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.

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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,

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