House Bill 1467 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.

Creating a vaccine adverse event reporting system (VAERS) in North Dakota would be burdensome for healthcare providers and financially irresponsible. Healthcare providers submit vaccine adverse events into the federal VAERS already, and creating an additional system for them in North Dakota would require duplicate entry of adverse events. VAERS data is publicly available, and anyone who is interested in North Dakota-specific data can download it online.

It is important to share what the federal Vaccine Adverse Event Reporting System is and what it can and cannot do to help you better understand the usefulness of this data in North Dakota.

VAERS is used by the FDA and the CDC to collect reports of adverse events (possible side effects) that happen after vaccination. The system relies on individuals to send in reports of adverse health events following vaccination – meaning anyone can and should report adverse events to VAERS. VAERS is designed to detect unusual or unexpected patterns. Scientists monitor VAERS reports to identify adverse events that need to be studied further. Reports of adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns are followed up with additional research to determine whether the adverse event that is happening after vaccination is occurring more often than would be expected without vaccination.

When safety signals are identified through VAERS, other safety monitoring systems are engaged to further study the issue. While VAERS may help identify safety issues, other safety monitoring systems allow us to determine if a vaccine is associated with a certain outcome and the rate at which it occurs.

Key strengths of the federal VAERS are its large size and speed. Because VAERS reports draw from across the country, even a very rare event can be quickly identified as a possible side effect. I would like to point out that a ND-specific VAERS system would not have this strength, as our small population size would lead to fewer adverse events being reported than what we see nationally, and it would take longer to identify rare adverse events because of the small population in ND and smaller number of vaccines administered (compared to nationally).

VAERS data does have its limitations. It must be interpreted with caution, as it is best used for safety signal detection and as a hypothesis generating system. (ex. Could this vaccine be causing

this adverse event?) It helps identify and clarify the questions we need to ask and assess using the other safety systems. A cause and effect relationship cannot be established using information from VAERS reports alone. And because there is no control group, VAERS also does not allow you to compare rates of adverse events in those who did and did not receive a vaccine to see if the adverse event is occurring more in those who were vaccinated versus those who were not vaccinated.

This is a direct quote from the VAERS website: "A report to VAERS generally does not prove that the identified vaccine(s) caused the adverse event described. It only confirms that the reported event occurred sometime after the vaccine was given. No proof that the event was caused by the vaccine is required in order for VAERS to accept the report. VAERS accepts all reports without judging whether the event was caused by the vaccine." From my many years in public health, I have seen many instances where VAERS data were interpreted alone or out of context, leading to erroneous conclusions about cause and effect as well as the risk of adverse events occurring following vaccination.

One of my big questions (and concerns) is: What will we do with this data if the bill passes, and how useful is it? Let's say in 2027 legislative management receives a report from NDHHS that states that there were 150 reports to the North Dakota system each year, and the majority of them were not serious adverse events (ex. sore arm). If in that report there is a report that someone received a vaccine and then developed a serious adverse event 3 weeks afterwards...what will we do with that data? Does it prove that vaccines are or aren't safe? It can't. So much more would be needed. But people will use that data to assume cause and effect, even though a VAERS system cannot do that.

At the end of the day, I think the bill sponsor and I would agree that we both want safe vaccines. I think we would also agree that we want to know how often adverse events are happening in our citizens. We have this data from the federal system, and unfortunately, this bill places a burden on our healthcare professionals.

Please vote "do not pass" on HB 1467.

Respectfully submitted,

Kylie Hall, MPH Fargo, ND - District 45