection and patient follow-up and to which no changes would be made without IRB review and approval.
- A reporting pathway defined for adverse event communication back to DHHS.
- State training of all persons who would be administering vaccine under an IND protocol including informed consent requirements, record keeping and reporting. Training would be provided using video conference over the Stagenet (IT backbone for state) and BTWAN (hospital network), as well as by web-casting if needed to reach additional entities not

tied into the videoconferencing system. State software used to register for and track training would be used to confirm participation in training for each site before the IND protocol could be used.

Until the time of the event, it will not be known what the extent of the utilization of a vaccine would be under an IND protocol. Once this is known, vaccine would be allocated to specific sites and duplicated consent form/protocols (duplicated through central duplication services of the state) would be distributed through the SNS system along with POD materials for clinic setup.

ATTACHMENT A
HOSPITAL PREPAREDNESS PROPOSAL FOR PANDEMIC INFLUENZA VACCINE DISTRIBUTION PRIORITIES

At this time, NDDoH is expecting that direct care providers in hospitals will be first line recipients of pandemic influenza vaccine. It is likely that initial vaccine shipments will not be sufficient to vaccinate all direct care providers; consequently, establishing a priority system for vaccination pre-event is necessary. At this time, no guidance is available for development of such a system.

Hospital preparedness representatives to the four regional HPP meetings were asked to describe a priority system for allocating the expected small numbers of vaccine doses which would initially be available to distribute to health care workers. Prioritization does not include other personnel who may be assigned vaccine outside the health care sector such as critical community infrastructure and public health.

To divide health care personnel into priority groups, the hospital planning committees were asked to only consider prioritization based on their perceptions of the approach that would save the most lives. In keeping with that overarching goal, it was recommended that they consider 1) whether the person had specialized skills which were necessary for patient care and difficult to replace (e.g., ventilator management); and 2) the level of exposure that the employee would likely have to persons infected with the pandemic strain. Since in smaller hospitals, many of the staff serve multiple roles, it was decided that the prioritization level of any individual would be based upon their highest level of priority. For example, a nurse covering both the floor and the ER would be considered ER for purposes of prioritization, since it was at a higher priority level.

PRIORITIZATION RECOMMENDATION

The following prioritization schedule represents a consensus of the hospital preparedness representatives. Tier 1 is numerically ordered with each numerical group being completed with two doses before starting the next numerical group. Lower tiers are not subdivided. If insufficient doses are available to vaccinate an entire tier (e.g., Tier 2A) or category (Tier 1 Category 1) that was eligible for vaccination, it would be up to the health care institution to decide who within the tier or category would receive the vaccine. It is expected that facilities would attempt to vaccinate some persons from across the categories represented within a tier in order to maintain all functions to the degree possible.

Tier 1

1. Critical Care Staff [ICU, ER, and Specialty Physicians (ICU, ER, and Infectious Disease)
2. Hospital designated urgent care staff (walk-in/triage area to minimize traffic in ER)
3. Primary Care Nursing Staff (RN, LPN, CNA)
4. Emergency Medical Services staff
5. Incident Commanders
6. Radiology Staff
7. Respiratory Therapy staff
8. Primary care physicians
9. General Surgeons

10. Laboratory/phlebotomy staff
11. Anesthesia
12. Inpatient pharmacy

Tier 2A

- All other physicians, nurses, CNAs
- Admitting staff
- Housekeeping
- Bio-medical staff
- Dietary staff
- Laundry staff
- Incident Command staff
- Chaplain staff

Tier 2B

- Medical records staff/ward clerks
- Central Supply staff
- Long term care staff
- Home health staff
- Social Workers/Discharge/Case managers
- Psychiatry staff/mental health providers
- General Incident Command Staff
- Security staff

Tier 3

- Purchasing staff
- Maintenance staff
- Information technology staff
- Rehab Therapy
- Admin Support
- Finance staff

Tier 4

- Any other staff without direct patient contact
- Family members of Tier 1 hospital staff

ALLOCATION

It is expected that when NDDoH receives the first shipment of vaccine, the Department Operation Center (DOC) would determine the percentage of vaccine that would go to several different domains (e.g., local public health, state public health, health care, first responders, municipal workers, and disaster management). The relative allocations between these groups will be an incident command decision guided by the situation in the state when the initial vaccine is made available and any CDC requirements. It is expected that the vast majority of doses would be allocated to health care. Based on the number of doses of vaccine available for allocation to that domain, recipient institutions would be asked to supply the number of persons who fall into each Tier 1 category. Incident command would designate which categories were eligible for vaccination, and recipients would have to agree to abide by these eligibility criteria in order to receive vaccine. For the purposes of this discussion, community

health care staff (within minimum care facilities) will be considered for vaccination based on their assigned role, as if they were hospital staff.

The available doses would be divided proportionate to the number of personnel in each of the categories that could be covered. It is the intent of NDDoH that the vaccine would be sent to destinations within 24 hours of receipt by the state. Facilities receiving vaccine would be asked to provide the vaccine to staff within 24 hours of receipt, keeping careful records of who received the vaccine and why. The receiving facility would need to provide for the security and storage of the vaccine including maintenance of cold chain.

If insufficient vaccine is available to vaccinate an entire priority group (e.g., ICU and ER), the hospital would need to decide how to allocate the vaccine. The decision needs to be logical and ethical. It could be by lottery, epidemiological risk (e.g., age), professional risk (e.g., assignment to care for pandemic patients specifically), availability to work through the pandemic or any other defensible method. The method chosen should be documented and as each person is vaccinated, it should be documented why that person was vaccinated and not someone else. These records would be made available to NDDoH on request, which would only be likely if questions were raised about ethical allocation. Given that vaccine receipt may determine whether certain persons live or die, public inquiry may occur after the pandemic.

PUBLIC HEALTH PANDEMIC INFLUENZA VACCINE PRIORITIZATION

Once the world enters into pandemic influenza, an effective vaccine is not expected to be available for several months. Although it is not possible to know how the situation will unfold, we are expecting that as vaccine is produced, it will be released to states in small quantities, and into the public sector (NDDoH) rather than the private sector. Past experience suggests that it will be up to states to determine how the vaccine will be allocated within their states within broad guidelines supplied by CDC. At this time, it is anticipated that two doses would be required by each vaccine recipient in order to acquire any protective immunity. Persons who had received one dose would be given a second dose (assuming sufficient time had elapsed) before an unvaccinated person was given their first dose.

It is expected that when NDDoH receives the first shipment of vaccine, the Department Operation Center (DOC) would determine the percentage of vaccine that would go to each of six domains as follows: local public health, state public health, health care, first responders, municipal workers, and disaster managers (listed in no particular order) in addition to any risk categories designated as high priority by CDC. The relative allocations between these groups will be guided by the situation in the state when the initial vaccine is made available. That is, different shipments of vaccine might be divided among the domains differently based on the situational assessment. It is anticipated that the largest quantity of vaccine in each shipment would be allocated to the health care domain.

The NDDoH Department Operation Center would designate which categories were eligible for vaccination and potential recipient institutions would be asked to supply the number of persons who fall into each specific eligible category. Recipients would have to agree to abide by these eligibility criteria in order to receive vaccine.

Priority
The tier table below represents the recommendation of local public health for vaccine prioritization. The final decision on eligible categories would be made by the NDDoH Department Operation. In the recommendation below, each tier and each numbered category within each tier below represents a higher priority level than the tiers or categories below it. Vaccination would be completed in the highest level tier or category before moving on to a lower category or tier. Regardless of category or tier, provision of second dose to those already having received their first dose takes precedence over provision of any first dose, assuming sufficient time as elapsed since the first dose was given.

<u>TIER 1:</u>

1. Nursing Staff
2. Public Health Officer (with direct patient contact)
3. Field Surveillance Workers

<u>TIER 2:</u>

1. PH staff at-risk of exposure*
2. Incident Command Staff

- Incident Commander
- Business Manager
- PIO
- Community members filling these functions
- EPR Coordinators

4. IT Staff

TIER 3:

1. Program Staff
2. Janitor
3. Board of Health Members
4. Primary and secondary POD people/managers
5. Families of Tier 1

* Persons having direct patient contact other than those listed above.

Local Vaccine Brokers

A local vaccine broker is a partner institution at the local level, typically a local public health unit or hospital, which has agreed to receive vaccine and administer according to state guidance and federal guidance. The role of the vaccine broker would include:

- Receipt and storage of vaccine including maintenance of cold chain;
- Security of the vaccine;
- Administration of the vaccine;
- Allocation of vaccine to end user organizations;
- Maintaining documentation of administration and reason for vaccination priority and providing that documentation on request;
- Ensuring persons receiving their initial dose receive an appropriately timed second dose, and;
- Setting clinics or PODs for mass vaccination.

Only a vaccine broker would be eligible to receive and administer the vaccine for priority vaccination of infrastructure. This would not be true of priority vaccine for demographic risk groups. All domains which were allocated doses would have to report to the vaccine broker in order to have the vaccine administered. If both a hospital and local public health unit were designated vaccine brokers, it is expected that in most cases, the local public health unit would be the primary broker responsible for splitting vials among domains and administering those doses.

ATTACHMENT C

Vaccine Management and Administration Roles During Priority Vaccination

Local Public Health Roles

By its nature, vaccination is considered to be primarily a local public health function. Local public health assumes this duty under legislative mandate and contract with NDDoH. The following are the anticipated roles of local public health:

- Receiving vaccine and signing for receipt (chain of custody)[17];
- Administering vaccine to all non-hospital priority recipients;
- Ensuring that vials which need to be split between two different groups are appropriately divided. This includes splitting vials for hospital employees when only part of the vial is allocated to hospital personnel. Those hospital employees receiving vaccine from a split vial will need to go to the LPHU to be vaccinated, unless other arrangements have been made with the LPHU.
- Ensuring that vaccinees receive their second dose as soon as possible after they become eligible for the second dose;
- Maintaining records for all priority recipients which include the reason why the person was selected for priority vaccination;
- Providing whole vials to institutions which agree to 1) perform self-administration and 2) maintain required vaccination records. (See section on custodial care.)
- Maintaining the vaccine between 35°and 46° at all times, and provide documentation of cold chain records;
- Maintaining refrigeration space in excess of daily, non-pandemic requirements sufficient to hold a local allocation equivalent to one dose per person – Given the uncertainty of potency of the vaccine and hence the number of vials of vaccine which might be received at any time, it is difficult to know with certainty the amount of refrigeration space required.
- Maintaining cold chain transportation from vaccine storage sites to public health operated clinics. That is, vaccine will be received at the LPHU; however, POD sites, one or more per region, may be at a different location. This will require transporting the vaccine from the LPHU to the vaccination site and storage of the vaccine at the site. (Vaccine which is released to other institutions for self-vaccination will also have to be kept cool, but this is the responsibility of the receiving institution. LPH would need to take care that it does not release vaccine to an entity which is packaging it for cold chain transport;
- Setting up and operating vaccine clinics of sufficient capacity to administer expeditiously the quantity of vaccine ready for administration. When vaccine quantities are small, vaccinations will occur at LPHU offices with transition to POD sites for large volume administration. The point of transition from office to POD will be at the discretion of local public health;
- Establishing hotlines which can receive reports of vaccine adverse events and forwarding adverse event reports to NDDoH;
- Entering data into the North Dakota Immunization Information System (NDIIS);
- Providing public communication in cooperation with regional and state public information officers.

Hospital Roles

[17] The receiving agent for vaccine within each local public health unit is the designee of the incident commander for the institution. NDDoH will make direct contact with the agency operations center for notification of vaccine shipments and signing custody transfer forms.

- Receiving shipments of vaccine from manufacturer or shipping agent and maintaining security and cold chain[18];
- Administering vaccine to own employees and volunteers, unless arrangements have been made specifically with local public health to complete this;
- Selecting individuals for priority vaccine within the guidelines provided by the state;
- Ensuring that employees due a second dose receive it in a timely manner;
- Maintaining records for all employees given priority vaccination including the reason why the person was selected for priority vaccination;
- Entering data into the North Dakota Immunization Information System (NDIIS);
- Receiving reports of adverse reactions caused by the vaccine and reporting that to NDDoH.

NDDoH Roles

- Designating the priority recipient groups based on pre-determined state and federal guidelines provided (responsibility of incident command in the DOC);
- Determining shipment allocations;
- Providing to the federal shipping agent the list of ship-to sites and the quantities to be shipped to each destination for each shipment;
- Receiving shipments from the manufacturer or their shipping agents and re-packaging vaccine for shipment to smaller geographic areas as necessary.
- Approving redistribution of vaccine if indicated -- If all persons within the approved priority groups in the jurisdiction of a LPHU have been vaccinated, but vaccine remains, the LPHU will call the Department Operations Center (DOC) of NDDoH which will determine whether to permit use at the local site or to re-allocate vaccine to another LPHU jurisdiction for use with priority designees in the approved groups (unlikely unless quantity of vaccine remaining unused is large). NDDoH will coordinate the transfer of the vaccine between the public health units if this becomes necessary.
- Reviewing adverse reactions to identify those of high severity or of an unusual nature which require investigation to assess the likelihood that the reaction was vaccine-related, or identify any reasons why reaction occurred (e.g., presence of a relative contraindication or absolute contraindication to vaccination). See section on adverse event reporting for additional detail.
- Providing aggregate reports to CDC in the manner requested by CDC. NOTE: In some circumstances, shipment sites will differ from administration sites (e.g., multiple PODs within the jurisdiction of a single health unit);
- Providing oversight to the NDIIS system and coordinating system changes with Noridian (Blue Cross/Blue Shield of North Dakota) which administers the software;
- Analyzing results from the NDIIS system to provide estimates of coverage, identification of local areas which appear to be experiencing barriers to rapid completion of vaccination, identification of individuals substantially overdue for second dose vaccination and identification of number of persons ready for second dose vaccination (for purposes of vaccine allocation);
- Taking the lead in working with the PIO for public communications about priority vaccination. It is expected that not all persons will willingly understand why they or their family members were not selected for priority vaccination. NDDoH will attempt to provide transparency to the process through media messages.
- Ensuring staff at the state level who are to receive priority vaccination are vaccinated. (State personnel prioritized for vaccination will be vaccinated through their local public health unit in the same way as priority vaccinees of other infrastructure institutions.)

[18] The receiving agent for vaccine within each hospital is the designee of the incident commander of the institution. NDDoH will make direct contact with the agency operations center for notification of vaccine shipments and signing custody transfer forms.

ATTACHMENT D

Prioritization of Infrastructure

Summarizing information for critical infrastructure recommendations other than the above from The Prioritization of Critical Infrastructure for a Pandemic Outbreak in the United States Working Group

www.dhs.gov/xlibrary/assets/niac/niac-**pandemic**-wg_v8-011707.pdf.

:

Tier 1	Law enforcement personnel Fire services personnel Key government leaders
Tier 2	Electricity sector personnel Natural gas personnel Communications personnel Water sector personnel Critical government personnel Community suppt. & emergency mgt. (e.g. Red Cross
Tier 3	Transportation sector personnel Food and agriculture sector personnel Banking and finance personnel Pharmaceutical sector personnel Chemical sector personnel Oil sector personnel Postal and shipping personnel Other important government personnel

Sector	**Tier 1 Functions**	**Tier 2 Functions**	**Tier 3 Functions**
Financial	• Federal funds, foreign exchange, and commercial paper; • U.S. Government and agency securities; • Corporate debt and equity securities. • Sufficient critical personnel to operate and maintain minimum cash availability to the public through the ATM network (1 ATM per bank branch office).	• Obtain cash on a broader basis through the ATM network • Maintain electronic payment systems (checking, wire transfer, ACH, retail lockbox, credit/debit card) throughout a pandemic.	

Chemical	50% of critical • Production and plant first-line management; • Production, plant and system assemblers and operators; • Material recording, scheduling, dispatching, and distributing; • Industrial machinery mechanics and machinery maintenance workers; • Transportation and material moving workers; and • Healthcare and safety and occupational health providers	Other 50% of critical personnel	
Commercial facilities	50% of the most critical • Lodging • Real estate • Retail maintenance • Media	Other 50% of critical personnel	
Communications	% of criticals • Wireless service providers; • Wireline service providers; • Other communications service providers; • Manufacturers, suppliers and vendors; • Networking companies; • Information Technology companies that characterize themselves as having a communications infrastructure or provider-related role; • Communications-related system integrators; • Owners/operators of infrastructure used within the sector including cable systems, other operators and broadcasters; • Trade and other associations representing sector members; • Infrastructure owners who have national assets used in the Emergency Alerting Systems		
Emergency Services	• Fire • EMS • Law Enforcement • Emergency Management • Local Jail/Corrections Officers • Dispatch		

Electricity	• Transmission System Operators • Distribution System Operators • Power Plant Operators • Outage Response Line Mechanics • Substation Operators • Substation Technicians • SCADA Technicians	• Maintenance Line Mechanics • Power Plant Maintenance Mechanics • Customer Service Representatives • Substation Maintenance Mechanics • Material Handlers, Management, Finance and Accounting • Regulatory Affairs, Engineers	• All remaining power plant personnel • Line mechanics • Substation mechanics • Dispatchers • Supply chain • Customer service • Finance • Accounting
Oil and Natural Gas	Mission criticals for: • Oil and Natural Gas Extraction • Petroleum Manufacturing • Petroleum Merchant Wholesalers • Gasoline Stations • Pipeline Transportation (Natural Gas)	Business criticals for: • Oil and Natural Gas Extraction • Petroleum Manufacturing • Petroleum Merchant Wholesalers • Gasoline Stations • Pipeline Transportation (Natural Gas)	
Food and Agriculture	None identified		
Health Care	See Above		
IT	Those providing onsite presence to customer support.		
Nuclear			
Postal and Shipping (Public sector)	10% of critical employees in • Field processing • Movement and delivery	20% of criticals for maintenance of service	
Postal and Shipping (Private sector)	5% of criticals in • Aviation • Truck delivery • Warehouse and material management	15% of warehouse and management	

Transportation	Criticals in • Aviation air traffic controllers and critical specialty commercial pilots; • 50 percent of maritime crew members and the most critical port workers, such as crane operators; • Some critical skilled maintenance workers • 50 percent of the most critical railroad locomotive engineers, operators, and maintenance workers; • 50 percent of total drivers and support personnel for critical specialty cargos and vehicle types.	Remaining 50% of criticals	
Water and Waste Water	Not defined		

In support of HB1468.

True “Informed Consent” is crucial for ANY medical intervention of ANY kind. Without this, you are falling into coercion or manipulation tactics. All possible reactions to vaccinations are all listed on the inserts but NOT on the vaccine information sheets.

After my MMR as a child, I had a fever of 107’ and my mother took me into the ER. Late that night my fever broke and I broke out in measles. My mother was never told that measles was a possible side effect of the MMR. At that time, only one MMR was a prerequisite to school. On the current schedule, two MMR’s are required. Doctors are not asking parents of children coming in for boosters, if they have in fact had those infections. Getting a booster for an infection a child has already had is setting them up for a possible cytokine storm or other reaction. My mother had no idea that exemptions for vaccinations existed until she had grandchildren.

Had I known some of the possible reactions to vaccinations during pregnancy and the fact that they are not tested for pregnant women, I would have investigated them more at the time. I trusted my physician who told me it was safe and normal protocol for pregnancy. Because of this, I ended up with Pre-eclampsia in my first pregnancy immediately following my pregnancy vaccination. Pre-eclampsia is a major side effect that is in fact listed on the insert for the TDaP vaccine. I had an emergency C-section after 30+ hours of labor and then that led to a double blood transfusion. They also proceeded to have me fill out paperwork for my child during labor and afterwards when I was completely taken over by pain medication. This is not appropriate when you are not in a stable state of mind. I also was not given informed consent to any vaccines or medication that my child was receiving at the time of birth.

My daughter quit breathing the very night of her vaccinations on two separate occasions. I was given the VIS after vaccination. At no point was I given an insert that would have told me that Apnea is a possible side effect. Giving the Vaccine Information sheet AFTER the vaccination is completely incompetent and not offering the insert for more information is barring people from the truth. I had no idea that exemptions for vaccinations existed until my oldest daughter was almost a year old.

Amanda Saueressig

1/24/2021

My name is Diane Kadrmas and I am in favor of HB 1468. I believe that having proper information starting at the doctors office would decrease the need for repeat visits, confusion, or disinformation for the future. People have the right to know about any and all adverse effects that could be caused by a product, ingredients in the product and knowledge of what the product is for as well as knowlege about the disease, virus, bacteria or any other health concern that is being discussed on which product is being given. Ex; this (insert disease here) has been known to cause these symptoms, (list symptoms) it has a (insert percentage) of causing death or other long term symptoms and how said disease is caused, and this (insert product being administered) has these ingredients (give insert and explain what they are) and have a (insert percentage) of causing these reactions, long term effects or death. Also, having knowledge on how many cases are being reported in the United States for certain diseases and how to prevent it naturally and other ways to treat if available.

Greetings, my name is Jessica Kuntz, and I am writing in SUPPORT of HB1468. I believe this bill is important in the step in providing full transparency regarding vaccines. I am disappointed that everything I learned about the vaccine ingredients, standard of testing, as well as manufacture liability, was discovered on my own rather than from the expert that administered them. If I would have been shown more transparency, I would not have felt so betrayed by the very person I trusted the most at the time.

I urge you to pass this bill and give parents/guardians the right to all the information so that they will feel they've made the best decision for their children.

Thank you.

1/24/2021

My name is Curtis Kadrmas and I am in favor of HB 1468. I believe that having proper information starting at the doctors office would decrease the need for repeat visits, confusion, or disinformation for the future. People have the right to know about any and all adverse effects that could be caused by a product, ingredients in the product and knowledge of what the product is for as well as knowlege about the disease, virus, bacteria or any other health concern that is being discussed on the product being given. Ex; this (insert disease here) has been known to cause these symptoms, (list symptoms) it has a (insert percentage) of causing death or other long term symptoms and how said disease is caused, and this (insert product being administered) has these ingredients (give insert and explain what they are) and have a (insert percentage) of causing these reactions, long term effects or death. Also, having knowledge on how many cases are being reported in the United States for certain diseases and how to prevent it naturally and other ways to treat if available.

Please support HB 1468 – HFND

As it will provide the additional information that is lacking with informed consent including manufacture inserts, school exemption forms and pregnancy/biologics/while in labor.

I support HB1468. I like this bill because it mandates full disclosure so one can make an informed decision. I'm strongly in favor of the vaccine insert being supplied. I've actually asked for one in the past and was denied the information. May God guide you and bless you all!

Committee members, my name is Jocelyn Backman and I am writing IN SUPPORT of HB 1468 relating to informed consent and notice of risks associated with vaccines; and to provide a penalty.

I will be attaching the CDC Vaccine schedule for Children up to 18 years of age for reference to my testimony. I will discuss the Hep B Vaccine due to time constraints; I will only also discuss the experience I've had with my 3-year-old son.

Hepatis B is given at Birth, 1-2 months, and 6-18 months, so 3 doses to be compliant based on the CDC schedule.

When I was in labor, it was never discussed what Vaccines my son would be given. I had an idea before I went in since I studied them but the hospital that I gave birth in didn't discuss Vaccines. After giving birth my son was taken away from me so he could be bathed as well as vitals checked. When he returned to me, I was notified he was Vaccinated for Hepatitis B and Vitamin K. I never gave the nurse or hospital consent to Vaccinate my son, so Informed consent was not given in any shape or form.

Now, what exactly is Hepatis B and how do you contract it? Hepatis B is a liver disease that is usually short term with symptoms ranging from fever, fatigue to loss of appetite and increases in severity depending on the health of the person. Now how is it contracted? Birth (if a mother has hepatitis B, her baby can become infected) Sharing items such as razors or toothbrushes with an infected person Contact with the blood or open sores of an infected person Sex with an infected partner Sharing needles, syringes, or other drug-injection equipment Exposure to blood from needlesticks or other sharp instruments. I do not have Hepatis B, so the reason a newborn baby is given this Vaccine is ludicrous to put it mildly. In my opinion this Vaccine should be offered as an adult, not for a brand-new baby.

I did some research on the VAERS website for Vaccine reactions around Hep B only. In 2020 I observed 967 reactions in the US that were reported to VAERS (symptoms ranging from fever, rash, cellulitis, blister, diarrhea, cough, nausea, vomiting, increased heart rate, flushing, etc etc.) It's an extremely large list. If you have any questions on this date you can go to VAERS.HHS.gov and run some reports. There is a lot of data out there around Vaccine injury that we never hear about.

My point of all of this is, I was never given any of the data that I presented. My son was vaccinated without me knowing and I had no knowledge of what the vaccine was, what the disease was he was being vaccinated for, and what adverse reactions I should watch out for. He was vaccinated with his 2nd and 3rd doses and was only presented with a fact sheet of what to watch out for, but never was presented with why a newborn baby was vaccinated for a sexually transmitted disease, as well as the list of adverse reactions nor the fact that I could in fact fill out an exemption if I didn't want to give the vaccines to him (personal, medical, religious). It's also important for medical professionals to discuss VAERS with their patients so parents can do research themselves.

Please render a DO PASS on HB1468.

Thank you for your leadership and service to our state.

VACCINE INFORMATION STATEMENT

Hepatitis B Vaccine:

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?

Hepatitis B vaccine can prevent **hepatitis B.** Hepatitis B is a liver disease that can cause mild illness lasting a few weeks, or it can lead to a serious, lifelong illness.

- **Acute hepatitis B infection** is a short-term illness that can lead to fever, fatigue, loss of appetite, nausea, vomiting, jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements), and pain in the muscles, joints, and stomach.
- **Chronic hepatitis B infection** is a long-term illness that occurs when the hepatitis B virus remains in a person's body. Most people who go on to develop chronic hepatitis B do not have symptoms, but it is still very serious and can lead to liver damage (cirrhosis), liver cancer, and death. Chronically-infected people can spread hepatitis B virus to others, even if they do not feel or look sick themselves.

Hepatitis B is spread when blood, semen, or other body fluid infected with the hepatitis B virus enters the body of a person who is not infected. People can become infected through:

- Birth (if a mother has hepatitis B, her baby can become infected)
- Sharing items such as razors or toothbrushes with an infected person
- Contact with the blood or open sores of an infected person
- Sex with an infected partner
- Sharing needles, syringes, or other drug-injection equipment
- Exposure to blood from needlesticks or other sharp instruments

Most people who are vaccinated with hepatitis B vaccine are immune for life.

2 Hepatitis B vaccine

Hepatitis B vaccine is usually given as 2, 3, or 4 shots.

Infants should get their first dose of hepatitis B vaccine at birth and will usually complete the series at 6 months of age (sometimes it will take longer than 6 months to complete the series).

Children and adolescents younger than 19 years of age who have not yet gotten the vaccine should also be vaccinated.

Hepatitis B vaccine is also recommended for certain **unvaccinated adults:**

- People whose sex partners have hepatitis B
- Sexually active persons who are not in a long-term monogamous relationship
- Persons seeking evaluation or treatment for a sexually transmitted disease
- Men who have sexual contact with other men
- People who share needles, syringes, or other drug-injection equipment
- People who have household contact with someone infected with the hepatitis B virus
- Health care and public safety workers at risk for exposure to blood or body fluids
- Residents and staff of facilities for developmentally disabled persons
- Persons in correctional facilities
- Victims of sexual assault or abuse
- Travelers to regions with increased rates of hepatitis B
- People with chronic liver disease, kidney disease, HIV infection, infection with hepatitis C, or diabetes
- Anyone who wants to be protected from hepatitis B

Hepatitis B vaccine may be given at the same time as other vaccines.

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

3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of hepatitis B vaccine**, or has any **severe, life-threatening allergies**.

In some cases, your health care provider may decide to postpone hepatitis B vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting hepatitis B vaccine.

Your health care provider can give you more information.

4 Risks of a vaccine reaction

- Soreness where the shot is given or fever can happen after hepatitis B vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do 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. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider.
- 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 **www.cdc.gov/vaccines**

2020 Recommended Immunizations for Children from Birth Through 6 Years Old

Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
HepB	HepB			HepB						
		RV	RV	RV						
		DTaP	DTaP	DTaP		DTaP				DTaP
		Hib	Hib	Hib	Hib					
		PCV13	PCV13	PCV13	PCV13					
		IPV	IPV	IPV						IPV
				Influenza (Yearly)*						
					MMR					MMR
					Varicella					Varicella
					HepA§					

Is your family growing? To protect your new baby against whooping cough, get a Tdap vaccine. The recommended time is the 27th through 36th week of pregnancy. Talk to your doctor for more details.

Shaded boxes indicate the vaccine can be given during shown age range.

NOTE:
If your child misses a shot, you don't need to start over. Just go back to your child's doctor for the next shot. Talk with your child's doctor if you have questions about vaccines.

FOOTNOTES:

* Two doses given at least four weeks apart are recommended for children age 6 months through 8 years of age who are getting an influenza (flu) vaccine for the first time and for some other children in this age group.

§ Two doses of HepA vaccine are needed for lasting protection. The first dose of HepA vaccine should be given between 12 months and 23 months of age. The second dose should be given 6 months after the first dose. All children and adolescents over 24 months of age who have not been vaccinated should also receive 2 doses of HepA vaccine.

If your child has any medical conditions that put him at risk for infection or is traveling outside the United States, talk to your child's doctor about additional vaccines that he or she may need.

See back page for more information on vaccine-preventable diseases and the vaccines that prevent them.

For more information, call toll-free
1-800-CDC-INFO (1-800-232-4636)
or visit
www.cdc.gov/vaccines/parents

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

AAFP
AMERICAN ACADEMY OF FAMILY PHYSICIANS

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Vaccine-Preventable Diseases and the Vaccines that Prevent Them

Disease	Vaccine	Disease spread by	Disease symptoms	Disease complications
Chickenpox	Varicella vaccine protects against chickenpox.	Air, direct contact	Rash, tiredness, headache, fever	Infected blisters, bleeding disorders, encephalitis (brain swelling), pneumonia (infection in the lungs)
Diphtheria	DTaP* vaccine protects against diphtheria.	Air, direct contact	Sore throat, mild fever, weakness, swollen glands in neck	Swelling of the heart muscle, heart failure, coma, paralysis, death
Hib	Hib vaccine protects against *Haemophilus influenzae* type b.	Air, direct contact	May be no symptoms unless bacteria enter the blood	Meningitis (infection of the covering around the brain and spinal cord), intellectual disability, epiglottitis (life-threatening infection that can block the windpipe and lead to serious breathing problems), pneumonia (infection in the lungs), death
Hepatitis A	HepA vaccine protects against hepatitis A.	Direct contact, contaminated food or water	May be no symptoms, fever, stomach pain, loss of appetite, fatigue, vomiting, jaundice (yellowing of skin and eyes), dark urine	Liver failure, arthralgia (joint pain), kidney, pancreatic and blood disorders
Hepatitis B	HepB vaccine protects against hepatitis B.	Contact with blood or body fluids	May be no symptoms, fever, headache, weakness, vomiting, jaundice (yellowing of skin and eyes), joint pain	Chronic liver infection, liver failure, liver cancer
Influenza (Flu)	Flu vaccine protects against influenza.	Air, direct contact	Fever, muscle pain, sore throat, cough, extreme fatigue	Pneumonia (infection in the lungs)
Measles	MMR** vaccine protects against measles.	Air, direct contact	Rash, fever, cough, runny nose, pink eye	Encephalitis (brain swelling), pneumonia (infection in the lungs), death
Mumps	MMR**vaccine protects against mumps.	Air, direct contact	Swollen salivary glands (under the jaw), fever, headache, tiredness, muscle pain	Meningitis (infection of the covering around the brain and spinal cord) , encephalitis (brain swelling), inflammation of testicles or ovaries, deafness
Pertussis	DTaP* vaccine protects against pertussis (whooping cough).	Air, direct contact	Severe cough, runny nose, apnea (a pause in breathing in infants)	Pneumonia (infection in the lungs), death
Polio	IPV vaccine protects against polio.	Air, direct contact, through the mouth	May be no symptoms, sore throat, fever, nausea, headache	Paralysis, death
Pneumococcal	PCV13 vaccine protects against pneumococcus.	Air, direct contact	May be no symptoms, pneumonia (infection in the lungs)	Bacteremia (blood infection), meningitis (infection of the covering around the brain and spinal cord), death
Rotavirus	RV vaccine protects against rotavirus.	Through the mouth	Diarrhea, fever, vomiting	Severe diarrhea, dehydration
Rubella	MMR** vaccine protects against rubella.	Air, direct contact	Sometimes rash, fever, swollen lymph nodes	Very serious in pregnant women—can lead to miscarriage, stillbirth, premature delivery, birth defects
Tetanus	DTaP* vaccine protects against tetanus.	Exposure through cuts in skin	Stiffness in neck and abdominal muscles, difficulty swallowing, muscle spasms, fever	Broken bones, breathing difficulty, death

* DTaP combines protection against diphtheria, tetanus, and pertussis.
** MMR combines protection against measles, mumps, and rubella.

Last updated January 2020 • CS314226-B

HB 1468:

Medical practitioners should be required to provide all disclosures of inoculation risks. Individuals should be educated on be fully educated on benefits and ALL risks to make an educated decision whether inoculation is the right choice for you and your family. Medical providers should also MUST fully disclose EXEMPTION options before administering. If all the mentioned information is not provided to individuals this is coercion, indoctrination and takes away personal liberties and freedoms. It is not government's job to make health decisions for citizens, this is a decision between citizens and their medical provider!

My name is Linda Mittlestadt. I am a resident of Mandan, ND.
I am submitting written testimony in SUPPORT of HB 1468.

It has already been proven that vaccines come with risks. Risks of permanent damage to an individual's health and can also cause death. Therefore, I believe that a person should be able to make an informed decision and that that decision should be given due respect.
Due to the risks involved, I believe that anyone with the authority to administer a vaccine should be required to provide ALL of the information to the recipient/parent/guardian before administering the vaccine and that the possibility of exemption be made known and available. In order to enforce, there needs to be penalty.
Typically a doctor or nurse will tell you the vaccine is safe and effective and that there will only be mild symptoms, such as redness or soreness at the injection site and possibly a slight fever or tiredness, and that these symptoms are "normal". The worst scenario, which many parents have been subjected to, are children's wellness visits where you are not given any information and the nurse simply walks in to the exam room with the shots ready to give the infant or child and at that time if the parent/guardian asks for information or declines the vaccine they are met with both hostile and belittling verbal responses. Then they are typically given a form to sign, which makes them feel like "the worst human being" (this is the words of my own daughter after one of these visits) and there is no mention of exemption forms. Some parents at this point are told that they are no longer welcome to bring their children to that doctor's office. This just leaves people in difficult circumstances.

There are proven risks with vaccines and where there are risks, information and choices need to be available.

I support HB 1468 to include more transparency in vaccines—details about long-term trials with placebo and actual vaccine tested on humans along with all possible side effects.

Dear Chair and Committee members

Please support a do pass on HB 1468

Thank you,

Bea Streifel

Medical practitioners must give full disclosure of inoculation risks!

Amy Thom

6480 Flickertail Drive

Bismarck, ND 58503

1/24/21

Representatives Skroch, Bellew, Fisher, Jones, Paulson, Rohr

HOUSE BILL NO. 1468

To Whom it May Concern,
I am providing written testimony in favor of this presented bill. As a parent that has a child who has experienced adverse reactions related to vaccines I wish I could have done things differently. Our child ended up in the hospital multiple times after her vaccines, and I wish I would have had the education at this time and known the risks involved. Instead I was told they were safe, and we had to do them. As a first time parent we simply listened. After our first child's experience, I started digging independently and read through the inserts online as these were not offered to me. Based on these adverse reactions our child experienced we have worked with our medical provider and chose a different course. Please provide the parents with unbiased education, let them trust their God given ability to decide, and not feel coerced.
Thank you for your time.

Sincerely,
Amy Thom

January 24, 2020

This is my written testimony for HB 1468. There needs to be additional information provided in an informed consent that has lacking information, including manufacture inserts, school exemption forms and pregnancy/biologics while in labor. Please vote yes on HB1468.

Thank You,
Rosemary Ames

I am writing in support of House Bill 1468. Medical practitioners must fully disclose of inoculation/vaccination risks including giving patients/parents package inserts and to fully disclose all exemption options before administering any vaccine. I have never once been given any information other than the one page “vaccines are safe” page from a pediatrician when I took my children to their doctor. Never once told their are package inserts that pages long of fine print information about the adverse reactions that can happen. Vaccines need to be discussed and never forced. Parents/families nor individuals should ever be coerced into getting something they have not been given full information on. In addition, as a chiropractor I rarely hear that parents get info before their child gets their first vaccination on day 1 of life nor at visits after that. This is not ok. We deserve info well before a procedure happens. Vote YES on HB 1468.

VACCINATE YOUR FAMILY
The Next Generation of Every Child By Two

Vaccine Information Statements (VISs) Provide Informed Consent on Vaccines

For meaningful informed consent about vaccinations, you need materials that:

- Are accurate
- Cover necessary information in a way that is understandable to most people
- Link to more detailed information for those who want it

Vaccine Information Statements (VIS) provide informed consent about the risks and benefits of vaccinations. Materials that are too technical, lengthy, unclear or provide confusing information can undermine informed consent.

What is a VIS?

- VISs are important sources of vaccine information for the public. They are written in easy-to-understand language to help vaccine-recipients (or their parents/caregivers) better understand the risks and benefits of vaccines.
- Each VIS includes the benefits and risks of each vaccine, and clearly outlines the process for reporting to the Vaccine Adverse Event Reporting System (VAERS) as well as filing a claim with the National Vaccine Injury Compensation Program (VICP), if necessary.
- Federal law requires that a VIS be provided to patients or parents/caregivers *before* each and every vaccine is administered. It must be given regardless of the age of the vaccine recipient.
- Healthcare providers must also record specific information in the patient's medical record or permanent office log, including the edition date of the VIS, the date the VIS was given, the vaccine administration date, the office address and name and title of the person who administers the vaccine, and the vaccine manufacturer and lot number.

Who writes a VIS?

- Each VIS is written by the Centers for Disease Control and Prevention (CDC), and the content is informed by a group of independent experts and parents, including representatives from Vaccinate Your Family and the National Vaccine Information Center – two organizations with divergent views of vaccinations.
- The wording of each VIS is carefully crafted to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of *The Patient Protection and Affordable Care Act of 2010*.
- Each VIS is reviewed and approved by the Advisory Committee on Childhood Vaccines (ACCV), which includes:
    - Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury.

- Three members who are attorneys, including at least one who represents individuals who may have been vaccine-injured.

Why are VISs given to patients instead of the vaccine package insert?

- Vaccine manufacturers are required by the FDA to report all events during a clinical trial. For example, if a child is involved in a car accident during the clinical trial and reports to the hospital with a broken arm, the manufacturer must report a broken arm as an adverse event of the vaccine even though we know they are not related.
- Sometimes, a VIS does not exactly match a manufacturer's product insert. That's because VISs follow the Advisory Committee for Immunization Practices' (ACIP's) recommendations. ACIP carefully considers whether adverse events reported during clinical trials could be causally linked to the vaccination.
- ACIP has the ability to remove non-related injuries for the sake of clarity on a VIS. However, it is important to note that the final section of each VIS - *How can I learn more?* - states that parents and patients can ask their healthcare providers for the package insert.

Where can I find more information about Vaccine Information Statements?

- The CDC has all of the English-language VISs on their website: www.cdc.gov/vaccines/hcp/vis/index.html
- The CDC has a page on Frequently-Asked Questions on VISs: www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html
- VISs have been translated into about 40 languages. These can be found on the Immunization Action Coalition's website: www.immunize.org/vis/

Vaccine Information Statements ensure patients and parents have enough information to make a truly informed decision whether to vaccinate themselves or their children.

Source

National Center for Immunization and Respiratory Diseases. "Vaccine Information Statements (VISs)." *Centers for Disease Control and Prevention.* www.cdc.gov/vaccines/hcp/vis/index.html. Last Accessed: October 3, 2018.

HB 1469 Testimony
Human Services Committee
January 25, 2021 2:00 p.m.

Good afternoon, Chairman Weisz and members of the Human Services Committee. My name is Kylie Hall, and I am writing to state my opposition to this bill. I have a Master's Degree in Public Health and have worked at the North Dakota State University Center for Immunization Research and Education for the past 5 and 1/2 years. I would like to make clear that my comments today are not on behalf of NDSU.

What is HB 1468?

A BILL relating to informed consent and notice of risks associated with vaccines; and to provide a penalty.

Why This Bill Should Not Be Passed

Informed consent is currently part of the vaccination process. Vaccine Information Statements provide informed consent for vaccination. They are readable, updated regularly, and translated for use in 40 languages.

Package inserts are too technical, very lengthy, and may be confusing to the average person.

Multiple medical organizations do not support non-medical exemptions to vaccination.

Vaccination for pregnant women is important and the best way to protect the mother and child.

This bill dictates how healthcare providers practice, and this is an overreach of government into the practice of medicine. If passed, providers **MUST** offer the package insert. Providers **MUST** mention exemptions and offer the exemption form. They **MUST** talk about vaccine safety studies in pregnant women with a witness present. Anyone who deviates from the requirements will be guilty of an infraction.

Informed Consent and Vaccine Information Statements (VIS)

We all want informed consent for vaccines. It is the right thing to do, as parents and patients need reliable immunization information. Informed consent is **currently** part of the vaccination process.

In 1986, the National Childhood Vaccine Injury Act (NCVIA) passed and created the National Vaccine Injury Compensation Program (NVICP) and the Vaccine Adverse Events Reporting System (VAERS). NCVIA mandated the development and distribution of written information on vaccines.

In the 1990s and 2000s, Vaccine Information Statements (VIS) were developed and refined. **VISs provide informed consent on vaccines.** Vaccine information statements:

- Are accurate and updated regularly
- Are produced in multiple languages
- Cover necessary information in a way that is understandable to most people (ex. description of disease the vaccine prevents, risks and benefits of vaccination, common side effects, how to submit a report to VAERS)
- Link to more detailed information for those who want it, and
- Are typically 1-2 pages in length.

Federal law mandates that providers give a patient/guardian a VIS **BEFORE** vaccination. VIS should be handed out for each vaccine received and each time a dose of a vaccine is administered (not just for the first dose). VISs must be given regardless of the age of the vaccine recipient.

VISs are produced by the Centers for Disease Control and Prevention (CDC). They are reviewed by the Advisory Committee on Childhood Vaccines (ACCV), which includes:

- Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury,
- And three members who are attorneys, including at least one who represents individuals who may have been vaccine-injured.

Informed Consent Using Package Inserts vs. VISs

This bill seeks to provide the patient or parent with the risks and benefits of vaccination through the use of the vaccine package insert. To our knowledge, healthcare providers and pharmacists are not required to provide such details routinely about other injections administered in the office.

Package inserts are legal documents regulated by the U.S. Food and Drug Administration and are intended to provide information to prescribing physicians. Package inserts **do not** contain information on the disease the vaccine is meant to protect against or the risks and benefits of vaccination.

Package inserts are very technical, lengthy (the average package insert is ~20 pages long), are not intended for public consumption, and may provide unclear or confusing information that can undermine informed consent. Because of this, they are not more informative for most people than a VIS, and they are far too long to read at an office visit.

- If parents/guardians must be provided "ample time" to review these documents for all vaccines to be administered during an office visit, the immunization process would be extraordinarily and unnecessarily time-consuming for both parent/guardians and medical provider offices and would invariably reduce the limited time available for actual patient care.

Vaccine manufacturers are required by law to report (via the package insert) any adverse event that occurred after the product was administered during clinical trials as well as during post-marketing surveillance, whether causally related to the vaccination or not.

Along the same lines, a VIS does not always exactly match a manufacturer's product insert. This is because VISs follow the Advisory Committee on Immunization Practices' (ACIP's) recommendations. ACIP carefully considers whether adverse events reported during clinical trials could be causally linked to the vaccination.

- For example, package inserts must include all adverse events reported during clinical trials, regardless of whether or not they are related to vaccination. The package insert for the measles, mumps and rubella (MMR) vaccine lists otitis media (ear infection) as an adverse reaction that occurred during clinical trials. This does not mean the vaccine caused an ear infection, only that an ear infection was reported in a vaccine recipient following vaccination. ACIP has determined that ear infection cannot be caused by the MMR vaccine, so it is not listed on the VIS.

In reality, provision of the package insert would likely mislead individuals and result in public misunderstanding regarding post-vaccination adverse events, causing unwarranted and excessive alarm that could result in the refusal of vaccinations.

The most often misunderstood or misrepresented part of the package insert pertains to nonclinical toxicology – this section describes the potential of carcinogenesis (causing cancer), mutagenesis (causing mutation) or impairment of fertility from the drug. This section has little applicability to vaccines, since they have no carcinogenic, mutagenic, or fertility effect, given that the level of the vaccine's ingredients' dosage falls far below the lower threshold of any dose response test of these issues. The package insert may state some innocuous verbiage such as "no known information" meaning that in the 10-15 years of research and study, there is no evidence that the vaccine is carcinogenic or mutagenic.

- This section is frequently misused by those against vaccination, using the argument from ignorance – they think that because the vaccine hasn't been tested for cancer, it could cause cancer. However, there is no biologically plausible mechanism whereby vaccines could convincingly be linked to any cancer. In fact, some vaccines prevent cancer (Hep B, HPV).

Package inserts are not updated regularly. This is problematic, as new and evolving information may not be added. For example, the risk of anaphylaxis following COVID-19 vaccine approval was not listed in the package insert, but when the vaccine is licensed, it would be included on a VIS, as they are updated regularly.

Package inserts existed when the NCVIA was enacted. If Congress had thought they could help patients make educated decisions, it would probably have mandated that providers give package inserts instead of VISs.

In 2020, 689,890 doses of vaccine were administered in North Dakota. The cost of printing vaccine package inserts is estimated to cost over **one million dollars** in the upcoming biennium (2021-2022).

- Printing package inserts would be a financial and logistical burden to North Dakota's healthcare providers and health systems.
- Hundreds of thousands of COVID-19 vaccine doses will be administered in this biennium, which could potentially double the estimated costs of printing.

Exemptions

Under HB 1468, any provider recommending vaccination must also offer information on exemptions and make the exemption form available.

Many medical organizations (AAFP, AAP, ACOG, ACP, AMA, ANA, IDSA, NAPNP, March of Dimes) do not support the use of non-medical exemptions.

The World Health Organization (WHO) suggests that consent procedures based on opt-out approaches are likely to result in higher acceptance of vaccination than using opt-in.

However, it is important to note that healthcare providers are not trying to manipulate parents or patients into consenting for vaccination. Healthcare providers should welcome questions and patient-provider dialogue. However, the overwhelming medical consensus is that vaccinations are safe and effective, which is why vaccinations are recommend for nearly all patients. Vaccines help keep patients healthy and free of disease.

Pregnancy and Vaccination

Immunization during pregnancy has emerged as an important and successful public health intervention, and the American College of Obstetricians and Gynecologists continues to recommend immunization during pregnancy. A pregnant woman should get vaccinated against whopping cough (Tdap vaccine) and

influenza during each pregnancy to protect herself and her baby. Tdap and influenza vaccines are safe for pregnant women and their unborn babies.

The benefits of maternal vaccination have been recognized for years. When vaccinated, the mother's immune system creates antibodies in response to the vaccine, and the mother passes the antibodies to the baby through the placenta or through breast milk. The antibodies protect the infant from disease. This is called passive immunization.

There are some vaccines that we do not give to pregnant women because of the theoretical risk of the live virus passing from mother and infecting the fetus. Live vaccines, which contain a weakened version of the virus, include MMR and varicella vaccines, and are never given to pregnant women. However, there is no evidence of adverse fetal effects from vaccinating pregnant women with inactivated virus, bacterial vaccines, or toxoids, and a growing body of data demonstrate the safety of such use. (Influenza is an inactivated virus, and Tdap is composed of inactivated toxins.)

Pregnant women are systemically excluded from most vaccine clinical trials in the United States. Pregnant women are classified as a "vulnerable" population for all research studies, so investigators must take additional steps to enroll them to ensure minimal risk. Also – there is very limited data on what pregnant women can safety be exposed to. Most of the time, investigators choose to exclude pregnant women, even if they might benefit from the study intervention.

So how do we get information on the safety of vaccines in pregnant women? Vaccines recommended for pregnant women are first licensed and approved for use based on safety and effectiveness data in non-pregnant women. These vaccines are then recommended by public health policy makers for pregnant women based on their perceived benefit and minimal risk for the mother and infant. Then, large safety studies are conducted to assure that vaccines are safe in pregnant women and cause no unintended harm to the fetus.

Numerous studies looking at hundreds of thousands of women and infants continue to support the long-term safety and effectiveness of vaccinating in pregnancy for *both* the mother and infants. Further, vaccines are continuously monitored after they are licensed and recommended to *assure* that vaccines are both *safe* and *effective.* Studies on influenza vaccine safety during pregnancy can be found here. Studies on Tdap vaccine safety during pregnancy can be found here.

Infractions

Any provider who does not offer the package insert, does not offer information on exemptions, make the exemption form available, or provide information on vaccine studies in pregnant women with a witness present, is guilty of an infraction.

I am writing to provide my strong support for HB 1468 and recommend a Do PASS.

I strongly believe that informed consent is very important when making health care decisions for yourself and your children. Informed consent is to be neutral and to provide all the risks and benefits for a person to consider and weigh prior to making a decision.

Recently, I have become more informed about the history of vaccines, ingredients in vaccines, injuries occurring due to vaccines, the pressures medical providers face to support and not question vaccine safety, and the blatant censorship surrounding vaccine hesitancy. I began researching this more in depth after my son had a significant negative reaction following an immunization. When I called my provider back to report the sever reaction and to ask more questions regarding side effects, my provider discounted that the immunization was responsible and felt it was more coincidental. The provider then urged me to make an appointment for the 2nd immunization to complete the series. My health care provider was not forth coming about the extensive history to vaccine injuries from this particular immunization. I felt great pressure to comply with the immunization schedule and there was never any mention of my choice to decline or how to access an exemption form.

Vaccine hesitancy is a normal response when someone is given proper informed consent. It is important to really weight the risks and benefits and have no outside pressure to conform. Isn't it odd that we need to create a bill to ensure that government officials, health care providers, and employers provide information about potential risks and make the public aware of their choice to be exempt? By not openly providing this information it feels more like a hidden agenda to have people conform to pre-set norms.

This bill is allowing true informed consent to occur, and I strongly recommend you DO PASS.

Respectfully submitted,

Jennifer Vesey

Rod & Linda Widicker
232 40th Ave NE
Bowdon, ND 58418

January 24, 2021

TO: District 14 Representatives: Robin Weisz and Jon O. Nelson

REGARDING: HOUSE BILL NO. 1468

We are providing written testimony in favor of HOUSE BILL NO. 1468.

We have a grandchild who has experienced adverse reactions related to vaccines. Our granddaughter was hospitalized multiple times following her vaccinations. The vaccinations were not safe for our granddaughter … and the risks were not clearly presented to her parents (our daughter and her husband).

We are asking that you support HOUSE BILL NO. 1468, so that parents may be provided with unbiased education regarding the benefits and/or risks involved with each and every vaccination. Parents should have the option to request an exemption when a vaccine presents a very real risk to their child. We believe it is extremely important that every parent be allowed to exercise their God-given right to decide what is best for their child's particular health needs.

This is a very real issue that has caused concern and distress for our family. Thank you for listening.

Respectfully,
Rod & Linda Widicker
District 14 Constituents

Dear Committee Member,

Please **support** and enact HB 1468 relating to informed consent and notice of risks associated with vaccines. True and complete informed consent is an essential cornerstone of medicine. I believe that every person, acting as a patient or acting as patient's parent/guardian, should have unrestricted access to information that will affect their healthcare. A Vaccine Information Statement (VIS) does not contain adequate information to fully communicate the perceived benefits and potential risks of receiving a vaccine which would enable a person to make the best decision for their health.

Please uphold North Dakota's citizens' right to medical informed consent and submit HB 1468 with a **DO PASS** recommendation.

Thank you for your consideration.

Austin Dvirnak

1120 Alder Avenue

Dickinson, ND 58601

Lisa Pulkrabek
4795 Co Rd 82
Mandan, ND 58554
Wadenlisa@aol.com
701-663-4294
701-595-4264

Dear Human Services Committee Members,

I am writing to you today regarding HB 1468 Relating to informed consent and notice of risks associated with vaccines; and to provide a penalty. I am in FAVOR of this bill and am asking you to DO PASS this bill.

It is very important that patients, consumers of medical treatments and drugs, must be properly informed about all health risks related to a product before they accept that treatment, drug, medicine, vaccine, biologic, whatever it is. Informed consent is crucial for healthy people.

Again please DO Pass this bill HB 1468. Thank you for your time!
Lisa Pulkrabek

Greetings Senator Weisz and members of the Human Services Committee. My name is Becca Bakke, and I am writing in opposition to HB 1468. I am a native North Dakotan, mother of four, and have been a board-certified pediatrician for more than ten years.

Vaccines are the most important public health advancement in modern times. Our routine childhood immunization schedule protects infants and children against 14 different deadly diseases. Vaccines save lives, money and heartache. Despite what you are likely to hear today, vaccines are not a controversial topic in the medical community. Every doctor I know vaccinates his or her children on schedule.

I want to focus today on section 3 of this bill, which refers to pregnant women. First, informed consent is already a requirement prior to any medical procedure, including vaccines. Pregnant women (and all patients) need and deserve honest and accurate information, and our current laws already require that. One way we assure this happens is by making sure patients receive a Vaccine Information Statement (VIS) prior to the administration of any vaccine. We are required to give this to every patient (or parent, in pediatric patients) every time he or she comes in for a vaccine appointment. The VIS is a 1-2 page document describing the disease the vaccine prevents, common and rare side effects of the vaccine, and how to report adverse vaccine events. The VIS is frequently updated, and it is written in a way that can be easily understood for most lay persons. The VIS assures that all patients receive uniform, accurate, up-to-date information prior to consenting to vaccination, and of course, physicians and nurses are trained to answer any additional questions.

The implication that vaccines have not been studied in pregnancy is patently false. I will include a list of relevant references below. Because pregnant women are considered a vulnerable population, they are not included in clinical trials for new vaccines. However, if vaccines are proven safe in non-pregnant persons, they can be recommended for pregnant women if the science suggests that they would be safe and effective in that population. The vaccines currently recommended for all pregnant women are influenza and Tdap vaccines, and because they have been recommended in pregnancy for years, numerous studies have been done that confirm their safety in both pregnant women and their unborn children.

Talk of vaccines during pregnancy always includes discussion of potential risk, and for good reason, as we have an obligation to protect the most vulnerable among us. But we must also ask ourselves a different question: What is the risk of NOT vaccinating pregnant women? To answer this question, I am going to share a personal story.

When I was pregnant with my first child, I followed all the rules. I avoided sushi. I cut back on caffeine. I got my flu shot. I did not get a Tdap vaccine, because in 2010, it wasn't yet recommended during pregnancy. When my daughter Claire was born, she was a wonderfully bald, blue -eyed baby weighing just under 6 pounds. She was perfect, and we were smitten. I had a mild cough that I had picked up from working in the Emergency Department before she was born, but distracted by new motherhood, I ignored it and focused on my baby. When Claire

was 5 weeks old and just starting to smile, she started to cough. At first it was mild, but within a couple of days it became severe, and I panicked. I realized then that my cough had lasted for over 6 weeks, and while my cough wasn't otherwise very unusual, Claire's was starting to sound an awful lot like pertussis (whooping cough). We took her to the pediatrician, and he called the next day to confirm my worst fear: Claire had pertussis. And I knew she had gotten it from me.

The weeks that followed were the darkest of my life. If you have ever seen a child with pertussis, you know why it is called "whooping" cough. Babies with pertussis have prolonged coughing spells that last until their lungs are completely out of air, then they inhale desperately ("whoop"), and the coughing starts again. Claire coughed until she vomited so many times she lost weight. She coughed until she turned blue. She literally spent hours each day coughing and it lasted for weeks. I was exhausted and terrified. I knew the risks. Pneumonia. Bleeding in the brain. Apnea. Death.

We were lucky. Claire is now a healthy 11-year-old. But I have cared for babies who have died from pertussis, and every year when she blows out her birthday candles, I think about what might have been. Even now, a decade later, the guilt is suffocating.

Tdap vaccination is now recommended during pregnancy for two reasons. First, it prevents mothers from contracting pertussis and infecting their newborns, like I did. But vaccinating the mother also protects the infant from getting pertussis from other adults and children, because the protective antibodies produced by the mom pass through the placenta and offer some immunity to the baby during those first vulnerable months.

Please oppose this bill. Vaccines are an essential component of medical care for which informed consent is already required. Vaccines are safe in pregnancy, and requiring additional communication about their very rare risks is unnecessary at best, and has the potential to scare patients, frustrate doctors, and put a vulnerable population in harm's way. Let's leave medical decision-making where it belongs, in the hands of capable North Dakotans and their trusted doctors. Thank you.

Safety Research on Flu Vaccine and Pregnancy

1. Moro, P., Baumblatt, J., Lewis, P. et al. Surveillance of Adverse Events After Seasonal Influenza Vaccination in Pregnant Women and Their Infants in the Vaccine Adverse Event Reporting System, July 2010–May 2016.external icon *Drug Saf* (2016). doi:10.1007/s40264-016-0482-1
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Note: Presentations given to the Advisory Committee on Immunization Practices are available onlineor by request to acip@cdc.gov.

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HB 1468

I strongly urge you for a “DO PASS” vote on this bill.

I have four children, have supported women in birth, and work every day in health care, so I have seen the obvious need for a bill supporting informed consent regarding vaccinations. I have personally witnessed health providers use guilt and fear mongering to ensure that the patient agreed/did not refuse an injection. I’ve also witnessed injuries be excused because they couldn’t be from the vaccine. Things such as:

“Tell her she will die if she doesn’t take it.”
“Don’t tell her it’s a flu shot, just tell her you have some medicine to give her.”
“You have to be up to date with your vaccinations to go to school.”
“Your son screaming all night was a normal reaction.”
“I don’t know what caused it, but it couldn’t be the vaccine.”
“There’s no risk in getting vaccines. We know they are safe.”

With medications, the health provider and pharmacist are expected to review side effects, allergies, and contraindications. If you question if the medication may be worse than what it treats, you are not accused of being anti-medicine. Medicines are known to cause injuries (the risks are even stated in the commercials) and you are supposed to be informed of those before you start taking the medicine. If it is found that the medicine is dangerous or causing too many injuries, you can stop taking the medicine, the company can be sued for injuries, and the medicine can be forced off of the market. Pharmaceutical companies have been forced to pay billions for injuries and deaths that medicines caused. They have been found guilty for knowing medications were dangerous and not taking them out of circulation. These same pharmaceutical companies make biologics.

With biologics, otherwise called vaccines, the health provider gives the vaccine and then sometimes supplies a brief information sheet saying how “safe and effective” it is. I hear of no one being told of the side effects, allergies, and contraindications. If you have a question if the vaccine may be worse than what it treats, you are accused of being anti-vaccine. Some recipients are aware that vaccines cause injuries and that the Vaccine Injury Compensation Program has awarded over $4 billion dollars in funds due to injury (representing a tiny fraction of those that apply, as most cannot afford to fight or miss the window of submitting a claim because of not receiving informed consent). But most people are told incorrectly that any adverse reaction is “normal” and expected, even a “good sign” that it is working. We know that health providers report less than 1% of adverse events to the Vaccine Adverse Events Reporting System (VAERS) so they are not admitting the adverse events or they are not informed themselves enough to identify them. It is this same passive reporting system charged with determining if the vaccines are dangerous or causing too many injuries. This broken system has led to years of injuries before a vaccine is removed from use. A vaccine, once injected, cannot be “stopped” like a medication, so it is even more vital that informed consent be provided. Pharmaceutical companies are

not held liable for any injuries or deaths resulting from their use. Neither is the health provider who did or did not offer informed consent before it was given.

I understand the common view that “vaccines are safe and effective.” In fact, I’m sure that you will hear pediatrician testimony claiming that as fact. This however is not fact.

Because governmental agencies both sell vaccines and choose which ones to add to the schedule, they are hardly unbiased in their research and recommendations. Health providers are fed this research and told not to question the “science.”

Because they are biologics, they are not required to be studied for years and against inert placebos.

Because there is no liability, no one is to blame or helps to cover medical and lifelong living costs due to injury.

Because they are accepted by most health providers as safe, adverse events are excused and injuries go unreported.

Because they are “required”, people don’t even know that they have a choice and don’t know there are exemptions.

We need to ensure we are leaving the decision to vaccinate or not to vaccinate up to the ones who will be left responsible.

We need to give informed consent so that health decisions can be made, not forced.

We need to allow people to make their own risk vs benefit analysis after being informed, not pressured.

Please pass this bill to show your support for protecting our most basic right, the right for health freedom.

Erin McSparron

January 24, 2021

RE: SUPPORT - (HB 1468 - A BILL for an Act to create and enact a new section to chapter 23-12 of the North Dakota Century Code, relating to informed consent and notice of risks associated with vaccines; and to provide a penalty)

Dear Chairman Weisz and Committee Members: My name is Jennifer Kadrmas and I am a North Dakota resident who resides in district 7.

I am in SUPPORT for HB1468 as informed consent is important to make any decision, especially when dealing with a person's health. Why this bill is important for myself, my family and the state of North Dakota residents are because of the following:

Vaccination is a medical intervention that carries a risk of injury or death, the right to informed consent to any medical intervention that can kill or injure you or your child is a human right.

The definition of doctor means teacher… But into today's world, there is very little of this teaching. Most of the time you have only 15 minutes with the doctor and then you are out the door. Any patient that has questions, most doctors will disregard their concerns or be irritated by taking more time out of the schedule. Doctors might complain that it is an inconvenience to have the inserts available for the patients to review, and most of the information be over their heads. However isn't this what you call true informed consent? Any pharmaceutical product can cause harm, every person is an individual, and should never be a one size fits all thought process. However, with the vaccine program, every child/adult is assumed to be the same. And the soundbits are always "SAFE and EFFECTIVE". But how does one know it is safe for each individual?

There are web pages on the American Academy of Pediatricians that teaches doctors and nurses how to deal with vaccine hesitant parents. This does not provide informed consent but tries to make the parent feel like they have to vaccinate their child. This is not neutral information with the risk/benefit of both the vaccine vs infection.

Vaccine Hesitant Parents (aap.org)

Strategies for Talking to Parents:

Presumptive Vs. Participatory Recommendations - "Researchers found that pediatricians who provided a "presumptive recommendation" – informed parents that shots were due, rather than a "participatory recommendation" – asking what the parent thought about shots, were more likely to see parents accept vaccines."

Opel, et al. The Architecture of Provider-Parent Vaccine Discussions at Health Supervision Visits. 2013. *Pediatrics, 134*, 139, 2013-2037.
http://pediatrics.aappublications.org/content/early/2013/10/30/peds.2013-2037.abstract.

With just this information, I would hope you would agree that it is important that informed consent is important and vote DO PASS on this bill.

Thank you,

Sincerely,

Jennifer Kadrmas
District 7

I'm writing in favor of HB 1468. I support every North Dakotan receiving true informed consent for themselves and children when having a medical procedure, including vaccinations.

I'm writing in favor of HB 1468. I support every North Dakotan receiving full informed consent for themselves and children when receiving a medicine/biologic. I currently receive information on any other medicine, members in my household take by the doctor or pharmacy, including the manufacturer insert.

HB1468

Thank you for taking the time to read my written testimony. My name is Janelle Anderson and I am from rural Alexander, ND in District 39. I am a mother of 4 children, ages 9 months to 16 years old. My husband and I ranch together, as well as own/run multiple other businesses.

I am writing this today in reference to House Bill 1468, which deals with Informed Consent. I want you to know that I **SUPPORT** HB1468.

This bill is important to me because I as a parent and a patient, have the right to be informed FULLY about the risks before consenting to a vaccine or any medical procedure or medicine. HHS explains that the "voluntary consent of the human subject is absolutely essential."[1] Without being informed of all of the risks of vaccination, my basic human rights are being violated.

Knowing that some may argue a VIS is Informed consent, I am submitting to you a link for the current VIS given out by my school district at the instruction of our local public health department vs the actual insert of the Fluarix (influenza) Vaccine. What I hope you will notice is the major difference in information, or should I say lack of information on the VIS compared to the actual insert. VIS[2] (Pages 3 + 4 of link in footnote). Fluarix Insert[3]. There are two pages for the VIS and 30 for the actual insert. I would also like to submit to you, how is there informed consent when papers are handed out from a district health nurse and not a face to face dialogue with a doctor?

Lastly, I would like to briefly share my experiences with vaccinations and informed consent I have had with my children and myself. When attending a well baby checkup or an appointment for vaccines, not once was I given the full risks associated with each vaccine my child was given. In fact, the VIS, which is not full Informed Consent, was given after the vaccines were administered. That is a travesty in itself. Furthermore, I was told that swelling, fevers, crying, discomfort are normal. I disagree, "**Common Does Not Mean Normal**." My youngest had an adverse reaction, but I was never informed what to do about it. My own experience as an adult with vaccines and the lack of informed consent happened in 2016. While at a yearly drs visit, I was told my Tetanus Vaccine was not up to date. I refused several times, saying I did not want it on the visit. Finally, after being told over and over again that I needed the Tetanus Vaccine since I lived on a Ranch, I said okay. After the vaccination on my way out the door, they handed me a paper (the VIS) and I went home. Later I experienced some pain and swelling in my arm, so I looked at the paper to see if they had any instructions on how to alleviate the pain, that is when I discovered they had given me the TDAP, Tetanus - Diphtheria - Acellular Pertussis. I

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[1] https://ori.hhs.gov/chapter-3-The-Protection-of-Human-Subjects-nuremberg-code-directives-human-experimentation

[2] https://core-docs.s3.amazonaws.com/documents/asset/uploaded_file/479430/Vaccine_Administration_Forms.pdf

[3] https://www.fda.gov/media/115744/download

had no idea that when they said Tetanus Vaccine that it was a combination vaccine of those three. I was NOT given Informed Consent.

Our families experiences are unfortunately quite common. I ask you all as a committee, to give HB1468 a **PASS.** This bill is much needed.

Thank you committee members for your ears, your time serving your constituents, and being open to hear why our family fully **SUPPORTS** HB1468.

Sincerely,

Janelle Anderson
Rural Alexander, ND
District 39

Hello, I am the mother of four children. I write to ask you to pass HB 1468. My three oldest have autoimmune disorders that are known side effects of multiple vaccines and were fully vaccinated up to ages 9, 4 and 2. Our youngest has not yet been vaccinated and does not have any health issues at all. I have always been a very healthy person and followed every recommendation of my doctors prior to conceiving, while pregnant and while breastfeeding all of my children. Up until I discovered that vaccines have side effects that my doctors and medical practitioners NEVER informed me of, I followed every piece of medical advice to the letter. Both my husband and I are healthy, our families are healthy. There is no indication of the source of these illnesses and diseases except that they are known side effects of vaccinations. My oldest child has had 6 surgeries as a result of one of his autoimmune disorders. My 2nd child has had 4 surgeries and is so ill that we must homeschool to protect his health. My 3rd child has an extremely limited choice of foods that he can eat because of the pain caused by his autoimmune disorder. Again, each of their autoimmune disorders are listed as possible side effects due to vaccination on the package inserts that I was never once shown. We chose not to vaccinate our 4th child because we were very tired of life-threatening fevers, hallucinations, loss of communication abilities, and seizures from age 6 months to age 9. We were also tired of being told that these things were entirely normal and being ridiculed by clinic and ER staff for our concern for the health of our children.

Continuing in the state of North Dakota without House Bill 1468 sentences every other child and family to unknowingly facing the same possible fate. The hypocritic oath, requires that all doctors follow the mantra, “Do no harm.” In order to allow them to fulfill their oath, all side effects should be discussed prior to any treatment.

1839 East Capitol Ave

Suite B

Bismarck, ND 58501

To whom it may concern…

In regards to HB 1468, I am in support of this bill.

Why should a parent not be able to see all the potential risks of a medical procedure?

I have had several patients report when they have asked for more information the doctor, nurse or both chastised them, told them the information is not available right now, or in regards to the insert they can't find it.

Really?? These are the professionals we are supposed to trust with our health and the health of our children??

If the bias of the profession cannot be self-monitored then this bill is vital in controlling the one sided disclosure of information.

Helping Create Health and Wellness,

Dr. Allen Rudolph

HB1468

Thank you for taking the time to read my written testimony. My name is Paula Slow and I am from Arnegard, ND in District 39.

I am writing this today in reference to House Bill 1468, which deals with Informed Consent. I want you to know that I **SUPPORT** HB1468.

I ask you all as a committee, to give HB1468 a **PASS.**

Sincerely,

Paula Slow
Arnegard, ND
District 39

HB1468

Malinda M Weninger

701-527-8226

I write in complete support of HB1468 today. Contrary to what people say, there currently is discrimination out there against those that chose not to vaccinate.

Had this bill been in place five years ago, I may have done my research on the potential harms of vaccines, specifically the Gardasil – HPV Vaccine. My daughter received this vaccine and had numerous reactions of which she suffered for four years thereafter.

Only now do I realize that her years of suffering from allergies and ear infections were due to the continued vaccination schedule I followed as recommended.

People need to be informed and also allowed the opportunity to realize that there is an exemption available.

It is true when people have testified that doctor's offices and schools will discriminate against you if you are not willing to go along with their vaccine schedule. Take for example, a year ago when St. Mary's High School "thought" there was a measles outbreak and all the children that weren't vaccinated had to remain out of school for a very long period of time. This was DISCRIMINATION. Turned out it was a false alarm and these students were discriminated against. These student's parents had filed exemption from vaccines and thus they were asked to leave school.

I believe that attaching a penalty will help to enforce the actions of this bill.

To the teacher that testified last week at one of the hearings saying that they want to be kept safe and don't want all these unvaccinated kids floating around, I say

"If your vaccine that you took for whatever disease is so good and effective, you WILL BE protected and need not worry about others around you". YOU ARE PROTECTED.

Malinda Weninger
701-527-8226

I STRONGLY support HB1468 which would provide additional information and facts, which are greatly lacking, so parents and individuals are able to make a full informed consent decision before receiving any type of vaccine.This bill is important to me because I have vaccine injured children and grandchildren. All too often the doctors and nurses never give a warning on the side effects of vaccines other than possible fevers, crankiness, and fatigue. Everything is sugar coated make to look like the chances are next to nothing. Then when the injury happens we are told the vaccine could not have caused it even though the vaccine insert says otherwise. ALL vaccine information needs to be discussed LONG before the first vaccination is given. Thanks for listening.

Hi my name is Brady Lund from Watford City, ND and I am testifying in support of HB1468.

As a nurse I do not want to have to take care of children who are dying due to not having been vaccinated. Especially when it could have been prevented. I do not agree.

Hello
My name is Marvin Lepp and I am writing to you today in regards to HB 1468 regarding informed consent with vaccinations. I have dealt with the first hand pressure that is placed on individuals when it comes to vaccines and have dealt with the issues that arise after the fact. My wife was convinced to receive the HPV vaccine in 2010 by her Doctor shortly before our marriage. It was when the vaccine first came out and she was told that it would help prevent all sorts of issues including cervical cancer and was pressured into taking the shots.

I cannot express how much I wish this never would have happened. What the vaccine actually did was make a very healthy young woman near infertile. We spent the better part of 6 years and thousands of dollars trying to conceive our little miracle. She developed Polycystic Ovary Syndrome, has had to endure surgeries for the pain related to it, and last emotional health issues as this “CURE” permanently damaged her body.

This same vaccine is now in our school systems and on the “required list”.

Moving forward after we finally had our little miracle we dealt with a ton of pressure from our pediatrician, “the best in the state” Kathy Anderson. She was the same doctor who led the CHI dr. revolt and the one that has been spearheading all the letters to the Governor regarding masks and vaccines. The amount of pressure being pushed onto parents who only want the best for their children is alarming. The Doctors, their nurses, everyone pushes this issue and it disgusting the tactics that are taken to convince us for the “appropriate” vaccines.

Why do you think the only people opposing informed consent are doctors and members of the State Health Department. You know the same people who helped coordinate statewide lock downs, quarantine measures, and letters of encouragement to the governor.

This bill is amazing because it puts these people on notice. It’s time they are honest with us when they expect us to be honest with them.

There is no liability for vaccine damage. If there was it would not be a multi-billion dollar industry.
Thank you for bring this forward

To whom it may concern;

Good Morning, my name is Megan Martina and I have three beautiful kiddos that I would move mountains for. My oldest child, whom my husband tried for years to get pregnant with, was vaccine injured as an infant. Had her pediatrician been forward and honest with me, and truly given me the informed consent that both my daughter and I deserved, maybe she wouldn't have been injured. She suffers from seizures, a tic disorder, and brain damage that her neurologist has confirmed is the result of vaccine damage. The guilt that I carry everyday is so incredibly heavy. I did not know that vaccines came with the risk of negative side effects and her pediatrician nor the nurses in the office informed me of that. Parents and children deserve better. Parents should be informed of the risks and should be offered the vaccine manufacturers inserts when making the decision on what medications their children will be receiving. I am asking you, as someone whose child suffered as a result of the lack of informed consent, to support this bill.

Thank you,

Megan Martina

I am writing in favor of HB 1468. True informed consent should be given for all medical procedures and medications. People should know the benefits and risks of any procedure and make an informed decision for their medical care based on proper information. I passed out shortly after a flu shot while in the military and was never told that was a possibility. Had I been driving when it happened, it could have had devastating effects. To reiterate, I am in favor of HB 1468.

My name is Sara Williams, I am writing you today as a constituent of District 37 who supports HB1468. I believe where there is risk there must be choice and this bill would protect individuals making medical choices for themselves and ensure that informed consent truly occurs. The currently accepted model of informed consent is not sufficient, and this bill will provide for a more thorough consent process and protects individuals who may not be willing to accept the risk without being penalized. Thank for your consideration.

Hello my name is Kim Huebner, resident of Mandaree, North Dakota. I am testifying in SUPPORT of HB1468. I do not believe doctors administering vaccines are totally forthcoming on the dangers whether it comes from above them or due to them benefiting from the numbers of vaccines administered. If there was no benefit to the provider or health system, I believe they would be provided. If they were provided, most likely more parents would not vaccinate due to the risks/dangers and in turn providers/medical facility not reimbursed. Again I SUPPORT HB1468. Thank you.

Dear Committee Members,

About 4 years ago, I started looking more closely at vaccines that my children were receiving. Not because our family had experienced a vaccine injury or because we had had any adverse reactions, but because my sister-in-law and a few close friends who are medical providers encouraged me to look into them more and educate myself. I did so because I was going to disprove my 'anti-vaxer' friends and family. Little did I know, that I was the one that was going to be proved wrong.

I am a registered nurse and felt I had a pretty good handle on vaccines. In nursing school, we spent a whole semester in Community Health and one of our assignments was a project on vaccines. I thought I was well versed on vaccines, and I was; well versed in what the CDC and pharmaceutical companies wanted me to know. As I dug through more and more of the research into how vaccines are derived, the ingredients used, the medical trials for the FDA, and the legal cases involving vaccine injuries, I was shocked. As a devout Catholic, the fact that some vaccines are created using aborted fetal stem cells was absolutely appalling. As an RN who took an oath to do no harm to her patients and to not administer medicine that causes harm or death was also incredibly alarming as I read about all of the vaccine injuries – I had never once informed my patients about adverse effects outside of allergic reactions and some mild symptoms. Yes, I know that there are side effects and adverse outcomes whenever any medicine or procedure is performed, but it is my job and the job of EVERY medical practitioner to FULLY INFORM the patient of these things, not just what we want to the patient to hear because of our own personal biases or beliefs. That is why I ask that you recommend a 'Do Pass' for HB1468.

I additionally ask that you recommend a 'Do Pass' on HB1468 because of a recent well child visit I had for my six-year-old son at Sanford Clinic with a nurse practitioner. I politely declined the flu vaccine in addition to the recommended schedule of vaccines for a 6-year-old. What ensued was an attack on my intelligence, religion, and authority as a parent to make decisions for my child.

I am not an anti-vaxer and neither is my husband. We believe that vaccines are good and beneficial in certain instances, and my husband and I do vaccinate our children. However, we vigorously research ALL information before deciding when and which vaccines are administered. When I asked the nurse practitioner for vaccine inserts, particular research, etc he would not provide it. The only thing he did was go speak to their staff nurse who they call the "Vaccine Queen" and stated that she told him to tell me that my religious objection was not valid because the Pope said that vaccines are good. Yes, the Pope released a statement about the efficacy of vaccinations, however the nurse practitioner and the "Vaccine Queen" failed to mention that the Pope also stated in the same document that we as Catholics are to reject vaccines derived from aborted fetuses when we can. After more 'discussion' the nurse practitioner finally let my son and I leave.

As a well-educated and well-informed mother, I was able to defend myself and my family. However, I should not have to do this with my medical practitioner. I should be able to trust that my practitioner will be objective and truthful and give me all information, even if the practitioner has a personal biased on the subject matter. I have no problem with my practitioner giving me their opinion, and I actively seek it, because I am a firm believer that I need to do my best to seek all information whether I agree with it or not. I need to be able to make the best decisions for my family and myself and I cannot do that if I am fed half-truths by individuals I should be able to trust.

Thank you for your time. Please recommend a 'Do Pass' for HB1468.

Sincerely,

McKenzie McCoy
Watford City, ND
District 39

HB 1468: YES, SUPPORT

Chairman Weisz and the House Human Services Committee;

My name is Whitney Jeske, a resident of McKenzie County, ND. I am testifying in **SUPPORT** of HB 1468. As a Registered Nurse with the state of North Dakota let me first say that I am not anti-vax. I am pro-vaccine safety. I am pro- informed consent. I am appalled by the standard of informed consent I've personally experienced with my three small children in regards to vaccination. In visits with our former pediatrician, I had asked for the vaccine inserts, only to be given a simple, single paged guide. When correcting the nurse I was told "I'm not sure I can give you that. Let me check." This is not ok! This information should be readily available and disclosed. Parents should not have to demand this. If it weren't for my medical background, I would have blindly accepted the typically given risks of fever and redness/swelling at the injection site. Professionals know better, and they must do better. They must be held accountable. Where there is a risk, there must be a choice. No two children are the same and if an informed decision is to be made, one needs the truth. If a parent does not feel comfortable with the typical guidelines for vaccination, options for exemption should also be made known immediately. Again, I support HB 1468.

Re: HB 1468 Testimony Human Services Committee
January 25, 2021 2:15 p.m.

Good afternoon, Chairman Weisz and members of the Human Services Committee. I am writing to testify to my support for HB 1468. I have a co-worker whose father was just diagnosed with some severe health problems. She explained to me how the doctor sat down with her and her father to go through his treatment and what the side effects could be. She has 3 children and she explained how this is the first time she has had what she would consider to be actual informed consent. Vaccine injuries can and do happen. VAERS has been a system used for families to report vaccine injuries to and has paid out over $4 billion to such families thus far. This in itself shows that vaccine injuries do happen and I find it only appropriate for doctors to be honest with their patients so that parents and or adults can make the best decisions for them or themselves. I do not believe there should be any question about offering informed consent. Please vote yes on HB 1468.

Sincerely,

Melanie K Paape

I STRONGLY support HB1468 which would provide additional information and facts, which are greatly lacking, so parents and individuals are able to make a full informed consent decision before receiving any type of vaccine.

This bill is important to me because I have vaccine injured children and grandchildren. All too often the doctors and nurses never give a warning on the side effects of vaccines other than possible fevers, crankiness, and fatigue. Everything is sugar coated make to look like the chances are next to nothing. Then when the injury happens we are told the vaccine could not have caused it even though the vaccine insert says otherwise. ALL vaccine information needs to be discussed LONG before the first vaccination is given.

Thanks for listening.

To whom it may concern:

I am in opposition to bill 1469 and I believe it would a horrible government overreach to require ND residents to put something in their body they do not want.

My son was vaccine injured when he received his kindergarten shot series. Approximately 4 days after being inoculated his personality changed and he has since been a different person. He is now 24 years old. He was happy, energetic, and had a quick sense of humor. On day 4 he became quiet, withdrawn, and introverted.

I have the right as a free American citizen to determine what goes in my body and the body of my child. Now that I know better I do better. If the committee members have not researched vaccine inserts and vaccine injury, I highly recommend they do before they determine others' fate and future health conditions.

Additionally, if vaccines are safe and effective, why do the vaccine companies need protection against lawsuits for adverse reactions? I think you know why.

https://www.youtube.com/watch?v=3lj5euanY4Y

2972, 2981

I support HB1468 which deals with providing more information to parents when their kids are getting vaccinated. When my child was vaccinate, the risks of them was greatly underplayed. More information and facts need to be given to parents before vaccination for them to make a more educated risk vs reward choice instead of them just telling the parents they are safe. In the case of my child, they were not safe at all.

Thanks for reading.

Testimony to the House Human Services Committee on HB 1468
Testimony by Barbara Frydenlund Rolette County Public Health District Administrator

Good afternoon, Chairman Weisz and members of the House Human Services Committee. My name is Barbara Frydenlund, and I am the Nurse Administrator for Rolette County Public Health District. I am offering this testimony today in opposition of HB 1468.

Federal law requires that healthcare staff provide a Vaccine Information Sheet (VIS) to a patient, parent, or legal representative before each dose of vaccines is consented. Vaccine Information Statements (VISs) are information sheets produced by the CDC that explain both the benefits and risks of a vaccine to the recipients. VIS are available in multiple languages and are regularly updated with the latest information. Informed consent is part of the vaccination process in North Dakota.

The financial burden of additional printing costs and the expanded appointment time placed on health care providers will drive up medical costs and decrease the availability of appointment availability thus taxing an already over extended medical system. If the VIS is not deemed to provide enough information it should be the responsibility of the parent, guardian or individual to research additional literature from the vaccine company prior to the well child immunization visit or to make a separate appointment with their healthcare provider to specifically discuss immunizations. The request within HB 1468 to dictate to every healthcare provider that they must provide a multi-page legal document, known as a “package insert” designed for medical experts, to the parent, guardian or individual seeking a vaccine appears to undermine professional providers. It is the mission of the North Dakota Board of Medical Examiners and the North Dakota Board of Nursing to monitor the practice of those who they license, please allow process to work.

Sincerely,

Barbara Frydenlund, RN
Nurse Administrator
Rolette County Public Health District

HB1468

My name is Selenna Bolanos-Reyes resident of Williston, ND. I am testifying in **Support of** HB 1468. It is known that all pharmaceutical drugs/vaccines carry some sort of risk and/or side effect. It is up to the patient to make and informed decision on whether to accept that drug/ vaccine, however, it should also be the job of the individual administering the vaccine to provide all information- benefits and dangers- to the patient before administering it. Most doctors will tell you that the vaccine is safe and effective without stating the risk associated with the vaccine and not just state the normal reactions such an injection site soreness, fever , etc. I have never been informed rather only give a sheet of paper stating what vaccine being administered and prescription. There are/can be enormous risk associated with vaccines and its a major role in the person administering said vaccine to inform the patient of such risk and there should absolutely be a penalty it a patient isn't provided this information before administering a vaccine. I support this Bill.

In my work, I regularly analyze risk, due to this I am aware of the fine line that businesses and employers must walk. In order to mitigate future risk to both local medical professionals and the government entities that support them, it is in the best interest of the State of North Dakota to pass House Bill 1468. All persons receiving any medical treatment must be made aware of all of the potential dangers. Further as a tax payer, I do not wish for the state of North Dakota to be held liable for the damages incurred for even one citizen that should have been informed of the risks and was not.

HB 1469

Dear Representatives of House Bill 1469,

I am writing in direct opposition to 23-07-17.1.3.b as well as 23-07-17.1.8

I am in full support of the 1468 bill proposed, as well as the 1377 bill.

As a practicing clinician in a chiropractic and health center where our focus is on health restoration, we are often the last resort for very sick children. I am trained in removing triggers that lead to malfunction of the human body (as opposed to using drugs and surgery to control function) and to help to restore homeostasis.

Upon consulting, we ask about vaccination history, and if relevant, inquire as to whether they have concerns about safety. Most have significant concerns however report they have been scared, intimidated, and were never told about their options to opt out or what risks are.

I get about 1-5 contacts per month asking if we write exemptions because they cannot find a doctor willing to write them for their children or for their work. We don't write them. Parents are afraid because of how they are treated. They are intimidated, told that there are no risks, and when they express concerns about prior inoculations causing harm, they are very often flippantly dismissed.

Unfortunately, in giving my patients the time they deserve, I have not had the opportunity to thoroughly express why I am directly opposed to forcing biased information onto patients.

The NDDOH has been shown to minimize publicity of adverse events. Frankly, I do not trust them to put out unbiased information free from Industry (drug company) influence.

I had previously submitted a research study comparing fully inoculated individuals, partially inoculated, and those that had not had inoculations, and their likelihood of being diagnosed with various health problems. There ARE physiological mechanisms that cause these problems. However parents are grossly undereducated on the risks. They are taught to never question.

In regards to 1377, I am in full support, as exemption should be available whenever the producers of said product are considered free from any liability for damages. Drug companies, hospitals, and prescribing/administrating doctors are all exempt from liability if and when damage occurs. For that reason alone, no one should be forced/coerced for not wanting it or penalized for denying being injected with said product. **I don't know of any other product in the world that is free from manufacturer liability and at the same time, people are coerced into using it or penalized for not using it. The same companies that are free from liability are often convicted felons, some even hiding research causing damage from medications (avandia) from the public eye to continue to profit.**

For this reason, I believe 1377 would PROTECT people from impending mandates by companies influenced by drug industry lobbyists and pressure.

Thank you for your time and I apologize that this is not better formulated. If you have questions or would like further explanation, you may call me or email.

Dr. Steve Nagel

180 Health Solutions

Vote Yes to HB 1468

Dear Legislators,

Good Afternoon. Thank you for taking the time to hear and consider my thoughts as you make your decision about the proposed bill. Please vote yes to HB 1468 because it only makes sense to practice informed consent and because it is the law. This bill will ensure that our citizens will be protected by being given the full disclosure that they seek and that they deserve to have before choosing to be vaccinated. This is simple. No nonsense. The least we can do. Can we offer our citizens any less as a Great State?

On the flip side, by not providing the potential risks and side effects as well as the options for exemptions, we will be doing our citizens a great disservice. Please vote yes to HB 1468 because it will protect us from lawsuits and tragic outcomes and liabilities. Saying yes to this bill makes sense because research shows that there will most certainly be adverse effects for some in some cases. Each patient's medical history must be considered and each individual must have the right to be fully informed as they make their choice. Each individual can say no. Each individual can say yes. This freedom is what makes us a Democratic Republic. This is what our forefathers spilled their blood and died for. Liberty and justice for all! Thank you again for your consideration.

Thankful for freedom and liberty regarding health today,

Alida Arnegard

Health Freedom ND

Please note I tried submitting this through the website but it wouldn't let me.

Thank you for taking the time to read my letter. I am Kim Sheldon from Washburn, ND.

I am in favor of Bill 1468. I believe it is very important for everyone to have access to vaccine inserts before being vaccinated. The consent forms or material normally handed out is not complete in revealing all information regarding the vaccine.

For instance , in the vaccines you will see statements such as "has not been evaluated for carcinogenic or mutagenic potential". Also missing many times is a complete list of ingredients within the vaccine, which may include formaldehyde, polysorbate 80, aluminum, etc.

Everyone should have access and the right to know what they or their children are having injected into them and the possible outcomes. Again , the materials usually used are insufficient as compared to the vaccine inserts.

Thank you for hearing my concern.

NDLA, H HMS - Krause, Tamara

From: Melanie Joerger <mrs.joerger@gmail.com>
Sent: Monday, January 25, 2021 11:29 AM
To: NDLA, H HMS - Krause, Tamara
Subject: Testimony for HB1468

Hello,

I experienced technical difficulty submitting this bill via the legislative website and am submitting it here.

I urge you to pass HB1468. Having multiple children that have been vaccinated, I believe that it is important for parents to get all of the information available to them to make wise decisions about their own health and their children's health. Due to current events, I have done research into the approval of vaccines by the FDA and the process that ensures the safety of the recipients of the vaccines. The FDA is not monitored by Congress as thoroughly as it was prior to the 1992 Prescription Drug User Fee Act. This act has allowed pharmaceutical companies unprecedented influence over the FDA's approval of medicinal drugs as well as vaccines.

"Critics of the 1992 Prescription Drug User Fee Act argue that industry funding of the drug review and approval process gives pharmaceutical companies, and their lobbying arm, PhRMA, too much influence" The Fda - How Independent Is The Fda? | Dangerous Prescription | FRONTLINE | PBS

At the very least, parents and other individuals should have complete information from the vaccine inserts to help them determine if a vaccine is something that will provide benefits that outweigh the risks. Also, information about laws concerning vaccine exemptions should be presented to every person and parent that is considering a vaccine for their child.

Please suggest a "Do Pass" for this bill.

Thank you,

Melanie Joerger
15105 15th St NE
Mayville, ND 58257

HB1468:

In Support of

Yes! It took me months to recover from the flu shot that I was forced to get in order to, "keep my job"

Never, never again!

My name is Hilary Lund and I am testifying in support of HB1468. All vaccines come with an associated risk or side effect. The patient should be informed of all risks before they decide whether or not they want to take it. Most doctors will only tell you the most common reactions such as injection site soreness, headache, fever, etc. For some, those reactions can be life altering or even deadly. Those reactions shouldn't be overlooked or swept under the rug. It should be up to the healthcare provider to supply patients with ALL information regarding vaccines before they're administered

House Bill 1468 - In Opposition
Human Services Committee
67th Legislative Assembly in North Dakota
January 25, 2021

Good Afternoon Chairman Weisz, Vice Chair Rohr, and Human Services Committee Members,

My name is Kathy Anderson. I am President of the North Dakota American Academy of Pediatrics. I have been a general pediatrician in Bismarck for over 10 years, having served as chair of pediatrics at both CHI and Mid Dakota Clinic during that time. I am speaking in opposition to House Bill 1468.

I am a board certified general pediatrician and a board certified integrative medicine physician. My wholistic training provides me with a perspective that may be helpful in this discussion. I have spent additional time learning about nutrition, Ayurvedic Medicine, Traditional Chinese Medicine, osteopathic and chiropractic medicine. And, like most Americans, I do believe that there is a place for considering what is "outside the box" and how this can help augment care, quality of life, and outcomes. I think that the polarized environment within which much vaccine discussion occurs is narrow, uninformed, and not helpful to the individuals in our community that we are all trying to care for. I do not understand why we cannot both optimize our immune systems through ensuring all families access to sufficient high quality foods, toxin free water and air, while also providing vaccines to prevent infectious diseases that cause disability and death to children.

During a 15-30 minute appointment with a patient, providers are discussing parent and child concerns, discussing immunizations, assessing growth and development, assessing child and caregiver mental health, food insecurity, family stressors, counseling on preventing disease and injury, supporting healthy relationships, optimizing development and learning, and examining the child. Based on the discussion, assessment and exam, we are then developing a plan that prioritizes the needs of that patient and family, which may include close follow up for growth, referral for developmental concerns, or referral for physical exam findings, connection with resources or community support for food insecurity. Today's parents have a wealth of information from a variety of sources at their fingertips and come in with questions about various topics including vaccines. We take time providing information and answering questions. A bill like this will have may take away from valuable time needed to address other family stressors like mental health concerns or food insecurity.

Just like in any ecosystem, in our state, there is a delicate balance that exists which allows us to live the way that we are accustomed to. Especially in a year like this one, we can appreciate how much of a ripple effect occurs when one thing goes out of balance. Like COVID-19, many of the diseases for which we immunize children (and adults) are infectious and can easily spread around communities like ours, overwhelming our medical system and devastating our families.

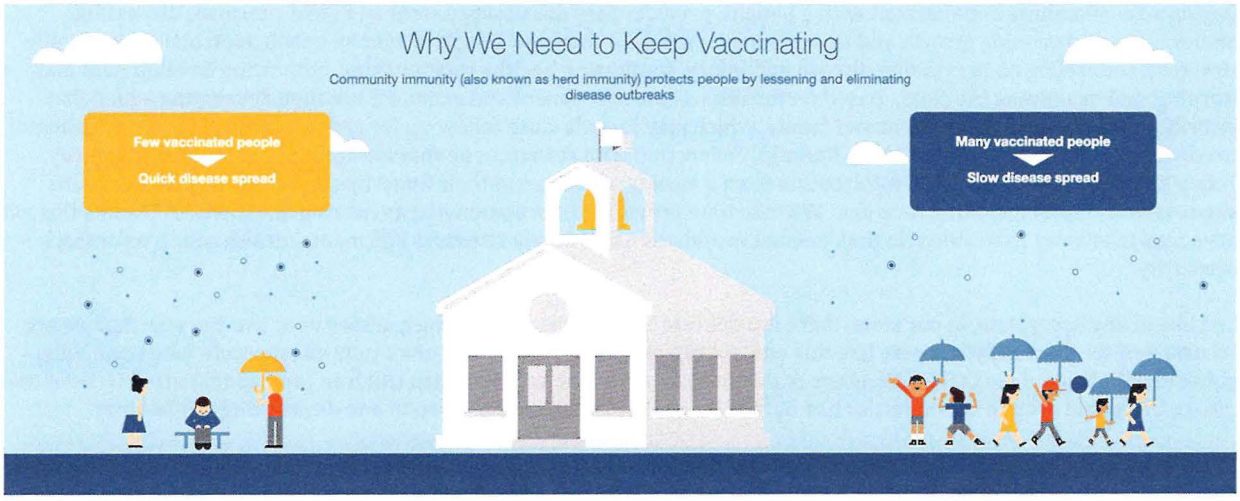
If you refer to the handout on vaccine preventable diseases and North Dakota, these were made to illustrate state vaccine rates by disease, and % immunization required to prevent infection spread within the community. Different diseases have different thresholds required to prevent disease spread (based on how infectious the actual organism is and its mode of transmission). As you can see, we are above threshold for many diseases except pertussis, meaning we have about enough immunity within the community to prevent spread of disease amongst our population that is un-immunized, whether by personal choice, or because they are not yet eligible due to young age. IF we do not maintain immunity rates within the community, and we spread these infectious diseases, we will experience very similar quarantines and lock downs like we have had to implement for COVID-19.

As a first generation American with parents from developing countries, I can tell you that there are not groups like this discussing reducing vaccine rates, there are people lined up outside the hospitals and clinics and around the block ensuring that they get their children vaccinated because they have a neighbor, or cousin, or coworker, who has lost a child to diseases that vaccines prevent. We are lucky to be able to have philosophical discussions like these on the efficacy of vaccines when strong evidence already exists, and to craft roadblocks to vaccine delivery, because our privilege of having higher than threshold immunization rates, allows us to. But this will not be the case if we continue to support this discussion, discourage families from protecting their children from devastating diseases, and ultimately drive down our community rates of immunity, we will see a rise in disease, disability, and death in both the population that desires vaccine before children are eligible, and in the population that does not vaccinate. This could send us back to infant/child mortality rates in the 0-4 population closer to where we were in the 1950s, or where some developing countries sit now, almost 10 times higher than our current national infant/child mortality rates.

Bills like these were introduced in over 16 states in 2019 and none were passed or went very far in legislative committees. These bills are crafted to place an unrealistic emphasis on the negative effects of vaccines. And in many of the states, these bills are being pushed forward by a group of people that have never had the responsibility of caring for a child who has been devastated by one of these diseases. By groups who have never had to give chest compressions to a 12 lbs baby in the ER because they stopped breathing at home, and subsequently learned they tested positive for pertussis. Or had to meet with a family on a daily basis whose 4 month old was in the ICU recovering from HIB meningitis, and discuss the small improvements in ventilator settings and chest x rays, when imaging studies of the brain show how much of a toll the disease took before it was controlled, and there remained great uncertainty as to what recovery and capacity would look like for this child.

For the reasons previously stated, with the strong body of evidence supporting current practice, and for the families and communities across the state, I ask that you vote in opposition of moving this bill forward.

Kathy Anderson, MD, FAAP, IBCLC, CEIM
President, North Dakota American Academy of Pediatrics, NDAAP
District VI Champion, Diversity, Inclusion, Equity, AAP
Board Certified General Pediatrics and Integrative Medicine



The State of North Dakota's Child Vaccination Rates

How North Dakota Compares with National Rates

North Dakota USA

DTaP vaccine (≥4 doses) in children 19-35 months old

86.1%

83.2%

MMR vaccine (≥1 dose) in children 19-35 months old

95.7%

91.5%

Varicella vaccine (≥1 dose) in children 19-35 months old

95%

91%

HPV vaccine (≥1 dose) in adolescents 13-17 years old

74.7% North Dakota females

70.4% North Dakota males

68.6% USA females

62.6% USA males

Influenza vaccine, cumulative flu-season coverage in children 6 months-17 years old

62.4%

57.9%

Combined 7-vaccine series in children 19-35 months old

Includes ≥4 DTaP doses, ≥3 Polio doses, ≥1 MMR dose, Hib full series, ≥3 HepB doses, ≥1 Varicella dose, and ≥4 PCV doses

78.8%

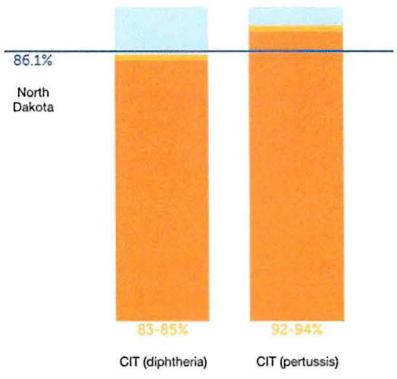
70.4%

Healthy People 2020 Target Goal: 80%

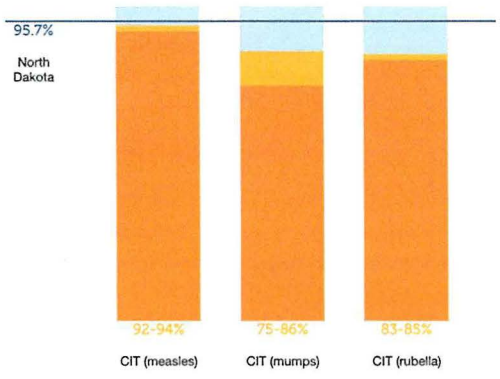
How North Dakota Compares with Community Immunity Thresholds (CIT)

Thresholds indicate the amount of vaccinated people needed to maintain community immunity—not all diseases have defined thresholds

DTaP vaccine (≥4 doses) in children 19-35 months old



MMR vaccine (≥1 dose) in children 19-35 months old



Exemptions from Vaccines Can Deter Meeting Community Immunity Thresholds

YES Religious exemptions allowed?

YES Philosophical exemptions allowed?

Testimony in Opposition
HB 1468
Human Services Committee
January 25, 2021

Good afternoon Chair Weisz, Vice Chair Rohr, and members of the Committee,

My name is Dr Ana Tobiasz, MD and I am a Maternal Fetal Medicine physician at Sanford Health in Bismarck. Thank you for the opportunity to testify in opposition to HB 1468. I am asking the committee to give this bill a Do Not Pass recommendation.

My medical training and expertise is in caring for women during high risk pregnancies. I was born and raised in Munich, ND and completed my undergraduate and medical school training at the University of North Dakota. After medical school I completed a 4 year residency training in Obstetrics and Gynecology in Grand Rapids, MI, followed by a 3 year fellowship training in Maternal Fetal Medicine at the University of Tennessee. I have worked as a maternal fetal medicine specialist at Sanford Bismarck since July 2017. I am the first and only MFM in Bismarck and one of only three within the entire state. I care for women who have underlying health conditions, as well as diagnose and manage fetal health conditions, and have a unique understanding of the interaction between the mother, placenta, and unborn fetus.

I strongly oppose this bill because the decision model for administering vaccines in pregnancy is not any different than any other medication I discuss with my patients, many of which have significant effects on their unborn child. We have never required a pregnant patient to sign a consent form or have a witness present for the discussion about medication use in pregnancy. This bill would harm the physician/patient relationship and will cause an unnecessary burden on the healthcare system with additional unnecessary documentation. We already have a method of documenting our counseling and discussion with patients in the electronic medical record.

Treating health conditions during pregnancy is challenging and unique due to the relationship between the mother and fetus. Many pregnant women have health conditions that are more harmful to both the mother and fetus if left untreated than if treated with a medication that may have adverse effects on one or both of them. Decisions regarding medication use in pregnancy are always made on a risk/benefit scale. I spend a great deal of time discussing this with my patients, and then documenting this discussion and the patient's decision in the medical record. Unfortunately due to the ethical limitations of studying medications during pregnancy, pregnant women are routinely excluded from research trials with new medications. This includes new vaccines. The average pregnant woman takes 2-3 prescription medications over the course of their pregnancy—none of which were likely studied during a randomized trial on the specific effects in pregnancy. We do generally have the benefit of animal studies on pregnant animals and extrapolate this data to human pregnancies. Information about the effects of the medications during pregnancy are obtained retrospectively after women are either incidentally or intentionally exposed to the medication during pregnancy. Many new medications and vaccines have drug registries where we have our patients register and the individual patient and their exposed fetus/child are then followed over time to see what the effects were after the exposure. At this time, we have years of data and retrospective studies on commonly administered vaccines in pregnancy.

There are two vaccines that are routinely given and recommended to be given during each and every pregnancy. This includes the influenza vaccine and the Tdap vaccine (tetanus, diphtheria, and pertussis vaccine). I have a very high uptake (85-90%) of these vaccines in my practice, with almost no women declining after discussing the risks and benefits of vaccination. I have had no serious adverse reactions as a result of vaccination for my patients. The time frame of vaccination is generally not at the time of admission for delivery, therefore women are not generally being offered vaccines under duress. I have had extensive training in counseling patients on medical treatments and procedures during labor—vaccinations are no different.

We give the influenza vaccine to protect the mother, as pregnant women are at a significantly higher risk of complications if they become ill with influenza as compared to a non-pregnant individual. I have cared for many pregnant women who were ill from influenza. I vividly remember one of my patients in my last year of fellowship training—one who nearly lost her life and the life of her unborn child. She had made the decision to not receive the influenza vaccine as was recommended, and ended up in the intensive care unit and required specialized medical treatments such as prone positioning, ventilator support and had to receive ECMO. ECMO is a medical treatment that is used to bypass the lungs for oxygenation and return the blood back to the body. This would have been avoidable with administration of the influenza vaccine.

The Tdap vaccine is given during each pregnancy to protect the infant after birth. When the vaccine is given during the third trimester, the antibodies produced by the mother will pass through the placenta and gives the infant protection in the first months of life, during which time they cannot receive the Tdap vaccine. This was all determined by retrospective studies.

There are many other vaccines that are acceptable to be given during pregnancy. In fact, the only vaccines which are not recommended in pregnancy are those that are considered live virus vaccines. This is due to the fact that if a person receives a live vaccine, they have a chance of becoming ill from the virus. The viral illnesses which are prevented with live vaccines, such as varicella, are unfortunately teratogenic to the fetus, therefore we do not give these vaccines during pregnancy.

The covid-19 vaccine is a new topic that I am discussing daily with my patients. This is not a live virus vaccine. The technology used for the currently available covid-19 vaccines is new, however based on the mechanism of these vaccines, there is unlikely to be harm to the fetus. The mother cannot become ill from receiving the covid-19 vaccine as it is not a live virus vaccine. The majority of the side effects that commonly occur would not be detrimental to the growing fetus and are short-lived. Despite our limitations of studying medications and vaccines directly in pregnancy during randomized trials, we do have evidence that pregnant women who become ill from covid-19 are at a substantially higher risk of severe complications. When weighing the risks of covid-19 infection versus the vaccine, the benefits of vaccine administration are clearly favored. These are the types of discussions and decisions I make on a daily basis with my patients.

In summary, I strongly oppose this bill, which proposes to add additional unnecessary intrusions into the patient/physician relationship and adds unnecessary and burdensome documentation to our healthcare system.

I strongly urge a Do Not Pass recommendation on HB 1468.

Dr Ana Tobiasz, MD
Maternal Fetal Medicine Physician
Sanford Health Bismarck
Phone: 218-779-8497

My testimony for HB 1468:

I am writing in support of HB1468. Everyone should be given true informed consent when it comes to the risks, ingredients, and also benefits of vaccinations. A personal experience I have had being pregnant is getting shamed at two prenatal appointments for refusing the Influenza Vaccine. The nurse was rude, gave me no information on the potential risks associated with the vaccine during pregnancy, and finally asked why I was declining it. Luckily, I had done my own research on this vaccination and had read the actual vaccine insert all the way through. I answered her straight from what the insert said, that there are no studies proving the safety or efficiency in pregnancy. She didn't say another word and never bothered me again. However, it is very disheartening that many pregnant woman are not getting the full informed consent on the vaccines they are recommending. And this is also true for the entire CDC recommended schedule for children. Every person and parent deserves to know exactly what they are choosing to shoot into their bodies intramuscularly, what the potential side effects are, how the ingredients may trigger an individual's allergies, and the efficiency of the vaccination. Thank you for your consideration.

Thank you,
Kylee Ybarra

Chairman Weisz and the House Human Services Committee

RE: HB 1468

YES, SUPPORT

My name is James Jeske, a resident of McKenzie County, ND and a practicing Optometrist. I am testifying in SUPPORT of HB 1468. It is of my opinion that there is no logical reason not to provide informed consent when considering whether or not to vaccinate. Providing as much information as possible including options for exemptions is a must so that an individual can form an educated decision that they see best for them or their child. I consider this a freedom that must be maintained and any effort to oppose this HB gives the impression of a game of hide the ball.

Again, I write in support of HB 1468

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

HB 1468
1/27/2021

Relating to informed consent and notice of risks associated with vaccines; and to provide a penalty

Chairman Weisz opened the hearing at 3:32 p.m.

Representatives	Attendance
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	P
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Vaccination immunization statement
- Minor-provided exemption information
- Biologics description

Rep. Kathy Skroch (3:32) presented **Amendment 21.0956.01002** and Christmas Tree Version of HB 1468 - #5670

Rep. Kathy Skroch moved to adopt **Amendment 21.0956.01002**.

Rep. Bill Tveit seconded the motion.

Voice Vote – Motion Carried

Rep. Todd Porter (3:56) made a motion for a **Do Not Pass.**

Rep. Mary Schneider seconded the motion.

Representatives	Vote
Representative Robin Weisz	Y
Representative Karen M. Rohr	N
Representative Mike Beltz	Y
Representative Chuck Damschen	N
Representative Bill Devlin	Y
Representative Gretchen Dobervich	Y
Representative Clayton Fegley	Y
Representative Dwight Kiefert	N
Representative Todd Porter	Y
Representative Matthew Ruby	N
Representative Mary Schneider	Y
Representative Kathy Skroch	N
Representative Bill Tveit	N
Representative Greg Westlind	Y

Motion Carried Do Not Pass As Amended 8-6-0

Bill Carrier: Rep. Gretchen Dobervich

Chairman Weisz adjourned at 4:05 p.m.

Tamara Krause, Committee Clerk

21.0956.01002
Title.02000

Prepared by the Legislative Council staff for
Representative Skroch
January 27, 2021

1/27/21

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1468

Page 1, line 11, after "individual" insert ", or if the individual is a minor, to the individual's parent or guardian,"

Page 1, line 13, replace "The" with "A current vaccination immunization statement produced by the federal centers for disease control and prevention and, upon request of the individual, parent, or guardian, the"

Page 1, line 13, remove the underscored comma

Page 1, line 14, replace "Information" with "If the patient is a minor, information"

Page 1, line 22, after "vaccination" insert "to a minor"

Page 2, line 1, remove "individual,"

Page 2, line 1, remove the second underscored comma

Page 2, line 2, after the underscored period insert "The individual providing a vaccination may not use tactics that threaten, coerce, or intimidate a patient, or if the patient is a minor, the parent or guardian, to decide to receive a vaccine."

Page 2, line 4, replace "biologics" with "biological products"

Page 2, line 7, remove "must be witnessed and"

Page 2, after line 12, insert:

"6. As used in this section, the term "biological product" has the same meaning as provided under section 19-02.1-14.3."

Renumber accordingly

REPORT OF STANDING COMMITTEE

HB 1468: Human Services Committee (Rep. Weisz, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO NOT PASS** (8 YEAS, 6 NAYS, 0 ABSENT AND NOT VOTING). HB 1468 was placed on the Sixth order on the calendar.

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21.0956.01002
Title.

Prepared by the Legislative Council staff for
Representative Skroch
January 27, 2021

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Sixty-seventh
Legislative Assembly
of North Dakota

HOUSE BILL NO. 1468

Introduced by

Representatives Skroch, Bellew, Fisher, Jones, Paulson, Rohr

Senators Dwyer, O. Larsen, Myrdal

A BILL for an Act to create and enact a new section to chapter 23-12 of the North Dakota Century Code, relating to informed consent and notice of risks associated with vaccines; and to provide a penalty.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 23-12 of the North Dakota Century Code is created and enacted as follows:

Informed consent for vaccines - Notice of risk - Penalty.

1. Every government official, health care provider, and employer that provides an immunization or in the official capacity as a public official or public health officer formally provides information on immunizations, shall provide information of the potential risks of vaccination. This information must be provided to an individual, or if the individual is a minor, to the individual's parent or guardian, before a vaccine is administered and must include:
   a. ~~The~~A current vaccination immunization statement produced by the federal centers for disease control and prevention and, upon request of the individual, parent, or guardian, the vaccine package insert~~,~~ provided by the manufacturer; and
   b. ~~Information~~If the patient is a minor, information regarding exemptions for vaccination as provided under section 23-07-17.1.
2. The state department of health shall make a vaccine exemption form publicly available on the department's website and in all public schools. The department also shall publish a document detailing vaccine exemption information clearly linked to the immunization information on the department's website. The exemption form must include a statement indicating the individual or, if a minor, the individual's parent or

guardian, understands the benefits and risks of immunizations and the benefits and risks of not being immunized. Before administering a vaccination to a minor, the government official, medical provider, and employer providing or requiring immunization shall inform the ~~individual,~~ parent~~.~~ or guardian of the right to an exemption and make the exemption form available. The individual providing a vaccination may not use tactics that threaten, coerce, or intimidate a patient, or if the patient is a minor, the parent or guardian, to decide to receive a vaccine.

3. Every medical provider providing services to a pregnant woman shall provide a clear and detailed explanation of all vaccinations included in any consent for ~~biologics~~biological products. The fact that vaccinations have never been studied in pregnant women must be provided to the patient before administering a vaccination. Dissemination of this information ~~must be witnessed and~~ may not be issued while the woman is in labor or under duress.

4. This section does not reduce or remove liability for a manufacturer of immunizations as liability relates to vaccine injury.

5. A government official, medical provider, or employer that violates this section is guilty of an infraction.

6. As used in this section, the term "biological product" has the same meaning as provided under section 19-02.1-14.3.