
Good morning, Chairman Weisz and members of the House Human Services Committee. I am Molly Howell, the Immunization Director for the North Dakota Department of Health and Human Services (Department). I am providing testimony in opposition to HB1406.

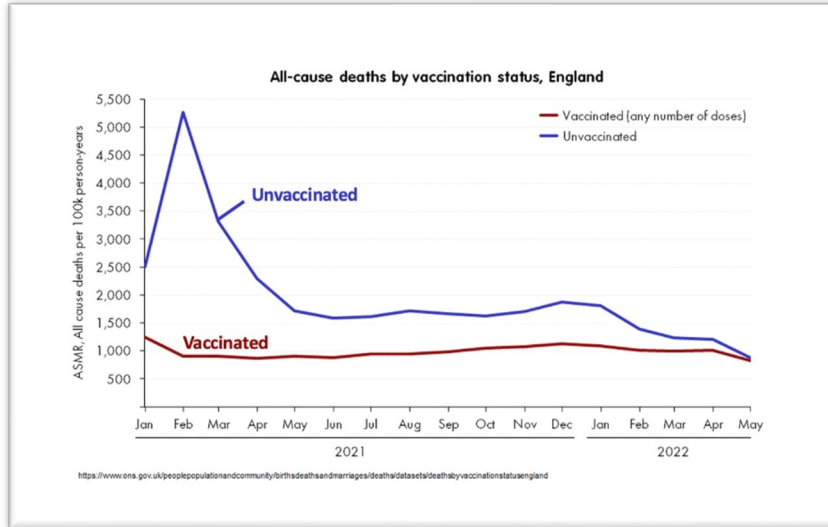
Section 1 of HB1406 proposes a vaccine study. The Department is not opposed to the continuous monitoring and study of vaccine safety. It is the Department's position that this type of monitoring and study is best done at the national level, as it is currently.

The study proposed in HB 1406 would require a general fund appropriation because federal vaccine funding cannot be utilized for research. Additional guidance regarding the scope of the study would be needed to provide an adequate estimate of the cost.

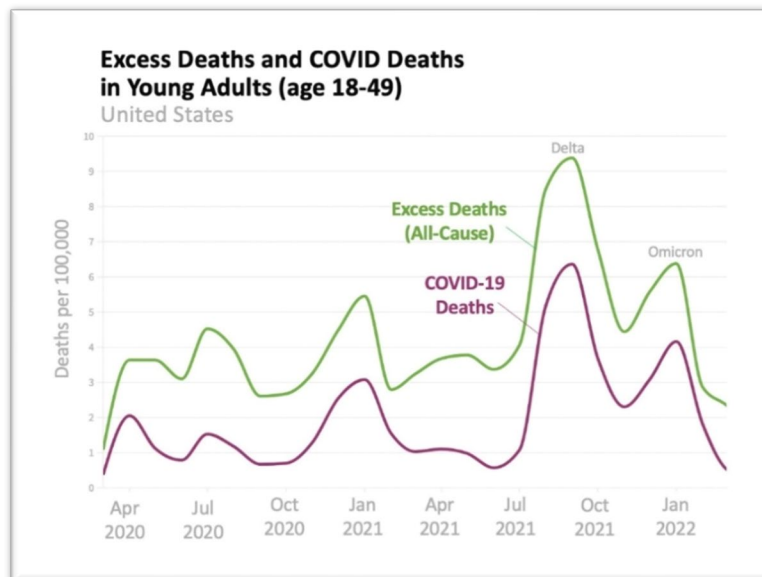
Clarification would also be needed to define the parameters of the study including whether the intent of the study is to count individuals who happened to have died within 30 days of a COVID-19 vaccine, or to determine the association or causation of health events from the COVID-19 vaccine. Without a control group (unvaccinated individuals) and medical chart reviews, it would be very difficult to identify an association between an event and the COVID-19 vaccine. North Dakota's small population size and low vaccination rates may also make it difficult to identify rare adverse events. For example, anaphylaxis (a severe allergic reaction) occurs at a rate of five cases per one million individuals vaccinated with the COVID-19 vaccine.

Attached is a document outlining the various vaccine safety surveillance systems already in place. Death is one of the many potential adverse events that is reviewed. Healthcare providers are required to report deaths suspected to be associated with vaccination to the Vaccine Adverse Events Reporting System ([VAERS](#)). Below is a graph from the [United Kingdom](#) showing all cause

of deaths (COVID-19, car accidents, suicide, strokes) by vaccination status.ⁱ As you can see, vaccinated individuals are not dying at a higher rate than unvaccinated individuals.ⁱⁱ



Below is data from a [study](#) showing excess deaths and COVID-19 deaths in young adults (ages 18-49) in the United States. Scientists found that excess deaths increased starting in the spring of 2020 at the beginning of the pandemic, well before vaccines were introduced into the population. Furthermore, excess deaths tightly mirror COVID deaths, even for working-age adults.ⁱⁱⁱ



The Department also requests a definition for “promotes” in Section 1, #2. It is not clear if providing information to the public and providers about the availability of COVID-19 would constitute vaccine promotion or if providing updates regarding COVID-19 vaccine safety, dosage changes or effectiveness would be considered promotion. The language says, “any messenger ribonucleic acid vaccine,” so this legislation would apply to mRNA vaccines that may become available in the future. mRNA vaccines for respiratory syncytial virus (RSV), influenza and cancer are currently in development.

The [National Childhood Vaccine Injury Act of 1986](#), as amended, created the National Vaccine Injury Compensation Program (VICP), a no-fault alternative to the traditional tort system. It provides streamlined compensation to people found to be injured by certain vaccines. The VICP was established after lawsuits against vaccine manufacturers and health care providers threatened to cause vaccine shortages and reduce vaccination rates. Serious adverse events related to vaccination are extremely [rare](#). Vaccine manufacturers are not liable for unforeseen adverse events, however, they are liable for negligence. Attached is a factsheet for additional information about the VICP.

To encourage expedient development of medical countermeasures during a public health crisis, the [PREP Act](#) was created in 2005. The PREP Act authorizes the Secretary of the US Department of Health and Human Services (HHS) to issue a PREP Act Declaration that provides immunity from liability for any loss caused, arising out of, relating to, or resulting from the administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency. Previous PREP Act declarations have been issued numerous times, including those for the H1N1 pandemic in 2009. The PREP Act does provide manufacturers of countermeasures (i.e., COVID-19 vaccines, treatment) some immunity from liability, but this does not mean COVID-19 vaccine injuries are not covered or compensated for. They are covered under the Countermeasures Injury Compensation Program (CICP). The PREP Act authorizes CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures identified in and administered or used under the PREP Act declaration.

Section 1, #2 of this legislation would require the Department to also compensate individuals who have “any physical injury” after COVID-19 vaccination. This would require general fund appropriation. The amount of the appropriation would be dependent on how “physical injury due to receiving the vaccine” is defined. Funding would also be dependent on how this program is to be administered.

Based on the definition of “medical product” in Section 2 of HB1406, this legislation would apply to all, not just COVID-19, testing and treatment during declared emergencies.

In conclusion, the Department would appreciate further clarification regarding the vaccine study. Additional clarification is also needed regarding which physical injuries due to the vaccine would be covered by the Department and how that determination will be made. A general fund appropriation would be needed to conduct the study outlined in this legislation. Federal programs are already available to provide compensation to individuals who experience rare adverse events after vaccination. Vaccine safety is of the utmost priority to the Department and is currently monitored using a vast network of safety surveillance systems in the United States.

Thank you for the opportunity to appear before you today. I would be happy to respond to any questions you may have.

ⁱ [Deaths by vaccination status, England - Office for National Statistics](#)

ⁱⁱ [COVID-19 vaccines and sudden deaths: Separating fact from fiction \(substack.com\)](#)

ⁱⁱⁱ [Two years of COVID-19: Excess mortality by age, region, gender, and race/ethnicity in the United States during the COVID-19 pandemic, March 1, 2020, through February 28, 2022 | medRxiv](#)