House Bill 1457
Human Services Committee
February 4, 2025

Good morning, Chairman Ruby and members of the Human Services Committee. My name is Kylie Hall, and I live in District 45 in North Fargo. 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 9 and 1/2 years. I would like to make clear that my comments today are not on behalf of NDSU.

As the bill is currently written, no vaccines could be required in North Dakota without an exemption because vaccines do not meet the criteria written in Section 3. In learning that vaccines do not meet the criteria in Section 3, you may be concerned. My goal is to provide some context in my testimony to help ease any concerns.

But first, I think it is important to say that I do not know of any employers that require vaccinations for their employees "just because"; often vaccine requirements are put into place to protect the employee and those they serve, and vaccine requirements are very specific. Here are a few examples: a veterinary clinic may require certain staff to receive a rabies vaccination. Laboratory workers who often come in contact with bacteria that cause meningococcal meningitis may require their laboratory workers to receive a meningococcal vaccine. Similarly, a laboratory that often tests animals for rabies may require their staff to have this vaccine. In another example, an employer (ex. law enforcement) may require that their staff receive hepatitis B vaccination if they are at an increased risk for exposure to hepatitis B, either through blood exposure, needle sticks, or sharps injuries. If this bill is passed, health systems may not be able to require vaccinations for their employees. In healthcare, vaccine requirements are made to protect the staff member, the patients, and their family members.

We often see language in vaccine bills around manufacturer liability, clinical trial lengths and the use of placebo controlled studies. Let me expand on why a vaccine may not meet these criteria.

<u>Clinical Trial Length</u>

We know from decades of vaccine clinical trials and vaccine safety monitoring that if a vaccine is going to cause a side effect, it almost always occurs within the first 6-8 weeks after vaccination. Why is that? Because this is when the vaccine is at the highest levels in your body, but also when your immune system is working the hardest to build protection. Vaccine ingredients are quickly eliminated from your body, and all that remains is your immune response. While it is certainly possible to study vaccines for significant periods of time following the clinical trial, it is unnecessary, and we have other safety monitoring systems in place that can

watch for any unforeseen side effects, either short term or long term. It would also be incredibly expensive for pharmaceutical companies to conduct longer trials, as conducting clinical trials already costs billions of dollars. Lastly, requiring a one-year follow-up period could delay the timeline for a life-saving vaccine to be approved.

Clinical Trials and the Use of a Placebo

Using a placebo in clinical trials is acceptable when no effective vaccine is available and the new vaccine is intended to benefit the population being studied. However, using placebos is considered unacceptable when there is already an effective and safe vaccine accessible. In such cases, it would be unethical to withhold the existing vaccine from participants if not receiving it would pose a significant risk to their health. For example, if a new measles vaccine came to market, the clinical trial would likely consist of comparing the new vaccine to the current vaccine, as it would be unethical to refuse measles vaccination to a young child.

Liability

Questions about vaccine manufacturer liability come up regularly. I understand how hearing that vaccine manufacturers are not liable for injury caused by their products would seem concerning, but I would like to offer some perspective that I hope will help alleviate your concerns.

This true story starts in the 1970s. At the time, there were vaccines against smallpox, measles, mumps, rubella, polio, diphtheria, tetanus and pertussis. The DPT (diphtheria, pertussis, and tetanus) vaccine was known to be very reactogenic, which means it caused a lot of side effects. It wasn't uncommon for vaccine recipients to have injection site reactions, high fevers, and some even had febrile seizures and whole-limb swelling. These short-term side effects did not cause any long-term problems, but public concerns about the vaccine were growing. Some thought the vaccine caused brain injuries (further studies showed no association), and a TV documentary blamed the vaccine on intellectual and physical disabilities (the claims were unfounded; no association was found).

Through the 1970s and 1980s, many lawsuits were filed against vaccine manufacturers. Manufacturers made large payouts to those claiming vaccine injury, many of them tied to the DPT vaccine. More and more lawsuits were filed, and they became more expensive. In 1985, vaccine manufacturers knew that a successful vaccine could prevent hundreds of thousands of cases of a deadly disease, but it could also lead to multi-million dollar lawsuits for any bad thing that happened to a child, even if a causal link could not be established. The vaccine manufacturers struggled to obtain liability insurance. Vaccines had low profit margins, so manufacturers began to withdraw their DPT vaccines from the market. By the end of 1985, only one vaccine manufacturer was still making DPT. Vaccine prices soared, so providers limited their purchases. Experts saw the writing on the wall – if this continued, there would be a limited supply of vaccines to prevent infectious diseases and vaccine-preventable diseases would return.

Additionally, the development of new vaccines would be halted by pharmaceutical companies because the risk was too high.

The United States government stepped in. Congress passed, and President Ronald Reagan signed, the National Childhood Vaccine Injury Act – it was meant to 1) eliminate the potential financial liability of vaccine manufacturers due to vaccine injury claims, 2) help ensure a stable supply of vaccines, 3) stabilize vaccine costs, and 4) provide cost-effective arbitration for vaccine injury claims.

This act created the National Vaccine Injury Compensation Program – often referred to as NVICP or VICP. This is the program that will compensate individuals that experience rare, serious side effects from vaccination. It's also worth mentioning that while vaccine manufacturers are not liable for unforeseen events, they are liable for negligence.

We see the liability language pop up in bills from time to time, and I really can understand how someone who doesn't understand the history and the program would be alarmed and think that vaccines are not safe. But the truth is, if you look closely at the data from the compensation program, it shows that vaccines are extremely safe. Approximately one compensation happens for every million doses of vaccine received.

Please vote "do not pass" on House Bill 1457.

Respectfully submitted,

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