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.