House Bill 1406
Human Services Committee
January 23rd, 2023

Good morning, Chairman Weisz and members of the House Human Services Committee. My name is Kylie Hall. I currently reside in north Fargo in District 45. I feel uniquely qualified to testify on this bill because I have a Master's Degree in Public Health, with an emphasis in the management of infectious diseases. I have spent the last 7.5 years working on vaccine-related projects at North Dakota State University in the Center for Immunization Research and Education, where I am the currently the Operations Director. I would like to make clear that my comments today are not on behalf of North Dakota State University.

At the heart of many of the vaccine bills presented before the legislature this session is the issue of vaccine safety. How do we know vaccines are safe, and what do we consider safe? We all want safe vaccines, I think that is one thing we can all agree on. But the two things the sponsors of this bill and I disagree on is 1) how do we know vaccines are safe and 2) what is defined as "safe"? I believe that when you truly understand 1) the rigorous processes behind vaccine development and safety monitoring in this country and 2) the incredibly high standards that vaccines are held to – you, too, will understand how unnecessary bills like this are in North Dakota.

In the last two years, 1.31 million COVID-19 vaccines have been administered in North Dakota. Billions of doses have been administered worldwide, and we have more safety data on these vaccines than we do on almost any other vaccine available today. Public concerns about many adverse events, including death, following vaccination continue, even though no data has shown an association between death and mRNA COVID-19 vaccines. It's just the contrary – COVID-19 vaccines have saved lives.

I want to start my testimony today by talking about how often bad health-related outcomes occur, regardless of an intervention (like vaccination). If I gave 10 million people (roughly the population of Michigan) a sugar cube and just watched them for 2 months, there would be approximately 4,025 heart attacks, 1,700 blood clots (DVT), 3,975 strokes, 9,500 new cases of cancer, and 14,000 deaths. Unfortunate things happen to people every day, and they likely would have happened whether they were given a sugar pill or a vaccine.

Knowing how often bad things happens, think about adding in an international vaccine campaign. At its peak, the United States was administering about 20 million doses of COVID-19 vaccine per week. And in the weeks that followed the administration of those doses, people were going to happen to have heart attacks, blood clots, strokes, be diagnosed with cancer, and die - regardless of receiving the vaccine. It's natural for us as humans to create associations, in fact, it's how we have survived for thousands of years. But it is important that we examine things carefully if we are moving from saying something happened *after* the vaccine to something happened *because* of the vaccine.

This bill calls for the North Dakota Department of Health and Human Services (NDHHS) to study the COVID-19 vaccine, with a specific focus on those who have died within 30 days of

receiving the vaccine. As the bill is currently written, I wonder how the study would be conducted, specifically what the study question is, which methods would be used to conduct the research, and what the expected outcomes from the study would be. But let's imagine the bill was written to look at everyone who died within 30 days of receiving the vaccine, and we want to know if this is more deaths than we would have expected. We may also try and determine if the vaccine could have caused this particular outcome. What would we need to do?

First – let's talk about size. Sample size refers to the number of participants (or observations) included in a study. The size of your sample can influence how precise your estimates are, and the ability of your study to draw conclusions.

To offer you a quick glimpse into the importance of having an appropriate sample size, let's say I wanted to determine the average age of those living in North Dakota. How many people do I need to sample to be confident in my results? The more, the better. I'm going to start my sampling in the House Human Services Committee. There are 14 members here in this committee, and let's say the average age is 50. But so far, I've only sampled 14 members of one committee, and I think I need to sample some more to draw any sort of conclusion about the average age of North Dakotans. So now I move into the House Chamber. I gather everyone's age – and now I determine the average is 45 years old. But I still am not confident in my results. So I visit a local school district, I head to the nursing home, I catch the ages of people at the grocery store, two churches on Sunday, and a college basketball game. At the end of the week, I've asked 500 people their age, and I've come to the conclusion that the average age of North Dakotans is 39 years old. As my sample size increased, I have more and more confidence in the accuracy of my results. (The median age of North Dakotans is 35.2 years, if you're wondering!)

Next, you need baseline rates, which I talked about at the beginning when I gave the expected outcomes when you give 10 million people a sugar cube. Unfortunately, but predictably, people die every single day. They die from strokes, heart attacks, car accidents, lighting strikes, and everything in between. We know that in the United States, about 8,000 people die every single day, which equates to about 56,000 people every week.

One thing that would be necessary to figure out is how many people die on average, every day, in North Dakota – which happens to be approximately 20 people each day. Why is determining the baseline rate important? Because without it, it is hard to determine if any changes have occurred. Consider a statement like this, "There were ten strokes in North Dakota last week." Well, that certainly is an interesting statistic, but unless you understand how often strokes happen in the general population – your baseline rate, it's nothing more than just a statistic. If your local neurosurgeon tells you that there are usually only three strokes a week, knowing there were 10 strokes last week may be concerning. But maybe you come to learn that there are usually 50 strokes a week, so it was a very quiet week in the stroke units across North Dakota. To put a reported number into context (ex. number of strokes weekly), we have to understand the underlying rate at which an event occurs.

Now let's go back to the study proposed in this bill.

For this study, you would need to go through all death certificates and determine which ones were vaccinated against COVID-19, and how long ago the vaccination occurred. In science, we would consider those falling into the "vaccinated in the last 30 days" as our intervention, treatment, or experimental group.

And then, we would need a control group, which serves as our baseline in this study, and helps us determine if an outcome is due to the intervention, as opposed to being due to some other variable. In this case, we would need to determine if COVID-19 vaccination may be causing death, or if something else is causing death. We would need to compare individuals who received the COVID-19 vaccine to individuals that did not to see if rates of death are different. In a study with a control group, it is also important to try and closely match the characteristics of each individual in the control group to an individual in the intervention group – for example, match females to other females or diabetic patients to other diabetic patients. Matching helps us compare two individuals who are very similar, with their one differing characteristic being the intervention, to see if outcomes are different.

The last thing I want to touch on in this section is sample sizes required to detect rare, adverse events. To determine an adequate sample size for detecting a rare event, we use what is called the "Rule of 3". The rule of three says: to have a good chance of detecting a 1/x events, one must observe 3x people. For example, to detect at least one event if the underlying rate is 1/1,000, one would need to observe 3,000 people. To date, the CDC has not identified any COVID-19 deaths that are due to mRNA COVID-19 vaccination in the 30 days after vaccination. If this was a real event, however rare, let's say 1 in a million, we would need to have 3 million people in our sample size to detect this rare adverse event. North Dakota does not have 3 million people or 3 million mRNA COVID-19 vaccine doses administered.

A similar study to the one being proposed was recently done in Florida. It is deeply flawed and not peer-reviewed, but it is worth noting that of their statewide population of 22.2 million people, there were 20 deaths reported in their analysis: less than one death per million. Even if this were the true rate, North Dakota's population is likely not large enough to detect an adverse event this rare. And again, it is worth stating that there are a large number of high-quality, high-powered studies that have shown that COVID-19 vaccines are safe, and the benefits of vaccination far outweigh any risks.

So how would we do this study, and how big of a sample size would we need to be confident in our results? I can't answer that by myself, but my guess is that with a population like North Dakota's (779,000), where only 405,000 people have completed their primary series with 1.31 million total doses administered, with only 20 deaths a day, and with death in the 30 days following vaccination being extremely rare, I honestly don't think you can do this study in North Dakota and have reliable conclusions.

These studies are being done on a national and international level, in databases that include millions of people (large sample sizes give us more confidence in our results), and they use a control group. And to date, there are no studies that have found death to be associated with mRNA COVID-19 vaccination.

HB1402 also required NDHHS to create a vaccine injury compensation program if it promotes, markets, or advertises mRNA vaccines or COVID-19 vaccines. It is worth noting that the way the bill is currently written, it would include all mRNA vaccines in the vaccine development pipeline, including vaccines against respiratory syncytial virus (RSV), Ebola, influenza, and cancer.

There is also already a national program, the National Vaccine Injury Compensation Program (NVICP), to compensate individuals who experience rare, adverse events following vaccination. The proposed program would be duplicative and make North Dakota taxpayers liable for damages already covered by a federal program.

Questions about vaccine manufacturer liability come up regularly, and similar language is weaved in other bills before the legislature this session. 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.

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. In the end, 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 1406.

Respectfully submitted,

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