2023 HOUSE HUMAN SERVICES

HB 1406

2023 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

HB 1406
1/23/2023

Relating to studying vaccines and the medical liability of a governmental entity.

Chairman Weisz called the meeting to order at 11:26 AM

Chairman Robin Weisz, Vice Chairman Matthew Ruby, Reps. Karen A. Anderson, Mike Beltz, Clayton Fegley, Kathy Frelich, Dawson Holle, Carrie McLeod, Todd Porter, Brandon Prichard, Karen M. Rohr, Jayme Davis, and Gretchen Dobervich. Rep. Dwight Kiefert not present.

Discussion Topics:

- Representation of citizens
- Medical reports on causes of death in relation to COVID-19 and the COVID-19 vaccine.
- Vaccine side effects
- Vaccine effectiveness
- Vaccine mandates
- Duty of care among medical professionals
- FDA approval
- Safety surveillance systems for vaccines
- Accurate reporting of adverse side effects to VAERS
- COVID-19 vaccination demographics among North Dakota citizens
- Reliability of conclusions

Representative Hoverson introduced HB 1406 with supportive testimony (#15517)

Roberta Gaggle verbally offered testimony in support of bill.

Kathy Monty, from Berthold, ND, verbally spoke in favor of bill.

Marty Beard, ND citizen, verbally spoke in favor of bill.

Travis Zablotney, citzen from Minot, ND, verbally spoke in favor of bill.

Cody Scible, North Dakota citizen, verbally spoke in favor of bill.

Lisa Polkerbeck, North Dakota citizen from District 31, verbally spoke in favor of

bill. Collette Kramer, North Dakota resident, verbally testimony in support of bill.

Richard Jenson, citizen from Bismarck, North Dakota, verbally spoke in favor of

bill. Alexis Wangler, citizen from Linton, North Dakota, verbally spoke in favor of

bill.

Molly Howell, Immunization Director for the North Dakota Department of Health, and Human Services offered testimony in opposition to bill. (#14963) (#14962) (#14961)

Kylie Hall, citizen from Fargo, North Dakota, offered testimony in opposition to bill. (#15230)

Katie Fitzsimmons, with the North Dakota University System offered neutral testimony relating to bill and proposed an amendment. (#15277)

Additional written testimony:

- Seth Flamm, ND Resident, (#14856)
- Peggy Brown, ND Resident, (#14862)
- Patricia Burckhard, ND Resident, (#14880)
- Tara Duckart, ND Resident, (#14918)
- Amber Vibeto, ND Resident, (#14930)
- Lisa Pulkrabek, ND Resident, (#14975)
- Wade Pulkrabek, ND Resident, (#14976)
- Mariah Bates, ND Resident, (#15044)
- Rebekah Oliver, ND Resident, (#15053)
- Penny Crowder, ND Resident, (#15081)
- Shelby Downey, ND Resident, (#15085)
- Jewell Hamilton, ND Resident, (#15107)
- Jen Vesey, ND Resident, (#15144)
- Tiffany Ormonde, ND Resident, (#15151)
- David Ormonde, ND Resident, (#15178)
- Debra Bolte, ND Resident, (#15188)
- Rocky Babel, ND Resident, (#15199)
- Rosemary Ames, ND Resident, (#15222)
- Jennifer Kadrmas, ND Resident, (#15228)
- Suzanne Newell, ND Resident, (#15233)
- Andrea Leingang, ND Resident, (#15249)
- Doug Sharbono, ND Resident, (#15258)
- Rhonda Jolliffe, ND Resident, (#15264)
- Karen Krenz, ND Resident, (#15280)
- Kim Witczak, ND Resident, (#15295)
- Todd Kjelland, ND Resident, (#15305)
- Sandra Tibke, Director of the Foundation for a Healthy North Dakota (#15312)
- Cionda Holter, ND Resident, (#15323)
- Jacob Holter, ND Resident, (#15334)
- Dr. Edward F. Fogarty III, Iowa Resident and Doctor (#15343)

Chairman Weisz adjourned the meeting at 12:30 PM.

Phillip Jacobs, Committee Clerk By: Leah Kuball

2023 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

HB 1406
2/8/2023

Relating to studying vaccines and the medical liability of a governmental entity.

Chairman Weisz called the meeting to order at 4:12 PM.

Chairman Robin Weisz, Vice Chairman Matthew Ruby, Reps. Karen A. Anderson, Mike Beltz, Clayton Fegley, Kathy Frelich, Dawson Holle, Dwight Kiefert, Carrie McLeod, Todd Porter, Brandon Prichard, Karen M. Rohr, Jayme Davis, and Gretchen Dobervich. All present.

Discussion Topics:

- Committee work
- Proposed amendment (23.0712.02001)
- COVID-19 vaccines

Chairman Weisz called for a discussion on HB 1406.

Representative McLeod discussed the proposed amendment to HB 1406 and moved to amend bill. (23.0712.02001)

Seconded by Representative Anderson.

Roll Call Vote:

Representatives	Vote
Representative Robin Weisz	Y
Representative Matthew Ruby	Y
Representative Karen A. Anderson	Y
Representative Mike Beltz	Y
Representative Jayme Davis	N
Representative Gretchen Dobervich	N
Representative Clayton Fegley	N
Representative Kathy Frelich	Y
Representative Dawson Holle	Y
Representative Dwight Kiefert	Y
Representative Carrie McLeod	Y
Representative Todd Porter	N
Representative Brandon Prichard	Y
Representative Karen M. Rohr	Y

Motion carries 10-4-0.

Representative Prichard moved a do pass as amended on HB 1406.

Seconded by Representative Holle.

Roll Call Vote:

Representatives	Vote
Representative Robin Weisz	N
Representative Matthew Ruby	N
Representative Karen A. Anderson	N
Representative Mike Beltz	N
Representative Jayme Davis	N
Representative Gretchen Dobervich	N
Representative Clayton Fegley	N
Representative Kathy Frelich	Y
Representative Dawson Holle	Y
Representative Dwight Kiefert	N
Representative Carrie McLeod	N
Representative Todd Porter	N
Representative Brandon Prichard	Y
Representative Karen M. Rohr	AB

Motion fails 3-10-1.

Vice Chairman Ruby moved a do not pass as amended on HB 1406.

Seconded by Representative Porter.

Roll Call Vote:

Representatives	Vote
Representative Robin Weisz	Y
Representative Matthew Ruby	Y
Representative Karen A. Anderson	N
Representative Mike Beltz	Y
Representative Jayme Davis	Y
Representative Gretchen Dobervich	Y
Representative Clayton Fegley	Y
Representative Kathy Frelich	N
Representative Dawson Holle	N
Representative Dwight Kiefert	Y
Representative Carrie McLeod	Y
Representative Todd Porter	Y
Representative Brandon Prichard	N
Representative Karen M. Rohr	AB

Motion carries 9-4-1.

Bill carrier: Representative Ruby

Chairman Weisz adjourned the meeting at 4:34 PM

Phillip Jacobs, Committee Clerk By: Leah Kuball

23.0712.02001
Title.03000

Prepared by the Legislative Council staff for
Representative Hoverson
February 8, 2023

2-8-23

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1406

Page 1, line 2, remove "studying"

Page 1, line 7, replace "**study - Liability**" with "**liability**"

Page 1, remove lines 8 through 11

Page 1, line 12, remove "2."

Page 1, line 15, after "SARS-CoV-2" insert "as safe"

Page 1, line 21, after "manage" insert "SARS-CoV-2, any mutation or viral fragments of SARS-CoV-2, or"

Page 1, line 21, after "a" insert "future"

Renumber accordingly

REPORT OF STANDING COMMITTEE

HB 1406: Human Services Committee (Rep. Weisz, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO NOT PASS** (9 YEAS, 4 NAYS, 1 ABSENT AND NOT VOTING). HB 1406 was placed on the Sixth order on the calendar.

Page 1, line 2, remove "studying"

Page 1, line 7, replace "**study - Liability**" with "**liability**"

Page 1, remove lines 8 through 11

Page 1, line 12, remove "2."

Page 1, line 15, after "SARS-CoV-2" insert "as safe"

Page 1, line 21, after "manage" insert "SARS-CoV-2, any mutation or viral fragments of SARS-CoV-2, or"

Page 1, line 21, after "a" insert "future"

Renumber accordingly

TESTIMONY

HB 1406

“My name is Seth Flamm and I reside in District 27. I am asking that you please render a DO PASS on House Bill 1406.”

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Thousands of citizens received the COVID-19 vaccine at the recommendation of public health officials, and many have been seriously injured as a direct result and left with nowhere to turn for help. NDHHS should be accountable for the recommendations that they promote. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Seth Flamm

My name is Peggy Brown and I reside in **District 6**. I am asking that you please render a **DO PASS** on House Bill 1406. ND Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services for injuries that may be directly caused by their recommendations. Thousands of citizens received the COVID-19 vaccine at the recommendation of public health officials, and **many have been seriously injured** as a direct result and left with nowhere to turn for help. HDHHS should be accountable for the recommendations that they promote. Thank you for your consideration of this important matter and for your service to the state of ND.

Members of the House Human Services Committee,

"My name is Patricia Burckhard and I reside in District 15. I am asking that you please render a DO PASS on House Bill 1406."

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Thousands of citizens received the COVID-19 vaccine at the recommendation of public health officials, and many have been seriously injured as a direct result and left with nowhere to turn for help. NDHHS should be accountable for the recommendations that they promote. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Patricia Burckhard

Chairman Weisz and members of the House Human Services Committee,

My name is Tara Dukart. I am from District 33. I am submitting written testimony **IN FAVOR of House Bill 1406**.

Last year, my family member died in a North Dakota hospital due to complications from the COVID-19 vaccine. He was pressured into receiving the series of shots, because he was told that the experimental injections would "protect his wife." Now she is a widow.

Here are the facts: North Dakota Health and Human Services (NDHHS) promotes, recommends, and encourages COVID-19 vaccinations and boosters:

https://www.hhs.nd.gov/news/nddoh-encourages-covid-19-booster-vaccines-all-eligible-adults

https://www.hhs.nd.gov/health/coronavirus/covid-19-vaccine-information

However, NDHHS is not liable when a vaccine recipient becomes injured or dies as a result.

I believe that this bill is the first right step toward adequate, long-term safety testing and medical liability of a governmental entity. I urge you to support the passing of House Bill 1406.

Thank you for your service to the state of North Dakota and for working to protect our citizens.

Sincerely,

Tara Dukart

District 33

Members of the House Human Services Committee,

“My name is Amber Vibeto and I reside in District 3. I am asking that you please render a DO PASS on House Bill 1406.”

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Thousands of citizens received the COVID-19 vaccine at the recommendation of public health officials, and many have been seriously injured as a direct result and left with nowhere to turn for help. NDHHS should be accountable for the guidelines that they promote. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

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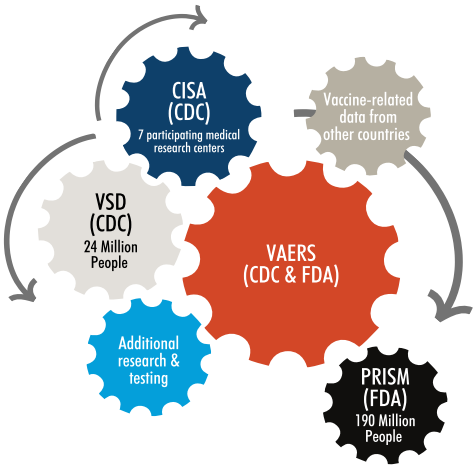
How is Vaccine Safety Monitored in the U.S.?

Vaccine safety monitoring systems in the U.S.

The success of vaccination programs depends not only on vaccines' effectiveness, but also on their safety. Because vaccines are given to millions of healthy people each year, they are held to a very high standard and are continuously monitored for safety.

The U.S. has one of the most advanced systems in the world for tracking vaccine safety. This includes a coordinated and overlapping approach using state-of-the-art technologies and systems working together. Each of the "gears", or systems, supplies a different type of data for researchers to analyze. Together, they work as a well-oiled machine to help provide a full, overall picture of vaccine safety in the U.S. Each of these systems is detailed below.



Why is it important to monitor vaccines post-licensure?

Monitoring a vaccine after it is licensed or authorized helps ensure that vaccines continue to be safe and effective and the benefits continue to outweigh the risks.

Clinical trials typically involve thousands of participants. However, even in large clinical trials, they generally lack adequate sample sizes to identify rare adverse events - an event that may occur after 1 in 100,000 or 1 in a million doses administered. Post-licensure safety studies help validate safety data from clinical trials and may detect adverse events that were not picked up in clinical trials.

Inclusion in clinical trials may exclude specific vulnerable sub-populations, such as pregnant women or immunocompromised adults, for whom a vaccine may be indicated. Studies done post-licensure monitor the safety, effectiveness and benefits of vaccination in these populations.

Vaccine Adverse Event Reporting System (VAERS)

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. 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, like VSD, allow us to determine if a vaccine is associated with a certain outcome and the rate at which it occurs.

What are the strengths of VAERS?

- Anyone can submit reports to VAERS (passive surveillance system)
- Serves as an early warning/hypothesis-generating system. For example, in early 2020, reports to VAERS indicated a need for further study of mRNA-based COVID-19 vaccines and a possible increased risk of severe allergic reactions following vaccination. Additional investigation indicated that these reactions are quite rare, happening in less than one in 200,000 vaccinated individuals.

What are the limitations of VAERS?

- Cannot determine if a vaccine caused the reported adverse event
- May lack details or contain errors
- Does not allow for a comparison of rates of adverse events in those who did and did not receive a vaccine (no control group)

Vaccine Safety Datalink (VSD)

The VSD is a network of thirteen managed care sites across the U.S. with a combined patient population of more than 24 million people. The VSD is used to determine if possible side effects identified using VAERS are actually related to vaccination, and it can identify safety signals using nearly real-time monitoring. Each week, VSD evaluates particular health-related outcomes that may be associated with vaccination and compares it to the expected number of outcomes in a comparison group.

What are the benefits of VSD?

- Conduct timely vaccine safety studies, including assessments of rare adverse events and longitudinal studies involving prolonged follow-up of individual patients
- Use of a control group – allowing for the comparison of adverse events in those who did and did not receive a vaccine (can compare vaccinated to unvaccinated)

What are the limitations of VSD?

- May not have enough patients to detect extremely rare adverse events
- May not capture vaccine administration data outside of the health system
- Cannot determine if an association between an adverse event and vaccination is causal

Clinical Immunization Safety Assessment Project (CISA)

The CISA Project is a national network of vaccine safety experts from the CDC, seven medical research centers, and other partners. The project addresses vaccine safety issues, conducts high quality research, and assesses complex clinical adverse events following vaccination through active surveillance.

What are the benefits of the CISA project?

- Serves as a vaccine safety resource for U.S. health care providers and assist CDC and its partners in evaluating emerging vaccine safety issues
- Can implement prospective, multi-site clinical studies with hundreds of subjects and has the ability to recruit controls
- Can assess vaccine safety in sub-populations (e.g. pregnant women, infants, and children)
- Receives detailed clinical data on patients and can collect biological samples from patients

What are the limitations of the CISA project?

- Small sample sizes may limit CISA's ability to study rare adverse events
- Clinical trials can be labor and resource intensive, and it can be challenging to recruit and retain subjects

Post-licensure Rapid Immunization Safety Monitoring System (PRISM)

PRISM is the largest vaccine safety surveillance system in the U.S., with access to information for over 190 million people. PRISM uses a database of health insurance claims to identify and evaluate possible safety issues for licensed vaccines.

What are the strengths of PRISM?

- Covers hundreds of millions of individuals, which allows for the system to identify and analyze rare health outcomes that would otherwise be difficult to assess
- Linked to some state-wide registries and birth registries - allowing for more complete vaccine exposure data
- Access to denominator data for vaccine exposure, which allows the FDA to estimate a measure of association between a vaccine and adverse events

What are the limitations of PRISM?

- There is a lag in time for accessing the PRISM data
- Medicare population is not as well represented in PRISM
- May not be representative of those without insurance coverage

V-safe

V-safe, a new active surveillance program in the U.S., is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 or mpox (Monkeypox) vaccine.

What are the strengths of V-safe?

- Anyone can enroll in V-safe
- Another way to quickly validate safety data from clinical trials or identify potential safety issues
- Regular reminders to complete a survey help to capture more safety data
- CDC will follow-up with participants and submit VAERS reports, as needed

What are the limitations of V-safe?

- May not properly represent older populations and socioeconomically disadvantaged populations who might not have access to electronic devices to complete web-based surveys and may be subject to under-reporting

Additional research and testing

There are a number of other organizations involved in assessing the safety of vaccines. The Department of Defense (DoD), the U.S. Department of Veterans Affairs (VA), and the Indian Health Service (IHS) have systems to monitor vaccine safety and do vaccine safety research. The National Institutes of Health (NIH) and the Office of Infectious Disease and HIV/AIDS Policy (OIDP) also support ongoing research on vaccines and vaccine safety.

Vaccine-related data from other countries

The U.S. also monitors and assesses high-quality data on vaccine safety and effectiveness out of other countries. For example, the U.K. and Qatar have large national healthcare-related datasets that allow for scientists and researchers to evaluate vaccine safety and compare large groups of people who have and have not been vaccinated and control for various factors and health outcomes. These data can validate U.S. safety monitoring results and provide insight on what signals the U.S. vaccine safety monitoring systems should be assessing and monitoring.

References

1. Bok K. Overview of the U.S. Vaccine Safety Surveillance System & Ongoing Scientific Activities to Monitor Maternal Vaccine Safety. Lecture presented on: September 9, 2014.
2. https://www.cdc.gov/vaccines/hcp/conversations/ensuring-safe-vaccines.html
3. https://www.cdc.gov/vaccinesafety/pdf/iso-factsheet1.pdf
4. https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Ensuring-the-Safety-of-Vaccines-in-the-United-States.pdf
5. CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington, D.C. Public Health Foundation, 2021.
6. https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html
7. https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html
8. https://www.fda.gov/vaccines-blood-biologics/workshops-meetings-conferences-biologics/public-workshop-sentinel-post-licensure-rapid-immunization-safety-monitoring-prism-system
9. Shimabukuro T. Enhanced safety monitoring for COVID-19 vaccines in early phase vaccination. Lecture presented on: September 22, 2020.

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The National Vaccine Injury Compensation Program (NVICP) and Vaccine Manufacturer Liability

Vaccines, like other medicines, can have side effects, as no medical intervention is completely risk free. When side effects do occur from vaccination, they are typically mild; serious adverse events following vaccination are very rare. In the event that a vaccine causes a serious adverse event and injury to the recipient, the United States (U.S.) has created the National Vaccine Injury Compensation Program (NVICP), which provides financial compensation to individuals that have been injured by a NVICP-covered vaccination.

The NVICP was the result of nearly two decades of controversy over whether and how adverse reactions to childhood vaccines should be addressed. Before the program became law, the only legal option for parents who felt that their children had been harmed by a vaccine was to sue the vaccine manufacturer, which was an expensive and time-consuming process. The NVICP was set up by the Department of Health and Human Services in the 1980s and provides financial compensation to individuals who have been injured by a NVICP-covered vaccine.

How the National Vaccine Injury Compensation Program came to be.

The NVICP was created in response to concerns about the pertussis portion of the DPT (diphtheria, pertussis, and tetanus) vaccine. The DPT vaccine was very reactogenic; it was known to cause significant injection site reactions, high fevers, and serious systemic reactions (febrile seizures, persistent crying, and whole-limb swelling). Although none of these side effects were associated with serious long-term sequelae (an aftereffect of a disease, condition, or injury), these side effects contributed to increasing public concerns about the safety of the DPT vaccine. Some claimed the pertussis component of the vaccine caused "pertussis vaccine encephalopathy", a permanent brain injury; further studies showed no true association between DTP and permanent brain injury. The alleged vaccine-induced brain damage proved to be an unrelated condition, infantile epilepsy. The whole-cell pertussis vaccine was also featured in a TV documentary and was blamed for causing various intellectual and physical disabilities.

Through the 1970s and 1980s, the number of lawsuits brought against vaccine manufacturers increased dramatically. Manufacturers made large payouts to individuals claiming vaccine injury, many of these claims tied to the DPT vaccination. For example, in 1978 only one lawsuit was filed, whereas 73 lawsuits were filed in 1984. During the seven-year period from 1978 to 1984, the average amount claimed per suit rose from $10 million to $46.5 million.

By 1985, vaccine manufacturers were still liable for any unforeseen and potentially rare injury linked to the vaccines they produced. While a successful vaccine could prevent hundreds of thousands of cases of deadly disease, it could also lead to a few rare incidences of side effects that could lead to multimillion-dollar lawsuits (In many cases, damages were awarded despite the absence of scientific evidence.). Manufacturers had difficulty obtaining liability insurance. The incentive for creating vaccines became highly unfavorable in the eyes of pharmaceutical companies; low profit margins and lawsuits related to vaccine safety led several manufacturers to withdraw their DPT vaccines from the market. The price of DPT vaccine skyrocketed, leading providers to curtail purchases, limiting vaccine availability. By the end of 1985, only one company was still manufacturing pertussis vaccine in the U.S. At the time, public health officials and vaccine experts noted that if the current lawsuit trend continued, it would pose an increasing threat to the development of new vaccines and availability of current vaccines in the U.S.

In 1986, in response to vaccine shortages and concerns about the return of vaccine-preventable diseases, Congress passed and President Ronald Reagan signed into law the NCVIA. The purpose of the NCVIA was to eliminate the potential financial liability of vaccine manufacturers due to vaccine injury claims, to ensure a stable supply of vaccines, to stabilize vaccine costs, and to provide cost-effective arbitration for vaccine injury claims.


The New York Times

WHITE HOUSE SAYS C.I.A. HAD A ROLE IN IRAN OPERATION

Reagan Signs Bill on Drug Exports And Payment for Vaccine Injuries

An OPEC Panel Urges Price Rise To $18 a Barrel

California Voters Calling Halt To Uncontrolled City Growth

Police and Union in New Talks on Transfer Plan

REAGAN SIGNS BILL ON DRUG EXPORTS AND PAYMENT FOR VACCINE INJURIES

The New York Times; November 15, 1986, Section 1, Page 1

The National Vaccine Injury Compensation Program (NVICP)

The NVICP is funded by an excise tax added on vaccines recommended by the CDC for routine administration. This program provides liability protection to vaccine manufacturers and vaccine administrators who administered covered vaccines. There are four key things to understand about NVICP:

1. Compensation doesn't prove causation.
2. People not happy with the outcome can still take their case to civil court.
3. Although the Act provides liability protections to vaccine manufacturers and vaccine administrators who administer covered vaccines in many circumstances, these protections are not absolute.
4. The requirements for claims filed with the NVICP are two-fold: the events (vaccine administration and injury) have to be temporally related AND some biologically-plausible explanation why the events could be related must be accounted for.

Under the NCVIA, the NVICP was created to compensate those injured by vaccine on a "no fault" basis. The program began accepting petitions (also called claims) in 1988. Individuals can appeal in civil court if their claim is unsuccessful under NVICP, but few do because it is widely considered harder for a petitioner to win in civil court. The NCVIA also created the Vaccine Adverse Event Reporting System (VAERS), established the National Vaccine Program Office (NVPO), and required healthcare providers to provide Vaccine Information Statements (VISs) to vaccine recipients or their parent/legal guardian.

Although the NVICP provides liability protections to vaccine manufacturers and vaccine administrators who administer covered vaccines in many circumstances, these protections are not absolute. Both vaccine manufacturers and administrators are still liable for negligence.

Unfortunately, misconceptions around this program make it an easy source of misinformation and is commonly used in efforts to convince parents that vaccines are not safe. If you look closely at data from the compensation program, you will see that the ratio of number of settlements awarded compared to the number of vaccines given annually shows that vaccines are extremely safe.

According to the CDC, from 2006 to 2019 over 4 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 8,941 petitions were adjudicated by the court, and of those, 6,390 were compensated. This means for every one million doses of vaccine that were distributed, approximately one individual was compensated.

Since 1988, over 25,152 petitions have been filed with the NVICP. Over that 30-year time period, 21,220 petitions have been adjudicated, with 9,070 of those determined to be compensable, while 12,150 were dismissed. Total compensation paid over the life of the program is approximately $4.8 billion.

The PREP Act and Countermeasures Injury Compensation Program

The Public Readiness & Emergency Preparedness (PREP) Act authorizes the Secretary of Health & Human Services to issue a declaration that provides immunity from liability (except for willful misconduct) for claims of loss resulting from administration or use of counter measures to diseases, threats and conditions determined to constitute a present or credible risk of a future public health emergency. This limited immunity from liability applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. PREP Act declarations have been issued for various anthrax, botulism, COVID-19, smallpox, and other medical countermeasures. The PREP Act and the NCVIA are similar in balancing liability protections for manufacturers with a clearer pathway for petitioners.

The PREP Act also authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits in case of physical injury due to covered countermeasures. With CICP, benefits must be requested within 1 year from the date of administration or use of the covered countermeasure alleged to have caused the injury. Examples of covered countermeasures in the case of the COVID-19 pandemic include specified diagnostic tests, treatments, and vaccines. For more information, see www.hrsa.gov/cicp.

References:

Some of the content of this handout was taken directly from the following resources:

1. HRSA. National Vaccine Injury Compensation Program. Accessed 11/9/2022. Available at: https://www.hrsa.gov/vaccine-compensation
2. CDC. Vaccine Information Statements (VISs). Accessed 11/10/2022. Available at: https://www.cdc.gov/vaccines/hcp/vis/index.html
3. IAC. Vaccine Injury Compensation Programs. Accessed 11/9/2022. Available at: https://www.immunize.org/catg.d/p2075.pdf
4. CDC. History of Vaccine Information Statements. Accessed 11/9/2022. Available at: https://www.cdc.gov/vaccines/hcp/vis/dowloads/vis-history.pdf
5. Immunize.org. You Must Provide Patients with Vaccine Information Statements (VISs) - It's Federal Law! Accessed 11/9/2022. Available at: https://www.immunize.org/catg.d/p2027.pdf
6. HRSA. National Vaccine Injury Compensation Program. Accessed 11/10/2022. Available at: https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-fact-sheet.pdf
7. History of Vaccines. Vaccine Injury Compensation Programs. Accessed 11/9/2022. Available at: https://historyofvaccines.org/vaccines-101/ethical-issues-and-vaccine-injury-compensation-programs
8. CDC. Historical Vaccine Safety Concerns. Accessed 11/9/2022. Available at: https://www.cdc.gov/vaccinesafety/concerns-history.html

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HB1406
House Human Services
January 23rd, 10:30 am

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.

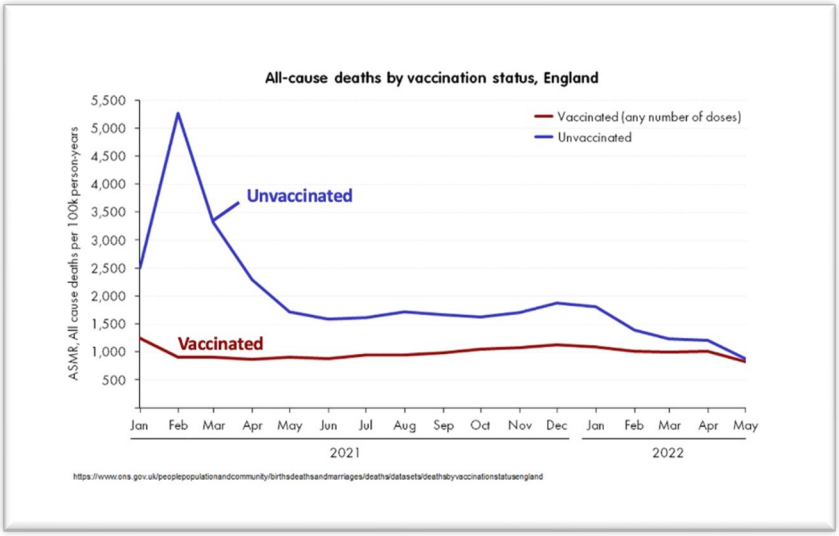
Section 1 of HB1406 proposes a vaccine study. The Department is not opposed to the continuous monitoring and study of vaccine safety. It is the Department's position that this type of monitoring and study is best done at the national level, as it is currently.

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.

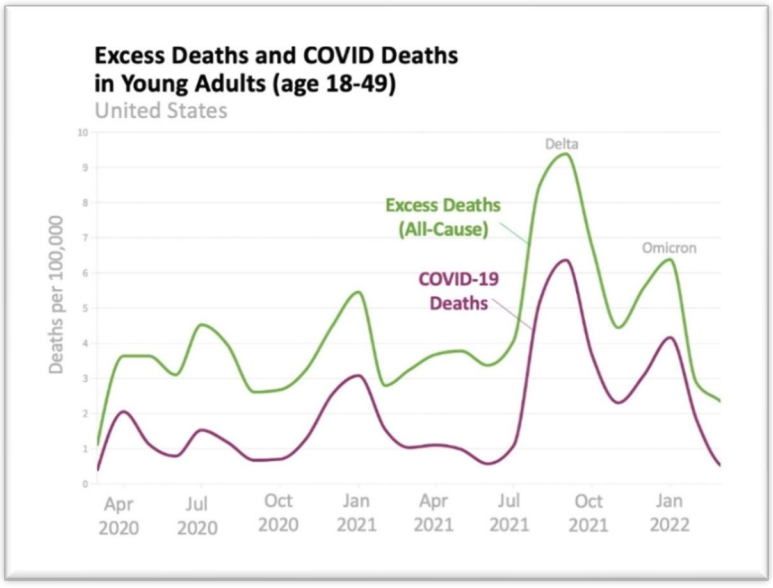
Clarification would also be needed to define the parameters of the study including whether the intent of the study is to count individuals who happened to have died within 30 days of a COVID-19 vaccine, or to determine the association or causation of health events from the COVID-19 vaccine. Without a 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.

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[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

Members of the House Human Services Committee,

“My name is Lisa Pulkrabek and I reside in District 31. I am asking that you please render a DO PASS on House Bill 1406.”

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Thousands of citizens received the COVID-19 vaccine at the recommendation of public health officials, and many have been seriously injured as a direct result and left with nowhere to turn for help. NDHHS should be accountable for the recommendations that they promote. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Lisa Pulkrabek

Members of the House Human Services Committee,

“My name is Wade Pulkrabek and I reside in District 31. I am asking that you please render a DO PASS on House Bill 1406.”

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Thousands of citizens received the COVID-19 vaccine at the recommendation of public health officials, and many have been seriously injured as a direct result and left with nowhere to turn for help. NDHHS should be accountable for the recommendations that they promote. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Wade Pulkrabek

Mariah Bates
Williston, North Dakota
House Bill 1406

Members of the House Human Services Committee,

My name is Mariah Bates and I reside in District 1. I am asking that you please render a DO PASS on House Bill 1406.

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Thousands of citizens received the COVID-19 vaccine at the recommendation of public health officials, and many have been seriously injured as a direct result and left with nowhere to turn for help. NDHHS should be accountable for the recommendations that they promote. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Mariah Bates

DO PASS - HB 1406

Dear Members of the House Human Services Committee,

Please render a DO PASS on House Bill 1406.

Agencies promoting, marketing, or mandating a medical product must also be accountable for adverse consequences.

Thank you for considering this critical bill, and for your service to North Dakota.

Sincerely,

Rebekah Oliver

District 11

My name is Penny Crowder and I reside in District16. I am asking that you please render a DO PASS on House Bill 1406."

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Thousands of citizens received the COVID-19 vaccine at the recommendation of public health officials, and many have been seriously injured as a direct result and left with nowhere to turn for help. NDHHS should be accountable for the recommendations that they promote. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Penny Crowder

Members of the House Human Services Committee,

My name is Shelby Downey and I reside in District #38. I am asking that you please render a DO NOT PASS on House Bill 1406.

I find section one of this bill to be misdirected towards the North Dakota Health and Human Services. While they have actively marketed and promoted COVID-19 vaccinations with no liability, I understand they are following the lead of larger organizations like the Centers for Disease Control and Prevention and the federal US Department of Health and Human Services. While I do think the NDHHS should be accountable for the recommendations that they promote, I urge you to NOT support the passing of House Bill 1406. They should not be required to study a vaccine that has first been promoted by the CDC or USDHHS. Those government entities should be doing their due diligence first and utilizing their government funding for such studies that then will make further recommendations to state entities like NDHHS.

I also strongly disagree with section two. State agencies, political subdivisions, or any other governmental entity should not have the ability to require an individual to take, receive or disclose whether the individual has taken or received a medical product REGARDLESS of if that medical product is liable for any death or serious injury caused by that medical product. While this bill has been aimed directly at the COVID-19 vaccine, ALL vaccines carry zero liability from their manufacturers, as just one example of medical products that are pushed on to the public by government entities. By passing this bill in to law, my fear is that we are setting precedent that any medical product that IS liable by its manufacturer is open to being required by state agencies, regardless of the potential adverse reactions and side effects of that medical product.

In my opinion this bill is extremely misguided and should be rendered DO NOT PASS on House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

- Shelby Downey

Legislative Committee,

My Name is Jewell Hamilton I live in Minot ND. I am writing to strongly support HB1406. The Covid 19 vaccination has been forced upon the citizens of ND in various health and Governmental agencies. There are multiple reports of Covid 19 Vaccine injuries. I agree the HHS to be required to study and maintain accurate records of the effects of any Covid Vaccinations, especially keeping accurate records of individuals who have died within 30 days of receiving Covid 19 vaccination. I also strongly agree if the Department of Health and Human Services promotes and Markets the Covid 19 Vaccination they should be required to cover the cost of treatment and diagnosis for any individual who suffers injury due receiving Covid 19 Vaccination.

No Government Agency, Elected or Non-elected, should have the power to force experimental Medical treatment on its citizens without excepting responsibility for adverse reactions to such medical treatment.

Thank You

Jewell Hamilton

Members of the House Human Services Committee,

My name is Jen Vesey and I reside in District 7. I am asking that you please render a DO PASS on House Bill 1406.

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Thousands of citizens received the COVID-19 vaccine at the recommendation of public health officials, and many have been seriously injured as a direct result and left with nowhere to turn for help. NDHHS should be accountable for the recommendations that they promote. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Jen Vesey

Hello Members of the House Human Services Committee,

My Name is Tiffany Ormonde and I reside in District 31. I am asking you to please render a DO PASS on House Bill 1406.
North Dakota HEalth and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Citizens are urged to receive these vaccinations and several have had serious side effects, yet there is no accountability from the NDHHS or the manufacturer of the vaccine. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Tiffany Ormonde

Hello Members of the Human Services Committee,

My Name is David Ormonde and I reside in District 31. I am asking you to please render a DO PASS on House Bill 1406.

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Citizens are urged to receive these vaccinations and several have had serious side effects, yet there is no accountability from the NDHHS or the manufacturer of the vaccine. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

David Ormonde

Hello Members of the Human Service Committee,

My Name is Debra Bolte and I reside in District 31. I am asking you to please render a DO PASS on House Bill 1406.

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Citizens are urged to receive these vaccinations and several have had serious side effects, yet there is no accountability from the NDHHS or the manufacturer of the vaccine. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Debra Bolte

Hello Members of the Human Service Committee,

My Name is Rocky Babel and I reside in District 32. I am asking you to please render a DO PASS on House Bill 1406.

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Citizens are urged to receive these vaccinations and several have had serious side effects, yet there is no accountability from the NDHHS or the manufacturer of the vaccine. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Rocky Babel

Members of the House Human Services Committee,

“My name is Rosemary Ames and I reside in District 9B. I am asking that you please render a DO PASS on House Bill 1406.”

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Thousands of citizens received the COVID-19 vaccine at the recommendation of public health officials, and many have been seriously injured as a direct result and left with nowhere to turn for help. NDHHS should be accountable for the recommendations that they promote. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Rosemary Ames

To: House Human Services Committee
68thND Legislative Assembly
ND State Capitol, Bismarck, ND

From: Jennifer Kadrmas
Lincoln, ND

Re: House Bill 1406 - relating to studying vaccines and the medical liability of a governmental entity.

Thank you for the opportunity to testify on the House Bill 1406. My name is Jennifer Kadrmas and I live in Lincoln, ND. I am in favor of this bill for the following reasons

- Section 1. This will provide transparency with the ND Department of Health and what is happening within a timeframe of the covid vaccine. Also the misinformation the ND health department has been spewing to North Dakotans the whole covid pandemic has been disheartening. They even shut off their comments because people were questioning the information posted on social media.
- Second 2. Freedom to choose what is used on or injected in a person's body.

Thank you Madam Chair and the Human Services Committee for reading my testimony and I urge the committee to support HB 1406

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,

Kylie Hall, MPH
Fargo, ND – District 45

HB 1406 - Relating to studying vaccines and the medical liability of a governmental entity.

Testimony - Suzanna Newell

My name is Suzanna Newell. I went from triathlete and long distance biker to wheelchair after having a severe reaction after my second Pfizer shot on April 13, 2021. I worked in Financial Services as a VP in Corporate America for over 25 years and I am now on disability. I suffer with nerve damage, heart issues including supraventricular tachycardia and postural orthostatic tachycardia, dizziness, blood coagulation, brain fog, muscle twitching, right pupil dilation issues, tinnitus, debilitating spine and joint pain, just to name a few. My entire life turned upside down overnight.

Immediately after having a severe reaction I expected both my government and the healthcare institutions would be very interested in my issues. I was wrong. After making calls to the CDC, Department of Health, Pfizer, and the Vaccine Adverse Event Reporting System it became quickly apparent I had been left to navigate these scary new symptoms on my own and no one was interested in tracking my progress or supporting me medically or financially. Thankfully, I connected online with a number of other covid vaccine injured people with symptoms just like mine. They became my lifeline. I joined other injured professionals, lawyers, doctors, nurses and am now on the Board of React19. We are a grassroots non profit of injured helping the injured. We are doing the job we thought our government would do. We fundraised and created a React CARE Fund to help those most in need pay some of their medical bills. We are now trying to build a Research Fund so we can do the research we hoped our government would be doing on us. Just as money, time, and research is being granted to study and support those with Long COVID, we are real, we are suffering and we deserve the same. Our symptoms are similar in many ways, yet we have been not only ignored, but hidden, censored and silenced.

It has been more than 2 years that COVID vaccine injured individuals have been suffering. We are out hundreds of thousands of dollars seeking treatment. I wholeheartedly support this bill and hope that all states follow suit. It is time the government acknowledges we exist, tracks and researches our reactions appropriately, and compensates us at the very least for our medical expenses. This is an issue of humanity. I hope you join us on the right side of history and support those suffering and those who have lost their lives by supporting this bill. Thank you.

Members of the House Human Services Committee,

“My name is Andrea Leingang and I reside in District 34. I am asking that you please render a DO PASS on House Bill 1406.”

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Thousands of citizens received the COVID-19 vaccine at the recommendation of public health officials, and many have been seriously injured as a direct result and left with nowhere to turn for help. NDHHS should be accountable for the recommendations that they promote. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Andrea Leingang

Do Pass Testimony
of Doug Sharbono, citizen of North Dakota
on HB1406
in the Sixty-eighth Legislative Assembly of North Dakota

Dear Chairman Weisz and members of the House Human Services Committee,

I am writing as a citizen and believe HB1406 is beneficial legislation. This legislation is common sense and is needed to answer questions on the efficacy and safety of the rapidly produced Covid-19 vaccinations with little to no clinical trials.

Initially critically questioned by top scientists, the Covid-19 vaccination has received wide belief founded on scant evidence that it is good. Belief is not science. The world's top Nobel Peace Prize virologist who isolated the HIV virus, the late Dr. Luc Montagnier, said the Covid-19 vaccination was a medical and a scientific error. When the world's top virologist says this about a viral vaccination, we should pause and take note.

This legislation provides better tracking, so science can be given a chance. Right now, there is very strong confirmation bias supporting the use of the Covid-19 vaccination. It is my hope HB1406 will provide some tools to get the science back on track.

While society has seen many unexpected deaths over the years, there has statistically been an unusual number of excess deaths in the past two years. Again, the scientific community has had little curiosity in researching these deaths. There is a recent adage, "it's easier to fool people than to convince them that they have been fooled."

There is a liability provision for this bill. That is a win-win. If the Covid-19 vaccinations are great, there is no liability. If they are not great, the people who are the current test subjects have some relief.

Please give HB1406 a Do Pass.

Thank you,

Douglas B. Sharbono

Doug Sharbono
1708 9th St S
Fargo, ND 58103

January 22,2023

Members of the House Human Services Committee,

“My name is Rhonda Jolliffe and I reside in District 35. I am asking that you please render a DO PASS on House Bill 1406.”

I am in my 26th year serving the Bismarck and surrounding area as a Nurse Practitioner prescribing medications and vaccinations.

I have grave concerns about the COVID-19 vaccination causing even more injuries than what is reported and strongly support a more robust monitoring system for useful statistics in making Public Health decisions. My concerns stem from what I am seeing clinically in my practice. Since the roll out of the vaccination, in my small practice, I have seen an unusual number of heart issues, thrombo-embolic events, neurological changes, new and reoccurring cancers, immune-system and menstrual changes. I have a few patients that have lost loved ones within a few weeks of their booster and they strongly believe it was related to the vaccination.

It is very difficult as a provider to respond when your patients of 20 plus years present with the changes in their condition and ask “could this be from the vaccination”. I favor of the North Dakota Health and Human Services to provide referral services for these people both physical and psychological if their stance is to continue to promote and market the COVID 19 Vaccination.

Lastly, with the most recent research and statistics on the COVID-19 vaccination injuries it is quite clear that risk to benefit analysis in those receiving the vaccination under age 65 is enough to reconsider the program in that age group.

I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Rhonda Jolliffe

NORTH DAKOTA
UNIVERSITY SYSTEM
ACCESS. INNOVATION. EXCELLENCE.

HB 1406
House Human Services Committee
January 23, 2023
Katie Fitzsimmons, Director of Student Affairs, NDUS
701.328.4109 | katie.fitzsimmons@ndus.edu

Chair Weisz and members of the House Human Services Committee. My name is Katie Fitzsimmons, and I serve as the Director of Student Affairs for the North Dakota University System. I am here today on behalf of the North Dakota University System and its eleven institutions to provide **neutral** testimony related to HB 1406, provide consideration for an amendment, and enlighten the committee about the current process used throughout the North Dakota University System.

Currently, with respect to vaccination data, the eleven campuses engage in a process to obtain sufficient records to ensure the safety of all students on campus in the event of an outbreak. Providing proof of vaccination is not required. Students are given two options: 1) Provide MMR and meningitis vaccination record to the campus OR 2) Complete the immunization exemption form and decline to provide records to the campus.

Option two is for students who prefer to not disclose whether or not they have received vaccinations. We do not ask why a student is requesting an exemption; we simply ask so we know the possible impact of an outbreak, should one occur on our campus or community. If an outbreak were to occur, the students who exempted from the requirement would be considered not vaccinated. As such, those students might not be allowed to attend classes in person or live on campus until the threat of disease is no longer present.

We do not require any vaccination information from faculty, staff, or visitors to our campuses. However, if a faculty or staff member chooses to enroll in a course and attend it in person, they must also provide records or complete the exemption form.

The proposed changes in section two of the bill would not allow the campuses to collect any vaccination data. This could present challenges if an outbreak were to occur. If this bill moves forward, the North Dakota University System requests an indemnification clause to lift the liability of severe injury, loss of access to education, and/or death if such circumstances were encountered due to a case of measles, mumps, rubella, or meningitis. Our concern lies in the ability to rapidly respond to possible cases of disease and we feel equipped to do so under our current process.

This concludes my testimony related to HB 1406. I respectfully request consideration of our amendment suggestion. If the committee finds that acceptable, I will gladly work with the clerk and Legislative Council to draft such an amendment. I stand for questions from Committee members.

Members of the House Human Services Committee,

My name is a Karen Krenz and I reside in District 1. I am asking that you please render a DO PASS on House Bill 1406.

North Dakota Health and Human Services actively markets and promotes COVID-19 vaccinations and yet is not liable, nor do they provide any services, for injuries that may be directly caused by their recommendations. Thousands of citizens received the COVID-19 vaccine at the recommendation of public health officials, and many have been seriously injured as a direct result and left with nowhere to turn for help. NDHHS should be accountable for the recommendations that they promote. I urge you to support the passing of House Bill 1406.

Thank you for your consideration of this important matter and for your service to the state of North Dakota.

Karen Krenz

Statement of Kim Witczak
On behalf of
Woodymatters
Before the
North Dakota House Human Services Public Hearing
On HB 1406
January 23, 2023

My name is Kim Witczak and I am speaking on behalf of Woodymatters, a drug safety organization started after the death of my husband due to an undisclosed side effect of antidepressants. We represent the voice of families, including the Covid vaccine injured, who live every day with the consequences of our current drug safety system. I am also on the board of directors for USA Patient Network, an independent patient voice advocating for safe, effective, and accessible medical treatments. I am here today in strong support of House Bill 1406.

In my nineteen years of drug safety experience since my husband's death which pharma considered acceptable collateral damage (or the cost of doing business), I have had to intimately learn how to connect the dots between pharma and the regulatory, legal, and legislative system. I also have the unique perspective of being a voting member on one of the FDA Advisory Committees reviewing new drugs coming to market. In addition, I have spent my entire professional career in advertising and marketing. We are in the business to change consumer behavior. I understand the marketing and messaging machine.

From the beginning of the one-size-fits all mass vaccination campaign, the fear of the virus and moral obligation was stamped into the human psyche. Trumpeted as “safe and effective”, the mass vaccination program was positioned as only way out of the pandemic. The public was told the Covid vaccines were completely “safe and effective” by everyone from POTUS, celebrities, the media, sports figures, local and state government officials, health departments, church leaders and doctors. You couldn’t question the science, the safety, or public narrative without backlash.

A huge red flag was learning that the government granted the vaccine manufacturers complete immunity from any legal liability for potential and future harms and deaths caused by their product. This was shocking to me especially since I was able to hold Pfizer accountable after my husband’s death by Zoloft-induced suicide. I had a failure to warn/wrongful death lawsuit against the company. Through litigation I was able to get out internal Pfizer and FDA documents that showed they knew about suicide risk since early 1990s. These documents were used in my lobbying efforts. The FDA eventually added Blackbox suicide warnings on antidepressants in 2004 -- One year after my husband’s death and thirteen years after the FDA first held advisory committee meetings in 1991 on link between violence and suicide.

I wonder how many people were told before taking the jab that they had no legal recourse should something happen to them? This most definitely should have been part of any informed consent.

Another red flag was the rushed and shortened clinical trials, coming to market within months, missing trial elements like biodistribution study and key groups like pregnant women not studied. The trials were then ultimately unblinded and the placebo group was offered the COVID vaccine for "ethical" reasons during a pandemic. To this day, there are still ongoing clinical trials, and without a control group, we lost the opportunity to learn about how long efficacy against virus lasts and crucial long term safety impacts. This is clinical trials 101.

In addition, the integrity of original clinical trial data has been questioned and is now the focus of a groundbreaking whistleblower lawsuit filed against Pfizer brought by clinical investigator, Brook Jackson, responsible for overseeing Pfizer's clinical trials.

Thankfully through FOIA litigation, the public is learning more about the original Pfizer clinical trial data submitted to the FDA for authorization. The FDA originally wanted 75 years to release this data, but the judge ruled it needed to be released immediately.

We have also learned that the CDC and FDA have long known about the side effects and injuries reported early in vaccine program but hid from the public. Instead, they keep pushing the product, boosters and for use in children. According to OpenVaers – the website tracking the reports of injures based on the FDA VAERS reporting system – there have been over 1.5M adverse events reported as of January 13, 2023.

But probably the most disconcerting for me is the gaslighting of those who have suffered injuries or deaths after the vaccines. They did their part as government requested, and now, they are left on the battlefield alone. There has been no interest from federal or state government officials or the medical establishment to consider injuries from the vaccines. No acknowledgment or help. Instead, harms are vilified by the media, censored by social media, and called “false and misleading. The injured have been discredited, silenced, and even called anti-vaxxers. The vaccine injured are left to fend for themselves, often left with huge medical bills and unable to work. They have started their own support groups and organizations like React 19 which is helping raise money for the vaccine injured medical treatments as well as a research fund to study their injuries.

One would think the government or medical community would have same interest in vaccine injuries as they do long covid.

Finally, I want to briefly touch on mandates. Thankfully, vaccine mandates are getting struck down by courts across the country with the Department of Defense most recently rescinding the COVID-19 vaccine mandate for the service members. However, healthcare workers and students are still being mandated. It makes no sense.

Where there is risk, there also must be choice. There's a dark irony in the era of patient-centered care and shared decision making in healthcare, neither is present in the conversation around mandates. People should not be coerced or forced to choose between their freedom to bodily autonomy or their livelihood or education. Public health may be a population-based approach, but we need to remember we are treating individuals and a "one size fits all" approach does not work. The public deserves true informed consent.

Thank you for the opportunity to voice my support for HB 1406. It is an important starting point in helping support the vaccine injured. They have paid the ultimate price, and this would be an first step to understanding their injuries, how we can learn from them, and ultimately help them heal. But first we need to recognize and acknowledge vaccine injuries are real, not rare.

Sixty-eighth Legislative Assembly of North Dakota
Re: Testimony in favor of HB 1406
Attn: Representatives,
I, Todd Kjelland am writing in strong favor of passing House Bill 1406. In lieu of new information continuously being publicly revealed regarding all aspects of public and private handling of the Covid 19 medical "emergency" it is in the best interest of the North Dakota citizens to hold North Dakota Department of Health responsible for any and all harm caused by intentional withholding and/or promotion of discredited information.
Thank you for your time. It's a DO PASS for HB 1406 for me.
Todd Kjelland
701-331-2956
emocoach@live.com

FOUNDATION for a Healthy North Dakota

HB 1406
House Human Services
January 23rd | 10:30 am

Good morning, Chairman Weisz and members of the House Human Services Committee. I am Sandy Tibke, Director of the Foundation for a Healthy North Dakota. I am providing testimony in opposition to HB1406.

The Foundation for a Healthy North Dakota supports monitoring and studying vaccine safety; however, the proposed study in this bill is already occurring at a national level, and these studies are publicly available. Also, there are robust vaccine monitoring systems in place at a national level that provides publicly available data, including Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD), and the Clinical Immunization Safety Assessment (CISA) Project. Therefore, a state-specific study would cost taxpayers money to replicate work that is already being done. The recommendation of this study is based on another state's unpublished, non-peer-reviewed research, which is now being criticized by numerous experts. [1,2,3]

Additionally, this bill would limit the ability of the North Dakota Health and Human Services (NDHHS) agency to promote any messenger ribonucleic acid vaccine (mRNA) vaccination, including potential, future cancer-preventing vaccines. Other mRNA vaccines in development include one for respiratory syncytial virus (RSV), which our state has recently experienced a surge of cases and hospitalizations.[4]

This bill's proposal to require our state's Health and Human Services agency to compensate individuals with "any physical injury" after a COVID-19 vaccination is also addressed at the national level. There is an existing compensation program to direct claims of vaccine injury called the National Vaccine Injury Compensation Program (VICP), and the Countermeasures Injury Compensation Program (CICP) handles COVID-19 vaccine injury claims. We do not need to use state taxpayer dollars to handle any claims of vaccine injury for North Dakotans due to this. Also, the VICP streamlines the process for individuals with vaccine-injury claims so that it is easier and more efficient to manage and be compensated.

Based on the definition of "medical product" in Section 2 of HB 1406, this legislation would apply to all, not just COVID-19, testing and treatment during declared emergencies. We shouldn't limit testing and treatment for citizens of North Dakota.

In conclusion, the Foundation for a Healthy North Dakota absolutely supports prioritizing vaccine safety for the citizens of our state. The study and monitoring of this is done at a

necessary and appropriate degree at the national level through the robust vaccine monitoring systems mentioned as well as the many studies focused on the safety of the COVID-19 vaccine. The VICP exists to handle the concern of vaccine injury claims, and the COVID-19 vaccine is a covered countermeasure under the CICP.

Thank you for the opportunity to speak to you today. I am happy to now answer any questions you may have for me.

References:

1. Dyer, O. (2023, January 16). *Covid-19: Florida's surgeon general used "careless" research practice in recommending against vaccination, his university finds*. The BMJ. Retrieved January 20, 2023, from https://doi.org/10.1136/bmj.p110.
2. Diamond, D. (2022, October 13). *Experts slam Florida surgeon general's warning on coronavirus vaccines*. The Washington Post. Retrieved January 20, 2023, from https://www.washingtonpost.com/health/2022/10/11/florida-surgeon-general-ladapo-covid-vaccines/?utm_source=substack&utm_medium=email.
3. *A critical review of Florida's new vaccine analysis*. You Can Know Things. (2022, October 11). Retrieved January 20, 2023, from https://youcanknowthings.com/2022/10/09/a-critical-review-of-floridas-new-vaccine-analysis/.
4. ND Health and Human Services recommends measures for RSV Prevention. Health and Human Services North Dakota. (n.d.). Retrieved January 20, 2023, from https://www.hhs.nd.gov/news/nd-health-and-human-services-recommends-measures-rsv-prevention.

Good day members of the House and Human Services Committee,

My name is Cionda Holter, I am from Surrey ND (District 3) and I am asking you today to render a do pass on HB 1406. North Dakota Health and Human Services actively promotes Covid 19 vaccinations and yet they are not liable for any of the injuries that may occur from taking the vaccine; nor do they provide any services for vaccine injuries that may be a direct cause of their recommendations.

If an organization feels so strongly about a medication/ vaccine that they are willing to push and promote it this strongly they should be willing to take responsibility for the outcome of it as well. If they are not willing to take on that responsibility, then they should not be promoting as strongly as they have been with the covid 19 vaccine.

Thank you for your consideration on this matter and thank you for your service to the state of North Dakota.

Sincerely,

Cionda Holter

Good day members of the House and Human Services Committee,

My name is Jacob Holter, I am from Surrey ND (District 3) and I am asking you today to render a do pass on HB 1406. North Dakota Health and Human Services actively promotes Covid 19 vaccinations and yet they are not liable for any of the injuries that may occur from taking the vaccine; nor do they provide any services for vaccine injuries that may be a direct cause of their recommendations.

If an organization feels so strongly about a medication/ vaccine that they are willing to push and promote it this strongly they should be willing to take responsibility for the outcome of it as well. If they are not willing to take on that responsibility, then they should not be promoting as strongly as they have been with the covid 19 vaccine.

Thank you for your consideration on this matter and thank you for your service to the state of North Dakota.

Sincerely,

Jacob Holter

North Dakota House House Human Services Committee Hearing: HB1406 January 23, 2023

Written Testimony of Dr. Edward F. Fogarty, III

Health and Human Services committee,

It is a privilege to be able to testify today and relate my experience in treating vaccine injured North Dakotans from across state lines between Iowa and Nebraska My practice based out of Northwest Iowa has seen several North Dakotans come physically to my clinic in Spirit Lake, Iowa for treatment of vaccine injuries.

One of these seminal cases involves a retired pharmacist who had multiple vaccines for COVID19, after the third vaccine she experienced a hypertensive crisis requiring emergency medical attention and was subsequently diagnosed in the following weeks with monoclonal gammopathy of undetermined significance (MGUS).

In treating this patient from Northwest North Dakota, I employed the North Dakota CARES ACT Grant innovations in medical countermeasures for pandemic viruses including spike protein mediated disease that Agriculture Commissioner Doug Goehring funded for Dr. Leslie Link and I to develop, broadcast and teach to everyone possible across the northern plains.

My patient's laboratory values from Mayo Clinic regarding MGUS had reached the threshold of concern for the development of multiple myeloma by the time she saw me in Iowa. The program of therapy that I designed for this retired pharmacist has now reversed the anti-body derangement. We continue to monitor her condition and have her in a regular program of mild hyperbaric therapy combined with primary glutathione amino acid precursors support, nitric oxide vascular conditioning agents and spirulina. Spirulina is a single celled organism that is used by NASA in the space station program. Spirulina added to CA2963131, a Canadian patented anti-viral system with beet root powder has been used in my practice to reverse cognitive decline/dementia and ejection fraction suppression after COVID19 infection and vaccination.

in this context that I feel that presented bill is extremely important for North Dakota citizens. Setting up the patient registry of injured individuals from North Dakota injured by vaccines for SARS CoV2 to include individuals with history of death is very important. I might add that there will need to be autopsy data including blood draws of spike protein levels within those who died or had serious adverse events. Autopsy documentation of the multifocal clotting seen in death by mRNA technology would be important but also, histopathology on cardiac electrical nodes and purkinje fibers would be paramount in autopsy diagnosis of mRNA biotech mediated “Sudden Adult Death Syndrome” - which was never taught at UND SOM as any sort of clinical syndrome to be aware of in my tenure as the Chairman of Radiology from 2006-2019.

From within the radiology community, we are finding a signature diagnosis of late gadolinium enhancement in cardiac MRI studies as a marker of vaccine-based injury to the myocardium from the spike protein bearing biotechnology and genetic manipulation system. It will be important for the Department of Health and Human Services to actually track this data on behalf of North Dakota citizens. I heard through my networks in medicine that the University of Minnesota did Cardiac MRIs on all of their football players after their vaccine/niotech role out in 2021.

Additionally, I might add that by involving the trial attorneys of North Dakota, those North Dakotans harmed by the biotech mRNA products could have a window of opportunity for legal recourse against the manufacturers of these products causing harm to the health of North accordance.

Medical liability of government entity section is extremely important. Our government agencies from the federal system down to even county based public health systems have participated in this global racketeering scheme through the unethical distribution of this vaccine biotech genetic engineering system into the human body and population. It would appear that the state legislature is the only entity that has the power to protect the people with laws such as this.

When Governor Bergman joined several other Governor's in requesting an end to the mandates for the military, it seems to me that that the end of mandates for North Dakotans should have come with that declaration. We are all basically constricted into a global war based on a bioweapons platform destroying mitochondria, therefore we are all veterans at some level. Johnson and Johnson got away with having the state of North Dakota pay for its GAIN OF FUNCTION product with their live attenuated GMO of an adenovirus containing Spike Protein.

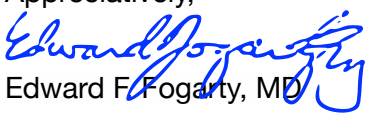
Our medical military readiness is dependent on this end of mandates in America and North Dakota now more than ever in the practice of medicine and nursing. We have suffered many losses occupationally and this biowarfare/psychological operations system. I brought forth concerns for just what we have been though in an open letter to the Washington state legislature in February 2019; foreshadowing fairly well where we are politically in terms of subterfuge and treasonous actions between enemies within America and affiliates in the racket between Wuhan China and even the bio-labs of Ukraine.

Unequivocally I am for this bill and would only suggest that we recodify these mRNA products as genetic modification agents and not as vaccines as this is the terminology has shielded these biotechnology products from liability. These are far from technological prior art in development of vaccines and therefore should not be called vaccines.

Lastly, my gravest concern is now in the development of Mad Cow disease of rapid onset after COVID mRNA bioweapon injection. The 1989 Bioweapons Anti-Terrorism Act of the 101st Congress would define Pfizer and Moderna corporations as bioweapons manufacturers.

Thank you for your time and attention.

Appreciatively,



Edward F. Fogarty, MD

2019 Open Letter to the State of Washington embedded here:
https://www.ndlegis.gov/assembly/67-2021/testimony/HHUMSER-1306-20210119-1626-F-FOGARTY_EDWARD.pdf

https://pubmed.ncbi.nlm.nih.gov/?term=late+gadolinium+enhancement+vaccine
56 Articles in the National Library of Medicine PUB MED Database

https://www.ijvtpr.com/index.php/IJVTPR/article/view/66
Mad Cow Disease in 26 person case series from France - shortly after mRNA biotech exposure.

https://www.mdpi.com/1467-3045/44/3/73
DNA incorporation of mRNA sequence above.

Sporadic Creutzfeldt-Jakob Disease After Receiving the Second Dose of Pfizer-BioNTech COVID-19 Vaccine

Andrea J. Folds MD[1,2], Melanie-Belle Ulrich MD[1,2], Sann Y. Htoo MD[2], Anjeza Chukus MD[1,2]
1. HCA Healthcare, Nashville, TN
2. Department of Internal Medicine, HCA Healthcare Aventura Hospital

Aventura Hospital and Medical Center

Abstract

- Human prion disease is a rare, highly progressive neurodegenerative disease that is ultimately fatal.
- The majority of cases occur sporadically, although some may be genetic or acquired.
- Here, we highlight a case of a 64-year-old woman who presents with rapidly declining memory loss, behavior changes, headaches, and gait disturbance approximately one week following administration of the second dose of the novel Pfizer-BioNTech messenger ribonucleic acid (mRNA) COVID-19 vaccine.
- After extensive investigation, conclusive evidence identified the fatal diagnosis of sporadic Creutzfeldt-Jakob disease.

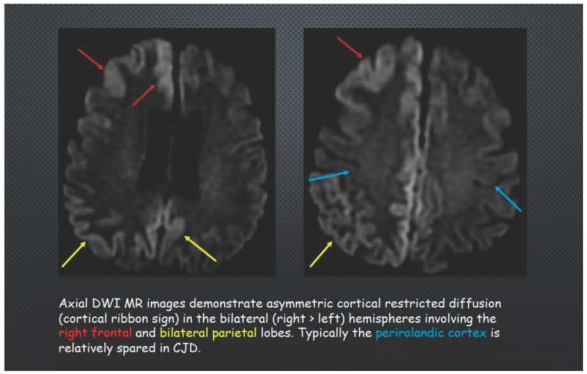
Introduction

Human prion diseases were first described in the early 1920s and are delineated into three categories: sporadic, inherited, or acquired by way of infection. Of the sporadic type, there are Creutzfeldt-Jakob disease (CJD), fatal insomnia, and variably protease-sensitive prionopathy. Approximately 90% of cases of prion disease are sporadic CJD, which can be further divided into five subtypes based on clinical features, histological findings on autopsy, and molecular structure of the abnormal protein [1]. The incidence of sCJD is very rare, approximately 1-2 cases per one million per population. In the case presented herein, the plausibility of the Pfizer-BioNTech COVID-19 vaccine triggering sCJD is explored.

Case

- A 64-year-old woman with a past medical history of bipolar depression and anxiety presents with rapidly progressive dementia, behavioral changes, headaches, and gait disturbance approximately one week after receiving the second dose of the Pfizer-BioNTech COVID-19 vaccine.
- Physical exam was essentially unremarkable except for confusion and significant distress regarding her condition.
- Initial labs, toxicology screening, and imaging were unremarkable except for a mildly increased white blood cell count.
- Psychiatry and neurology were consulted.
- Magnetic resonance (MR) imaging of the brain showed cortical diffusion restriction involving the bilateral frontal lobes, bilateral parietal lobes, and paramedian bilateral occipital lobes.
- Lumbar puncture: positive via the newest, highly sensitive real-time quaking-induced conversion (RT-QuIC) testing.
- T-tau protein measured at 38,979 (reference < 0-1,149).
- 14-3-3 protein was positive, neuron-specific enolase resulted at 16.3 (reference < 8.9).
- Exhibiting progressively worsening pyramidal and extrapyramidal symptoms, as well as akinetic mutism.
- Based on the Center for Disease Control and Prevention's diagnostic criteria, the findings place her case as probable sporadic CJD with a definitive diagnosis to be made by a proper autopsy with neuropathological studies.

Imaging



Axial DWI MR images demonstrate asymmetric cortical restricted diffusion (cortical ribbon sign) in the bilateral (right > left) hemispheres involving the right frontal and bilateral parietal lobes. Typically the perirolandic cortex is relatively spared in CJD.

References

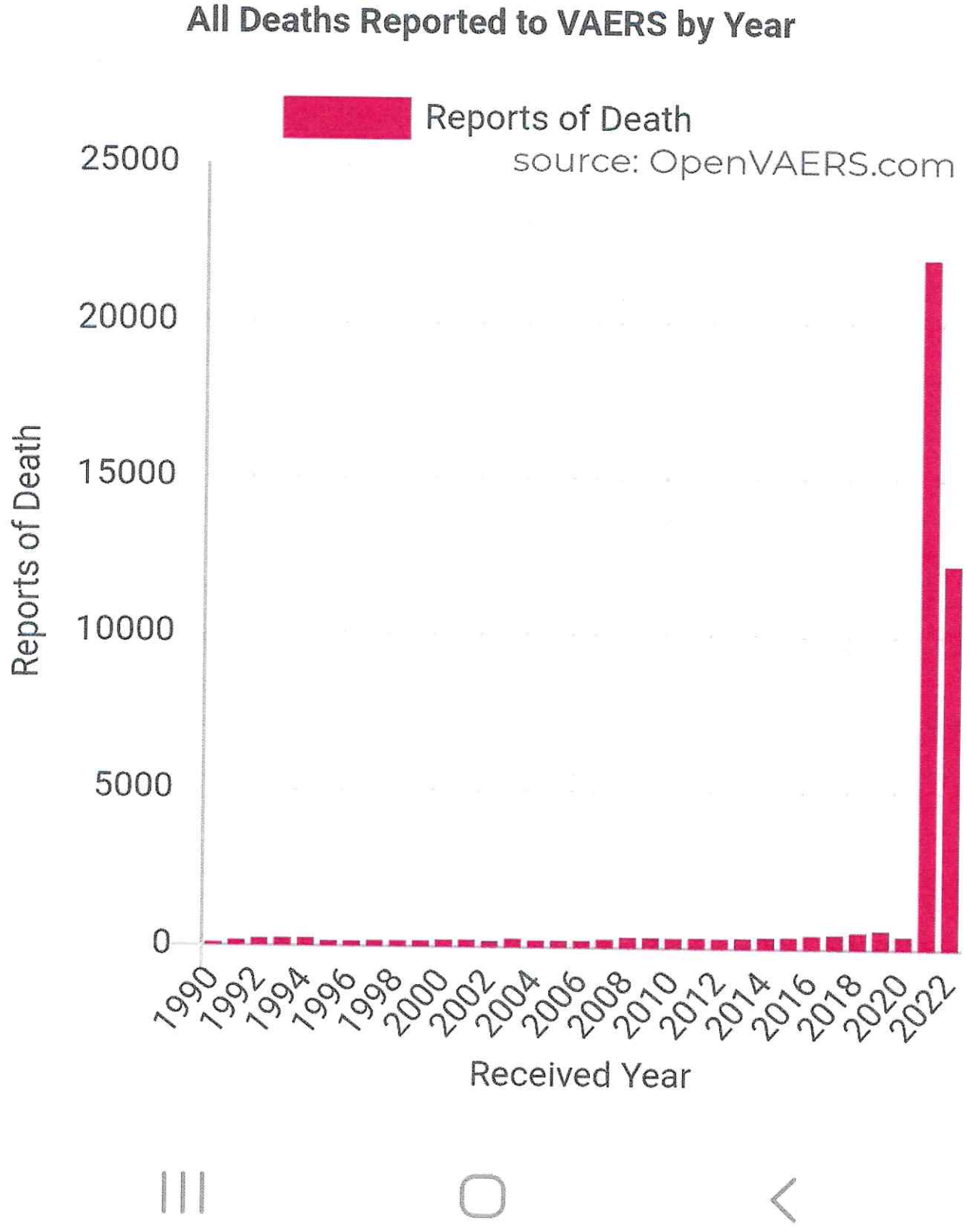
1. Puoti, G., Bizzi, A., Forloni, G., Safar, J. G., Tagliavini, F., & Gambetti, P. (2012). Sporadic human prion diseases: molecular insights and diagnosis. Lancet Neurol, 11(7), 618-628. https://doi.org/10.1016/S1474-4422(12)70063-7
2. Harris DA. Cellular biology of prion diseases. Clin Microbiol Rev. 1999 Jul;12(3):429-44. doi: 10.1128/CMR.12.3.429. PMID: 10398674; PMCID: PMC100247.
3. Brown P, Cathala F, Raubertas RF, Gajdusek DC, Castaigne P. The epidemiology of Creutzfeldt-Jakob disease: conclusion of a 15-year investigation in France and review of the world literature. Neurology. 1987 Jun;37(6):895-904. doi: 10.1212/wnl.37.6.895. PMID: 3295589.
4. Classen, J.B. (2021, February 28). COVID-19 RNA Based Vaccines and the Risk of Prion Disease. *Microbiology & Infectious Diseases*, *5*(1). https://doi.org/10.33425/2639-9458.1109
5. Linsell L, Cousens SN, Smith PG, Knight RS, Zeidler M, Stewart G, de Silva R, Esmonde TF, Ward HJ, Will RG. A case-control study of sporadic Creutzfeldt-Jakob disease in the United Kingdom: analysis of clustering. Neurology. 2004 Dec 14;63(11):2077-83. doi: 10.1212/01.wnl.0000145844.53251.bc. PMID: 15596753.
6. Kuo PH, Chiang CH, Wang YT, Doudeva LG, Yuan HS. The crystal structure of TDP-43 RRM1-DNA complex reveals the specific recognition for UG- and TG-rich nucleic acids. Nucleic Acids Res. 2014 Apr;42(7):4712-22. doi: 10.1093/nar/gkt1407. Epub 2014 Jan 23. PMID: 24464995; PMCID: PMC3985631.
7. Tetz, G.; Tetz, V. SARS-CoV-2 Prion-Like Domains in Spike Proteins Enable Higher Affinity to ACE2. Preprints 2020, 2020030422 (doi: 10.20944/preprints202003.0422.v1).
8. Young MJ, O'Hare M, Matiello M, Schmahmann JD. Creutzfeldt-Jakob disease in a man with COVID-19: SARS-CoV-2-accelerated neurodegeneration? Brain Behav Immun. 2020 Oct;89:601-603. doi: 10.1016/j.bbi.2020.07.007. Epub 2020 Jul 15. PMID: 32681865; PMCID: PMC7362815.
9. Iwasaki, Y. (2017) Creutzfeldt-Jakob disease. *Neuropathology*, 37: 174– 188. doi: 10.1111/neup.12355.
10. : J. Bart Classen. Review of COVID-19 Vaccines and the Risk of Chronic Adverse Events Including Neurological Degeneration. J Med - Clin Res & Rev. 2021; 5(3): 1-7
11. Angus-Leppan H, Rudge P, Mead S, Collinge J, Vincent A. Autoantibodies in Sporadic Creutzfeldt-Jakob Disease. JAMA Neurol. 2013;70(7):919–922. doi:10.1001/jamaneurol.2013.2077

Discussion

- Normal prion protein is converted into an infectious, auto-enzymatic protein that aggregates in the brain tissue destroying neuronal cells leading to extensive neurodegeneration.
- Human prion protein (PrP), is encoded by the PrP gene, PRNP, which is located on the short arm of chromosome 20.
- Conversion to the diseased prion protein, termed PrPSc, is determined by PRNP polymorphism involving methionine (Met) or valine (Val) at codon 129 and prion strain (type 1 PrPSc or type 2 PrPSc).
- Etiology has been thought to be a mostly sporadic disease with no known specific cause.
- Retrospective case-control study in the United Kingdom found that all sporadic Creutzfeldt-Jakob disease (sCJD) cases from 1990 - 1998 lived close together, suggesting plausible precipitating factor.
- mRNA contained in the Pfizer-BioNTech COVID-19 vaccine has the potential to bind to specific proteins and cause pathologic misfolding.
- Various portions of the COVID-19 mRNA Pfizer-BioNTech vaccine to have a high affinity for cytoplasmic proteins such as TAR DNA binding proteins (TDP-43) and Fused in Sarcoma (FUS) .
- Spike protein, which is translated by the mRNA, can increase intracellular zinc, which has been shown to cause the conversion of TDP-43 into its pathological prion.
- Kuo et.al demonstrated how TDP-43 binds to mRNA transcripts with long UG-repeats.
- Pfizer-BioNTech's COVID-19 vaccine contains many of these specific sequences.
- Tetz and Tetz identified a prion-like domain found in the receptor-binding domain of the S1 region of the SARS-CoV-2 spike protein.
- A case reported a previously healthy 60-year-old man who developed sudden onset sCJD with concurrent onset of symptoms of COVID-19.
- Case of a patient with sCJD whom also had positive serum neuronal antibodies to the voltage-gated potassium channel complex (VGKC complex) and glycine receptor (GlyR) antibodies, suggesting a possible auto-immune mechanism.

This research was supported (in whole or in part) by HCA Healthcare and/or an HCA Healthcare affiliated entity. The views expressed in this publication represent those of the author(s) and do not necessarily represent the official views of HCA Healthcare or any of its affiliated entities.

HCA Healthcare


All Deaths Reported to VAERS by Year
Reports of Death
source: OpenVAERS.com
25000
20000
15000
10000
5000
0
Reports of Death
1990
1992
1994
1996
1998
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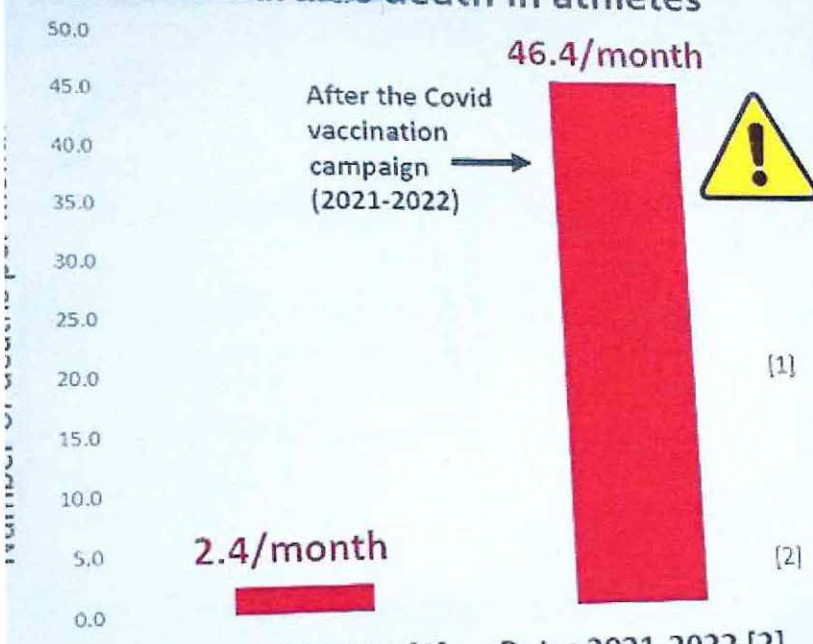
2002
2004
2006
2008
2010
2012
2014
2016
2018
2020
2022
Received Year

URTESY
GOOD SCIENCING

death in athletes



[1] Sudden cardiac death in athletes: the Lausanne Recommendations

[2]