2021 HOUSE HUMAN SERVICES

HB 1377

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

HB 1377
1/25/2021

Relating to immunization exemptions

Chairman Weisz opened the hearing at 6:39 p.m.

Representatives	Attendance
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	P
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Immunization requirement exemptions
- Safety trials

Rep. Jeff Hoverson, District 3 (6:39) introduced the bill, testified in favor, and submitted testimony #2841

Del Bigtree, Informed Consent Action Network (6:41) testified in favor.

Kolette Kramer, Denbigh, ND (6:50) testified in favor and submitted testimony #3233.

Matt Gardner, Greater North Dakota Chamber (6:53) testified in opposition.

Amy DeKok, Legal Council North Dakota School Board Association (6:54) testified in opposition and submitted testimony #2885.

Courtney Koebele, Executive Director North Dakota Medical Association (7:02) testified in opposition and submitted testimony for Dr. Misty Anderson #3042.

Molly Howell, Immunization Director North Dakota Department of Health (7:04) testified in opposition and submitted testimony #2532.

Additional written testimony: #2236, #2310, #2340, #2364, #2366, #2391, #2454, #2464, #2471, #2473, #2476, #2479, #2483, #2509, #2513, #2519, #2524, #2541, #2560, #2577, #2588, #2596, #2608, #2609, #2615, #2644, #2660, #2666, #2672, #2676, #2684, #2692, #2695, #2728, #2740, #2760, #2797, #2800, #2803, #2829, #2835, #2887, #2914, #2917, #2921, #2933, #2936, #2940, #2958, #2964, #2974, #2983, #2984, #3002, #3004, #3015, #3034, #3040, #3062, #3107, #3115, #3142, #3163

Chairman Weisz adjourned at 7:05 p.m.

Tamara Krause, Committee Clerk

Testimony and Introduction for Bill # 1377 - Human Services Committee

By Jeff Hoverson, House of Representatives; District 3

Monday, January 25, 2021

Who Is Del?

Del Bigtree is one of the preeminent voices of the Vaccine Risk Awareness Movement. His career as an Emmy-winning producer of the CBS talk show, *The Doctors*, changed profoundly when he produced the documentary, *Vaxxed: From Cover-up to Catastrophe*, which is credited with igniting a revolution against pharmaceutical tyranny around the world. Now Del's internet news show, *The HighWire*, is the fastest-growing program in the natural health arena with over 75 million views. His non-profit, the Informed Consent Action Network, or ICAN, is leading worldwide investigations into drug and vaccine fraud that have already resulted in multiple winning lawsuits against US Government agencies Health and Human Services, National Institutes of Health, CDC and FDA.

Because of the Highwire and Del's team of experts, attorneys, and staff, they were successful in getting the CDC to admit, in writing, they have never compared unvaccinated to vaccinated children which is thee critical test to disprove the utility of the 72 vaccines injected into our kids.

They also have recently, by exposing the truth, influenced the CDC to take down from their website the statement that say, "there is no connection between vaccines and autism".

And, they helped the Massachusetts legislature to eliminate the mandate for flu shots for schools.

This team knows what they are talking about and they do mean business. I hope you will give them your utmost attention, curiosity and questions.

This particular bill is neither pro or anti vaccine. It is a common sense bill to assure North Dakota citizens that proper control and placebo studies have been conducted for safety. The opposition to this bill will likely perpetuate the narrative that "all is fine" and there is "nothing to worry about". Actually, even most of them are unaware of growing number of compromises being accepted for the sake of speed, profits, and fear of reprisal.

2:45 Monday

I am in favor of HB 1377

This bill would provide people with the ability to exempt out of a vaccine if the vaccine manufacturer does not meet specific requirements. I do believe that vaccine companies should be liable, held to a higher standard of safety testing and studies, and that the risk of infection should far out weigh the risks of the vaccine itself.

I also believe that if it is forced or mandated, than whoever requires it of you should be held accountable for any injury, loss, or expense you may incur due to the required vaccination.

Placebo safety testing. My biggest problem with placebo safety testing is that when the trial phases for a vaccines expire, whether it be 6 months or a year, the people in the study who received the placebo, or no vaccine, are then offered the vaccine. So the study ends there and there are no long term safety studies being done after that. How can we compare the side effects if there is nothing to compare it to? "It is unethical" they say. I say it is unknown for safety and unproven. Say it is unknown, but don't say it is "safe and effective". Rumor has it that the phase 3 trial participants for covid vaccines are being offered the vaccine and the trials are not even done yet. They have Emergency Use Authorization, but they are not FDA approved. Will manufacturers be able to tell us they are safe and effective even though a placebo safety study has never been finished?

Vaccine awareness has skyrocketed this year thanks to covid. I'm sure you had never thought of all the bills that came your way because of it. This is an issue that was near and dear to my heart long before covid.

Another issue is why unvaccinated children are a risk to vaccinated children. Health care officials want to know who is unvaccinated so they can deny services to those without vaccinations in case of an outbreak. If your child is vaccinated, and the vaccine is safe and effective, there should be no reason for worry. Healthy unvaccinated children are not a risk to your vaccinated child. According to

HIPPAA, health information should be kept private. Should parents of vaccinated children know who the unvaccinated children are? Why are schools asked to be the vaccination police? Does their medical license warrant having those records on file? Should the DPI be able to withhold funding from schools based on their overall vaccine status?
The medical industry has come a long way. We have advances and treatments that we didn't have 100, or 50, or even 20 years ago. If the Brady Bunch wasn't worried about measles in the 70's, why should the parents and children be so worried about it today, in 2021?

Thank you for your time and serving our state in this capacity.

Kolette Hamer
Denbigh, ND

NDSBA
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HB 1377
Testimony of Amy DeKok
House Human Services Committee
January 25, 2021

Chairman Weisz and members of the House Human Services Committee, my name is Amy DeKok. I am in-house Legal Counsel for the North Dakota School Boards Association. NDSBA represents all 178 North Dakota public school districts and their boards. NDSBA stands in opposition to HB 1377.

Our schools serve arguably the most vulnerable population of citizens. Parents entrust their children to our schools to protect them and keep them safe from harm, especially preventable harm. If passed, HB 1377 will make it even more difficult for schools to keep kids safe and protected. School immunization requirements play an important role in increasing immunization rates and ensuring environments where children congregate are safe.

North Dakota already has one of the most relaxed school immunization policies in the country. North Dakota allows medical, religious, and moral/philosophical exemptions. Parents simply have to sign a document prior to school entry to claim a religious, moral/philosophical exemption. North Dakota is only one of 15 states that still allows moral/philosophical exemptions; many of the other states that allow philosophical exemptions require a notary signature or education from a healthcare provider prior to claiming such an exemption. Five states only allow medical exemptions and do not offer religious or philosophical exemptions. If HB 1377 were to pass, this would give parents yet another basis for an exemption and would further relax the already liberal school vaccination requirements. Additional exemptions are simply not necessary.

According to data from the ND Department of Health, North Dakota kindergarten exemption rates have increased most years. This past school year, personal belief (philosophical, religious) exemption rates were 3.91% (395 children). Up from 3.60% the previous year. Since the 2007-2008 school year, a 240 percent increase in exemptions has been reported in North Dakota. HB 1377, if passed, would continue and likely increase this dangerous trend.

NDSBA urges a Do Not Pass recommendation on HB 1377, and I would be happy to stand for any questions. Thank you.

NDMA
Est.1887 NORTH DAKOTA MEDICAL ASSOCIATION

House Human Services Committee
HB 1377
January 25, 2021

Chairman Weisz and Committee Members, I am Dr. Misty Anderson, president of the ND Medical Association. The North Dakota Medical Association is the professional membership organization for North Dakota physicians, residents, and medical students.

NDMA opposes HB 1377 and recommends a DO NOT PASS.

This bill creates vaccine safety standards at an unreasonable level. The Food and Drug Administration already applies a stringent approval process and through this process safety is paramount. The vaccine development process has been refined through the years and we know from past experience that the overwhelming majority of serious adverse events related to vaccination occur within weeks of receiving the vaccine.

Other provisions such as requiring the state health department to track vaccine injuries and disabilities would be redundant and added expense, since this is already tracked at the federal level.

More importantly, it takes a step backward in the face of public health by eliminating vaccine requirements for school-age children and health care institutions. The chances of a child getting a case of measles or chickenpox or whooping cough is low today due to the immunization requirements we have in place today. Let’s continue to keep our children protected.

Based on these concerns, we recommend a DO NOT PASS on HB 1377.

Thank you for the opportunity to testify today. I would be happy to answer any questions.

Misty Anderson, MD
President
ND Medical Association
Misty.anderson@sanfordhealth.org

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House Bill 1377
Human Services Committee
January 25, 2021, 2:45 p.m.

Good afternoon, Chairman Weisz and members of the Human Services Committee. My name is Molly Howell, and I am the Immunization Director at the North Dakota Department of Health (NDDoH). I am providing testimony in opposition to HB1377.

Before immunizations were available, diseases like diphtheria, measles, whooping cough, polio, *Haemophilus influenzae* type B and rubella caused severe illness, hospitalization and death in the United States. More than 15,000 Americans died of diphtheria in 1921, before there was a vaccine. Because of the successes of vaccines, many people have forgotten these diseases.

Most vaccine-preventable diseases are spread from person-to-person. Vaccines not only protect the individual receiving the vaccine, but they also protect others around them, including children and adults who are unable to be vaccinated for medical reasons or who have weakened immune systems. Most vaccines do not offer 100% protection to the individual who receives them, meaning sometimes those who are vaccinated can still be at risk of a vaccine preventable disease. The more people who are vaccinated, then the fewer opportunities there are to spread disease.

In addition to preventing disease, hospitalization and death, vaccination reduces costs. For every $1 spent on vaccines, the United States saves $10.90.[1] The vaccination of children born between 1994 and 2018 has saved the U.S. nearly $406 billion in direct medical costs and $1.88 trillion in total societal costs. Vaccination of one birth cohort (children born in 2009) will prevent ~42,000 early deaths, 20 million cases of disease, save $13.5 billion in direct costs and $68.8 billion in total societal costs.[2] In 2017, the Minnesota Department of Health spent $2.3 million in five months responding to an outbreak of 79 cases of measles.[3]

[1] https://doi.org/10.1542/peds.2013-0698
[2] Vaccines Are Cost Saving | Vaccinate Your Family
[3] MN Health Dept. Spent $2.3M During 5-Month Measles Outbreak – WCCO | CBS Minnesota (cbslocal.com)

Child care, school and university immunization requirements play an important role in increasing immunization rates and ensuring environments where children congregate are safe. North Dakota already has one of the most relaxed child care and school immunization policies in the United States. NDCC 23-07-17.1 allows medical, religious, and moral/philosophical exemptions. Parents simply have to sign a document prior to school entry to claim a religious, moral/philosophical exemption. North Dakota is only one of 15 states that still allow moral/philosophical exemptions; many of the other states that allow philosophical exemptions require a notary signature or education from a health care provider prior to claiming an exemption. Five states only allow medical exemptions and don't offer religious or philosophical exemptions.[4] States that have easily-obtained personal belief exemptions have higher rates of pertussis and measles.[5],[6] HB1377 supersedes NDCC 23-07-17.1 and is not needed, as a law and related rules are already in place to allow for exemptions. NDCC 23-07-17.1 and Administrative Rules 33-06-05 outline the process for claiming an exemption, documentation requirements, and exclusion of unvaccinated children during outbreaks.

HB1377 would prohibits employers, including hospitals and long-term care facilities from requiring influenza vaccine, putting staff, patients and residents at risk. Laboratorians may be required to receive rabies vaccine if working with specimens from potentially rabid animals. Many law enforcement agencies may require hepatitis B vaccination to protect employees against hepatitis B through needle sticks.

For the reasons I have outlined today, the NDDoH asks you to oppose HB1377. This concludes my testimony. I am happy to answer any questions you may have.

[4] States With Religious and Philosophical Exemptions From School Immunization Requirements (ncsl.org)
[5] Nonmedical Exemptions to School Immunization Requirements: Secular Trends and Association of State Policies With Pertussis Incidence | Infectious Diseases | JAMA | JAMA Network
[6] Individual and community risks of measles and pertussis associated with personal exemptions to immunization - PubMed (nih.gov)

My name is Stephanie Hager, and I am a resident of Mandan, North Dakota. I am testifying in SUPPORT of HB 1377.

January 25, 2021
Written Testimony of Salesha Olson in Support of HB 1377
relating to immunization exemptions

Chairman Weisz and members of the House Human Services Committee, I am writing in strong support of HB 1377.

It is common knowledge that health is a personal and complicated topic. However, it is uncommon to consider each person unique when it comes to vaccination schedules and recommendations. Medical choice should exist as a basic human freedom, now and always.

I'm aware that this is not a vaccine safety debate, however it is important to keep in mind that a statement from the United States Congress and acknowledged by the Supreme Court of the United States deems vaccines to be unavoidably unsafe. With that in mind, how can we NOT allow a person to exempt themselves from vaccination? There are a multitude of health conditions, allergies, and concerns that would prevent particular people from being able to safely receive a vaccination.

The right to choose an exemption should be a well-known and easily accessible option without beratement from medical providers, daycares, schools, employers, or anyone else.

I ask that you recommend a DO PASS on HB 1377 as originally written with no amendments.

Salesha Olson

Salesha Olson
Larimore, ND

Kyle Small

Re: Sixty-seventh Legislative Assembly of North Dakota

House Bill No. 1377

I work for a large oil-and-gas exploration company in the Bakken oilfield of North Dakota. For several months, employees and contractors within my company have been subjected to weekly COVID-19 testing as a prerequisite to access any company location or office building. A policy requiring mandatory vaccination has not yet been implemented, but many of us are legitimately concerned that it will be soon.

It has been a struggle to watch our individual liberties being incrementally encroached upon in the name of a virus that has an incredibly small mortality rate. As I, along with many others, have raised my concerns regarding an impending vaccination requirement to upper-management, I have been met with indifference and comments akin to “sure, you could refuse and get fired, but you’d probably be unable to find a job that didn’t require it.”

The proposal to allow for individual exemption based upon the listed conditions of the vaccine is a wonderful idea. And these conditions are highly reasonable. In circumstances where the typical exemptions regarding religious, moral, or philosophical convictions are removed, this proposal would ensure that individuals would not be forced to take a vaccination that has not been legitimately proven to be safe and effective.

I ask you to vote “yes” on House Bill 1377.

Thank you,

Kyle Small

Re: Testimony in favor of HB 1377

Attn: Committee Members,

I, Todd Kjelland am writing in favor of a DO PASS on HB 1377.

I am a former LTC worker (Sanford Health/ Good Samaritan Society) who has been directly affected by employment termination regarding corporate mandated vaccination policy. Besides the end result of losing my livelihood, I was harassed and discriminated against from July 2019 – September 2020 due to my filing for a religious exemption against the influenza vaccine. I have filed two complaints with the EEOC. The first is in administrative review. The second I have an additional interview in March 2021.

I would like to see legislative action to prohibit employers from mandating medical procedures as a requirement of employment. I believe by allowing this practice to continue, employers will have the precedent to force employees at will to become non-voluntary medical test subjects without future recourse.

In addition, Sanford Health, as well as any health facility which accepts Medicare/Medicaid, gains financially from forcing employees to be vaccinated or medically tested through CMS payment bonuses/penalties. This information is not freely disclosed to employees, thus violating Informed Consent laws for which forces employees to participate in medical procedures against their free will, inclusive of religious beliefs. This is Human Trafficking, a criminal action as defined by 18 U.S. Code Chapter 77, Title 18

I believe the practice of mandating vaccinations is not only illegal, but unethical and infringes upon my right to refuse medical intervention against my will.

While I am in favor of HB 1377, I would like to see additional verbiage to make sure this law does not negate doctor-to-patient, face-to-face informed consent requirements.

I believe many employees' rights can be preserved by taking legislative action now to assure our basic right to refuse unwanted medical testing and accepting injectables as mandated by employers is forbidden.

Todd Kjelland

113 Everett Ave

Park River, ND 58270

701-331-2956

Members of the House Human Services Committee,

I would like to express my support for HB 1377.

My name is Ashley Bruner, from Drake, District 6. As a citizen of North Dakota, I have the right and freedom to choose what happens to my body. I have the right and freedom to make informed decisions regarding medical procedures and/or medications. I have the right and freedom to choose to take vitamins, eat a healthy diet and get physical exercise. I weigh the risks and benefits, and make an educated choice for what is best for my own self (and that of my children).

Individuals facing an immunization requirement for any purpose, including as a condition of employment, or for children as a condition for school attendance, should be allowed an exemption. Citizens of North Dakota should not be subject to choose their jobs-their right to make a living, or the right to an education for their children, over their health and the risks of required vaccinations.

There is risk in all medical procedures, medicines and yes, there is risk in vaccines. Risks of vaccines include permanent disability or even death. Employers, schools, the State of North Dakota, etc. should have no right to demand something that includes these risks, without having an exemption. Vaccination is a personal health choice for an employee, student, etc. Where there is risk, there must be choice, and providing the exemption is that choice.

Maintain our rights and freedoms to choose in North Dakota!

I strongly support HB 1377 and encourage you to cast a Pass vote from this committee.

Thank you for your time and consideration!

Ashley Bruner

Drake, District 6

As a mother and American citizen I believe that it is of upmost importance that we pass this bill. It is a God-given right to maintain the liberty to make medical treatment decisions for yourself and children which is why vaccine exemptions are critical in order to uphold this right. Policies of any business or organization (including health care centers, hospitals, and schools) requiring a vaccination is an infringement on our Constitutional right to make medical decisions. These vaccine exemptions absolutely need made available and known, which is why I am in support of this bill.

Morgan Wisness

My name is Sarah Lepp and I am in favor of HB 1377. I agree that no school, business, employment should expect anyone to receive something that is not FDA approved, especially with the criteria listed in this bill. we have to have the ability to claim exemptions to ensure liability on the manufacturers of the vaccines. I agree there needs to be total transparency when it comes to these vaccines and all injuries, defects, and deaths should be reported and as they are currently not. Again, I support this bill and I would encourage a PASS. Thank you.

Vaccine Management Plan

North Dakota Department of Health

Scope

This plan represents a complete revision and consolidation of prior NDDoH plans related to vaccine management. Because a moderate or severe influenza pandemic puts the greatest stress on vaccine management, that will be the base scenario for development of this plan. Other scenarios to which this plan may apply are bioterrorism (anthrax, smallpox), community-based vaccination for a localized outbreak (e.g., meningitis) and seasonal influenza in which vaccine shortages are substantially impacting vaccine coverage of the population.

Response Goals for Pandemic Vaccination

- To maximize uptake of vaccine by the population;
- To ensure that those persons determined to be at highest priority for vaccination are vaccinated first;
- To ensure that specific population subgroups (e.g., age) receive the correct, FDA approved vaccine;
- To minimize the amount of time from receipt of vaccine in the state to administration;
- To maximize second dose administration as soon as possible after completion of the required interval after the first dose;
- To maintain the cold chain and security of the vaccine;
- To have vaccine allocation which is ethical and transparent;
- To ensure that adverse events associated with vaccine administration are captured and investigated as indicated;
- To minimize disease transmission which will arise from aggregating persons in vaccination clinics during a pandemic.

Assumptions For Pandemic Influenza Vaccination

- Vaccine for pandemic influenza will be administered to the entire population that accepts it.
- Vaccine which is specific to the pandemic strain will not be available until many months after the pandemic is identified, and once it becomes available, quantities will not be initially available to vaccinate all persons.
- Pandemic vaccine will be prioritized either to 1) high risk groups first, or 2) to high risk groups and critical infrastructure, depending on the nature of the pandemic.
- Receipt of vaccine into the state will be in proportion to the state population (about 0.2% of the US population), but may not take into account persons crossing over into North Dakota from other states.
- Initial vaccine dose will provide little, if any, protection against infection[1];
- Influenza is contagious during the 24 hours prior to symptom onset (making exclusion of all contagious individuals from vaccination clinics impossible) and vaccination clinics potentially have a strong anti-social distancing effect which, if not neutralized, may increase morbidity and mortality;
    - Anti-social distancing effect will be minimized by vaccination between waves.

[1] This assumption was not true for the H1N1 pandemic because the population already had some inherent immunity to H1N1, but it will remain as a planning assumption for most pandemics since it is likely to be true for many potential influenza pandemics (H5N1).

    - Some types of clinics (e.g., drive-through) are expected to minimize any anti-social distancing effect.
    - For indoor clinics, infection control procedures (screening for ill, cough hygiene, distancing between families) will be needed to minimize disease transmission.
- If vaccine for mass vaccination arrives during the first wave, rapid administration of the vaccine may not be possible in the face of high absenteeism among public health and health care staff.
- Second dose vaccination, if needed to secure immunity, will, in almost all circumstances, take precedence over first dose administration. That is, completion of immunity which is protective is more important than initiating immunity which is not protective. However, doses will not be held from a shipment to provide the second dose to persons who are not yet eligible to receive the second dose.
- Within NDDoH, the lead role for vaccine management policy will be taken by the Immunization Program of the Division of Disease Control. The Immunization Program will function as part of incident command under the Operations Section of the DOC, but will not be relocated to the DOC.
- The roles for the Immunization Program and the DOC in vaccination management will be different.
    - Immunization Program roles will include provider registration, vaccine ordering, allocation to registered sites, management and analysis of NDIIS, vaccine adverse events coordination, and communication with CDC Immunization Program.
    - DOC roles will be logistical management (including vaccine receipt, cold chain and distribution), public information and policy.
- In a moderate or severe pandemic for which vaccine is perceived as lifesaving, the vaccine may pose a security risk.

Refer to planning documents relevant to specific diseases (e.g., anthrax, smallpox) for assumptions for those conditions.

Background

Many factors that cannot be known prior to a major event will potentially affect vaccine management. These include the nature of the event (severity, public reaction to the pandemic and to the vaccine, impact on infrastructure), the characteristics of the vaccine (quantity available, timing, release rate, doses required, adjuvant required, toxicity, mode of administration, cold chain requirements and FDA approvals) and the response of the health care system. Each of these factors is discussed below.

<u>Nature of the Event</u>

In a pandemic setting, it is assumed that the entire population will be at risk and that the intent of the vaccine delivery process will be to reach every person with the vaccine. In an anthrax, smallpox or meningitis scenario, it is assumed that the vaccine will be targeted toward a much narrower part of the population actually at risk for illness; however, public and political pressure may result in broader use of the vaccine than is actually indicated (and broader adverse consequences). During a pandemic, the amount of public fear of the illness will likely be the strongest factor determining the extent of public uptake of the vaccine and the amount of political pressure.

In an influenza pandemic, it is expected that several months will elapse from the time the specific organism (clade) is typed to the time that vaccine becomes available, and all vaccine will not become available at the same time. This will result in prioritization of the vaccine. In the event of small impact on the national infrastructure, the vaccine will be targeted toward risk groups at highest risk of adverse outcome (e.g., pregnant women). If the pandemic is causing serious impacts on infrastructure, substantial portions of the vaccine will be directed toward persons responsible for maintaining the infrastructure. CDC plans call for this infrastructure allocation to extend to all critical sectors of the economy (e.g., transportation, energy production, communications) and not just the health care or emergency response sector. (See Attachment C.)

In a moderate or severe pandemic, timing of mass vaccine delivery would logically be impacted by concerns about the anti-social distancing effect of vaccination clinics. Mass vaccination during a pandemic wave, particularly for a vaccine which requires two doses to be protective, may actually increase the mortality rate. That is, providing the initial, non-protective dose in an anti-social distancing environment may increase illness rates while providing no protection. In some pandemic settings, waiting until after the wave is over to begin vaccination may be the best option for improving outcome, albeit an option of questionable political viability. Some regions of the state are prepared to deliver vaccine by drive-through clinics to minimize the anti-social distancing impact, but it is not clear that this could be done on a scale large enough for rapid vaccination of most of the population, and some regions have never exercised this approach[2].

Vaccine Characteristics

In an influenza pandemic, it is likely that two doses will be needed to achieve adequate protective antibodies. This might be altered by the use of an adjuvant. If a chemical (adjuvant) can be added to the vaccine when administered to increase the body's immunological reaction to the disease agent, less vaccine or fewer injections may be required. Mixing and matching of antigen and adjuvant at point of care may be required. Matching an antigen and adjuvant type from the first dose at the time the second dose is given may be needed. The exact combination of antigen and adjuvant administered for the first dose may also be needed for administration of the second dose. Introduction of adjuvants may cause public distrust of the vaccine since adjuvants have not previously been used in this country.

Influenza vaccine is currently being developed primarily using chicken embryos as the cell culture medium. This process is slow. During the H1N1 pandemic, the vaccine was released late and in a trickle. By the time substantial amounts of the vaccine were available, much of the public appeared to be "over it," particularly since the pandemic was mild and the initial wave was on the decline in many states. Cell culture-produced vaccine is now appearing

[2] It is not clear what the relative throughputs for drive through clinics and walk-in clinics are. However, an additional barrier is availability of venues for drive-through vaccination which are protected from the weather, have sufficient space and flow for many lanes and can safely handle vehicle exhaust.

which could decrease the wait time after the identification of a pandemic to vaccine availability, although it still may take several months to produce vaccine.

A transition to intradermal vaccination may result in improved vaccine coverage when quantities of the antigen are limited, since intradermal vaccination requires less antigen to achieve the same level of immune response now seen with intramuscular vaccination. Some vaccine for intradermal is now available but represents only a small fraction of the influenza vaccine in use.

If the influenza subtype is known in advance of the pandemic (e.g. H5N1), the U.S. government may have developed vaccine to the subtype which is not clade specific. That is, the vaccine would not offer substantial protection to the recipient, but may be quite adequate as a priming dose to improve response to the clade-specific vaccine. It is unlikely that generic subtype vaccine would be available to vaccinate a large percentage of the population, but may be sufficient to start the vaccination sequence for certain high risk subgroups or for infrastructure personnel.

Vaccines vary substantially in risk of adverse events. Influenza vaccine is very safe, but if given to millions of people, a few serious adverse events are inevitable. Some persons take this information and miscalculate their relative risk of receiving the vaccine versus not receiving the vaccine and refuse vaccination. Alternately, smallpox carries a higher risk of adverse events of the available vaccines. For this reason, and because smallpox spread can be quite effectively controlled using ring vaccination techniques, the preference of public health will be to avoid mass vaccination. However, fear of smallpox with political pressure to vaccinate everyone may make this impossible. People will tend to overestimate their risk of illness relative to the risk of the vaccine and demand vaccination[3]. This is not likely to be as big a problem with anthrax since the disease is not contagious, but a larger group than is actually exposed may demand prophylaxis. In the case of both smallpox and anthrax, unlike pandemic influenza, sufficient vaccine should be available immediately for all persons who need it.

Another characteristic of influenza vaccine that makes mass vaccination complicated is the number of different manufacturers and formulations with varying FDA approvals. Some products will be approved for infants, toddlers, pregnant women, immunocompromised persons, persons with egg allergy or persons over 65; however, a typical product will be approved for some of these categories but not for all. During H1N1, as vaccine trickled in, the specific products had to be allocated to specific providers according to the type and number of patients they expected to vaccinate who were eligible to be vaccinated with the vaccine that was available. This not only made allocation complicated, but was confusing to

[3] Just because people demand vaccination is not sufficient reason to provide it, any more than people demanding a narcotic should be given a prescription in the absence of a medical indication for treatment with a narcotic. Political mandates can alter public health action by taking the decision to vaccinate or withhold vaccination away from public health.

providers[4]. To the degree possible, Disease Control tried not to give many different vaccines to the same provider over time.

During H1N1, vaccine came in a variety of package formats including multi-dose vials, single dose pre-filled syringes and single dose nasal vaccine. The pharmaceutical industry has increasingly moved toward single dose formats due to higher safety. The primary impact of the dosage form on vaccine management is the amount of cold chain space required to store and transport the vaccine since single dose packaging is much bulkier. A marked increase in the amount of vaccine received in single dose containers could pose a storage problem at some local sites; however, the NDDoH warehouse is expected to have sufficient space to maintain the vaccine that it receives for re-distribution.

Health Care System Response

The health care system currently provides the vast majority of vaccinations; for influenza this is estimated at around 80%[5] of the doses given (exact number is pending). However, during seasonal influenza, a large percentage of the population does not request influenza vaccination. During the 2012 – 2013 flu season, only 48.9% of North Dakotans were vaccinated[6]. During a pandemic, more people will be requesting vaccine, more doses will be needed and the health care system may be overwhelmed by clinical care. Not only may the private health care system be unwilling to pick up the large number of extra vaccinations which need to be provided, they may not even have the resources to vaccinate the patients they would have vaccinated during a normal influenza season. What vaccine is not administered by the private health care sector will need to be administered by public health, pharmacies, long term care facilities or other non-traditional vaccine providers (e.g., contract vaccinators, employee-based clinics).

Physical Vaccine Management and Cold Chain

For a bioterrorism related outbreak, vaccine would likely come to the state via the SNS. For all other circumstances, NDDoH would request and receive vaccine through CDC's authorized contractor which in recent years has been [redacted] for North Dakota shipments). During H1N1, CDC authorized the direct shipment of full cases (100-dose increments) to providers authorized by the state to receive that much vaccine at one time. Because vaccine was released slowly, relatively few providers could be allocated full cases. Consequently, a high percentage of the vaccine had to be received by the NDDoH warehouse and re-apportioned into smaller quantities for shipment to specific sites. During the H1N1

[4] For example, a provider needing to vaccinate a seven year old child may have been able to do so with vaccine provided to his or her office one week but not with vaccine provided the following week with vaccine only approved for children eight and older. Keeping track of which vaccine can be given to which people and which vaccine the clinic has could be very difficult. During a normal influenza season the provider would have ordered only vaccine that he or she was familiar with.

[5] The percentage of H1N1 vaccine provided by various provider types has not been calculated, but it is believed that LPH provided a substantially larger percentage of the H1N1 vaccine than it normally provides of seasonal influenza vaccine.

[6] CDC Fluvax View: http://www.cdc.gov/flu/fluvaxview/reports/reporti1213/reporti/index.htm

pandemic, shipments of vaccine went to well over 100 public and private destinations, although not all these destinations would receive vaccine from every shipment.

Most vaccines, including influenza, are expected to be received as liquid that must be stored between 35º and 46º Fahrenheit (2º – 8º Celsius)[7]. Vaccines for some conditions (e.g.., smallpox) have traditionally shipped frozen and need to remain frozen. Mass shipment of influenza vaccine during winter months proved to be difficult due to the need to protect the vaccine from moderate warmth and severe cold[8]. The only methods proven to be reliable by trial and error were shipping in controlled temperature environments (i.e., portable refrigeration units in temperature controlled vehicles) and certified shippers, which had a small payload for the shipping weight making them an expensive and inefficient distribution option except in select circumstances (e.g., sites a long distance from Bismarck).

During H1N1, NDDoH had concern about the [redacted] shipments that it received. The shipments were packed in large Styrofoam containers which did not have thick walls. No temperature loggers were included in the shipments. NDDoH found that even containers with much thicker walls could not reliably prevent freezing during harsh winter conditions for the lengths of time which commercial shipping companies kept the vaccine containers out of doors[9]. In the event that forecasted temperatures dropped so low that [redacted] refused to ship, NDDoH developed plans for retrieval of vaccine from [redacted] directly using a temperature controlled aircraft. It never became necessary to implement this plan during H1N1. Substantial changes in federal shipment practices could occur for the next pandemic, but are not expected at this time.

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[7] Vaccine removed from refrigeration to a warm environment does not instantly reach ambient temperature and 46º is not a firm number above which the vaccine loses potency. Vaccine can likely tolerate periods (days to weeks) of moderate temperatures above 46º without substantial loss of potency (the warmer the temperature, the faster it will degrade), but this varies by vaccine and the temperature stabilizers added to the vaccine. At least one study found insignificant degradation of influenza vaccine after two weeks at room temperature (see abstract at http://www.ncbi.nlm.nih.gov/pubmed/16150515). Another study found no loss of influenza vaccine potency for live attenuated vaccine after three freeze-thaw cycles (see abstract at http://www.ncbi.nlm.nih.gov/pubmed/22341195). However, even if vaccine can stand freezing, it is typically packed with rubber stoppered bottles of diluent (e.g., sterile water). If the bottle diluent freezes, the stopper is forced part way or entirely out of the bottle so that it is no longer guaranteed to be sterile and must be discarded.

[8] Vaccine leaving the warehouse by commercial shipper during the winter would be packed in a warm room, be picked up by the commercial carrier where it might remain outside in an unheated truck overnight, be transferred to the cargo hold of a plane (variable temperature), again spend time on a truck, go to a warehouse belonging to the shipping agent, go back into a plane, go back on a truck and finally arrive at its destination where it may or may not be moved immediately to a refrigerator.

[9] It is not clear that this concern has been fully addressed at the federal level. Although NDDoH never proved that any Xxxxxxxx material froze, temperature monitoring was not present in the periphery of the containers near the walls.

Provider Recruitment

During H1N1

The first step in the vaccination process during H1N1 was provider recruitment. This was initiated upon CDC instructing to the states to begin; CDC also provided most of the language for enrollment documents. NDDoH held a series of video/webcast sessions to educate providers, including pharmacies, clinics, long term care facilities, hospitals and local public health. This was followed by a memo sent through multiple communication channels (e.g., email, HAN contacts, professional associations) providing information about the enrollment process. Since enrollment was the only means for providers to acquire the vaccine, it is thought that nearly all eligible vaccine providers chose to enroll. Enrollment occurred over a website; a paper enrollment option was not provided in order to eliminate data entry.

Enrollment was by vaccine delivery site. This meant for large health systems, which make up the bulk of health care providers in North Dakota, multiple enrollments would be necessary, one for each delivery point. Specific information required for shipping was collected at the time of enrollment and populated into a lookup table in the CDC vaccine ordering software. This information was used by both [redacted], to ship directly to providers, and by the warehouse for direct delivery. The registration site also provided a contact who could be called to ensure that someone would receive the vaccine when it arrived at the door.

Another action initiated by enrollment was ensuring providers where signed up and prepared to use NDIIS. Upon receipt of an enrollment request, the Immunization Program looked up the provider site in NDIIS to ensure that that site was using NDIIS. If not, the practice was contacted and required to enroll in NDIIS before they could become a vaccine recipient site.

The final action initiated by enrollment was a request to providers to estimate the number of each risk group that they believed they could vaccinate, so this information could be used as part of allocation. This is discussed below under allocation. To help providers make this estimate, they were provided with information from orders made during regular flu vaccination seasons.

No specific guidance was given to providers about accounting for out-of-state residents coming to North Dakota to get vaccinated. For Grand Forks, Fargo, Wahpeton and the western edge of North Dakota substantial numbers of people flow into the state for health care services. That is, the number of doses provided to out-of-state residents by North Dakota would substantially exceed the number of North Dakota residents who got their vaccination out of state. (No allocation adjustment was made by CDC for this during H1N1.)

The vaccine was provided free of charge, but vaccine providers were permitted to charge an administration fee up to a maximum set by CDC. The administration fee could be collected from insurance or out of pocket from the recipient, but providers were not allowed to turn anyone away for inability to pay[10]. Additional requirements set by CDC for vaccine eligibility

[10] No mechanisms were in place during H1N1 to ensure that non-pay patients weren't turned away, but anecdotal reports of this were not received by the state so attempting to monitor this is not needed unless a problem becomes evident.

included agreement to meet vaccine storage requirements (which may include continuous monitoring[11]), and agreement to abide by the prioritization of vaccine to the specified high risk groups CDC specified. The NDDoH required use of the NDIIS for vaccine administration documentation.

During H1N1 in two regions of the state, the local public health unit was allowed to become the local vaccine recipient and redistribution point for vaccine within that regional area. This was done at the request of those local public health units. While it had the advantage of decreasing the number of distribution points for NDDoH, it also created a substantial number of problems including provider complaints (e.g., unfair allocation, lack of transparency, excessive control, increased delay), primarily from one of the two areas. Having an additional drop-off and redistribution point, also created another opportunity for a break in cold chain.

Provider Recruitment for Future Pandemic

The process used for provider recruitment during H1N1 worked well. No substantial change is anticipated in the method unless changes imposed by CDC require it. It was not necessary during H1N1 to recruit additional providers after the initial enrollment due to the large percentage of providers who chose to enroll. In a future pandemic, if insufficient numbers of providers of specific types (e.g., pediatricians, obstetricians) are initially enrolled, these needed groups will be targeted specifically with enrollment messages. An enrollment cutoff date would be stated to try to get all providers on-board and trained before mass vaccination was needed, but in practice, enforcement of the cut-off date would be unlikely.

Non-traditional vaccinators (e.g., pharmacies, other private vaccination groups) received their allocations relatively late during H1N1. This was due to an incident command decision to preferentially direct vaccine toward providers providing longitudinal care of patients, and due to greater numbers of persons in clinics with influenza risk factors. If a future pandemic is more severe, the anticipated large gap in vaccination by clinic-based vaccination providers would have to be filled by public health and non-traditional vaccinators. Current law allows pharmacists to vaccinate against influenza down to age five. The greater need for vaccinators during a more severe pandemic may make an executive order allowing pharmacists to vaccinate young children advisable.

Future policy related to local redistribution will default to a strong no; however, it is possible that some compromise might have to be reached. If that becomes necessary it is proposed that LPH must:

- Obtain the consent of all provider recipients in the area; and,
- Develop and provide to NDDoH for approval a vaccine allocation and redistribution plan which addresses:
    - Communications;
    - Allocation algorithm including fairness and optimal use of vaccine;
    - Security;
    - Cold chain and storage;

[11] Many providers who have implemented continuous monitoring are finding substantial problems with vaccine storage which is necessitating replacing vaccine storage equipment.

- Timeliness;
- Transportation;
- Documentation (NDIIS); and,
- Transparency.

If these criteria could not be met, the vaccine would be distributed directly to providers by NDDoH.

Procedures for Vaccine Ordering by the State

During H1N1

A set amount of vaccine was allocated to the state by CDC as the vaccine became available; however, the state still had to order the vaccine. A computer program provided by CDC used for the ordering process during periods of non-pandemic was also used during H1N1. To complete the ordering process, the Immunization Program had to:

1) Populate the recipient lookup table which included the names and addresses of all registered vaccination sites eligible to receive vaccine (i.e., registered). This information was obtained from the data generated by the registration website, but had to be manually transferred into the ordering software.
2) Examine the specific vaccine (how supplied, manufacturer, quantity) which had been allocated to the state (provided daily by spreadsheet from CDC, even if no new vaccine was allocated during the previous 24 hours). From this information, the specific amounts of each vaccine to go to each provider were input into an excel spreadsheet.
3) Adjust quantities to try to reach full boxes for those destinations near that level, so that vaccine at least would not have to be repackaged and shipped from the NDDoH warehouse. This adjustment had to be done in a manner which was not unfair to smaller volume vaccinators who would never get enough vaccine at one time to make a full carton.
4) Orders were then entered into CDC's vaccine ordering system on behalf of providers. Orders had to be in 100-dose increments by vaccine type. Orders for providers receiving less than 100 doses by vaccine type were aggregated and ordered to be sent to the NDDoH warehouse for redistribution.
5) Update the allocation information into NDIIS (manual entry) and generate a packing slip for the warehouse in NDIIS which would describe the specific vaccine, quantity and destination. These packing slips were then sent to the warehouse by email or fax.
6) Populate a website where providers could look up how much of each vaccine they had been allocated.
7) For those sites which used a local regional health broker, the warehouse shipping point was ultimately different from the data in NDIIS (i.e., actual provider who administered the vaccine), so that information had to be corrected.

Vaccine Ordering for Future Pandemic

CDC is now using new vaccine ordering software, VTrcks, which should allow direct uploading of spreadsheets rather than manual entry. Additionally, NDIIS now has a vaccine ordering system where providers can enter orders for vaccine directly and then the orders are reviewed by Immunization Program staff, and if approved, electronically uploaded to VTrcks. The Immunization Program will be responsible for training providers as to how to use the NDIIS vaccine ordering system. During a pandemic, Immunization Program staff may have to

enter orders into the NDIIS on behalf of providers. A substantial burden of data entry would be expected, so Disease Control would work with the DOC to pre-plan additional assistance in the Immunization Program. Whether these needs would be filled by existing NDDoH staff redirected to emergency response or whether by temporary employees would be determined at the time.

One option for ordering in a pandemic would be to tell the local provider how much vaccine their site was allowed to order, but require the provider to go in and order the vaccine. The ordering system allows all vaccine orders from within the state to be reviewed and approved by NDDoH before the order goes to CDC for processing. The state would need to ensure that providers did not order a greater quantity of vaccine from the state allocation or order a different type of vaccine then they were told they could have. Vaccine orders in excess of the state allocation would mean that someone at the federal level would determine who would or would not receive vaccine in the state. To avoid this, the state will need to stay within its allocation limit.

An additional change that would streamline the ordering process would be a modification to NDIIS to improve its handling of spreadsheet data without manual re-entry of information. However, this would take a financial investment that is not available at this time.

The NDIIS ordering system does give providers a vaccine shipment tracking number, so they are able to track vaccine shipments, however, providers receiving vaccine from the NDDoH warehouse would not receive this tracking number. Also, if orders are directly entered into VTrcks, providers would not see this tracking number in NDIIS. A method would need to be developed to notify providers of vaccine shipments.

Vaccine Prioritization and Allocation

During H1N1

Prioritization of vaccine during H1N1 followed CDC guidelines; however, NDDoH did attempt to sub-prioritize CDC authorized risk groups to ensure that those at very highest risk were vaccinated first. This created some confusion on the part of the public re: who was eligible be vaccinated, and inconsistency between local sites with some vaccine providers moving on to vaccinate other sub-groups while others were still waiting for sufficient vaccine to reach the highest priority groups. Because the H1N1 pandemic did not threaten infrastructure, no infrastructure allocation was necessary other than the targeting of health care workers.

The allocation process during H1N1 was awkward and time consuming. Disease Control would determine number of vaccine doses of what type had been allocated to the state and assign each dose to a provider based on the best estimate of population need and provider ability to reach high risk groups. This would be input into the ordering system. When the vaccine arrived, Disease Control would use the NDIIS to generate a packing slip in NDIIS and transmit this to the warehouse by fax or email where it would be used to pack the right amounts and types of vaccine for each destination.

For allocation, Disease Control relied heavily on provider estimates of how many people in each risk group the site could vaccinate. After Disease Control received the vaccine quantity request, the amounts sometimes required adjustment. For instance, if the sum of providers serving a catchment area were ordering quantities believed to exceed likely ability to reach

persons needing vaccine, estimates were adjusted down. One local public health broker site that ordered enough vaccine for the entire population in their region had their allocation adjusted down, since this would not be achieved and was substantially out of line with estimates from other sites. (Sites estimating high tended to receive vaccine faster relative to the population size than sites which estimated low.)

As each provider was allocated vaccine, this was tracked on a cumulative basis with calculation of expected vaccine coverage in that area. Adjustments were made to the allocation of vaccine based on these estimates. Even with these adjustments, substantial unevenness in vaccine availability across the state appeared to exist. To some extent this was unavoidable, but better methods for determining how much vaccine to allocate to each provider were needed.

As vaccine come in which was suitable for specific risk groups, it was allocated to all providers who reporting being able to vaccinate that risk group. One problem with this was that it meant a provider might have to deal with many different vaccines with different approved indications rather than vaccines the provider was familiar with.

Priority Vaccination

The current plans for prioritization of vaccine are dependent on the severity of the pandemic and the potential for the pandemic to impact infrastructure. CDC has provided some planning guidance for covering critical infrastructure sectors including health care, transportation, energy production, community utility, community services (e.g., grocers) and others. The prioritization would not ignore high risk groups like pregnant women, but a substantial quantity of the early vaccine would be directed away from adverse outcome-based allocation to cover infrastructure. This would not happen in a milder pandemic in which damage to infrastructure was not expected to be substantial. DES has maintained lists of critical infrastructure which could be used to help make the allocation.

For the health care and public health sector, NDDoH has also planned for within sector prioritization. Hospitals especially would determine internally who received vaccine first in order to preserve its internal infrastructure. Generally ER and ICU personnel would be highest priority followed by other direct care providers, but portions of the support infrastructure (e.g., dietary, housekeeping, maintenance) would have be vaccinated reasonably early. For guidance on how within sector prioritization would occur and be documented, refer to the pandemic influenza plan re: prioritization and to attachments A and B.

Entities which received vaccine which required population prioritization (e.g., hospitals) would need to document how each dose was allocated. Since during a pandemic, people would be expected to become seriously ill or die due to vaccine shortage, the entities allocating vaccine within their system would need to be able to defend the appropriate use of the vaccine at a later date (e.g.., vaccine was not diverted away from high priority groups to lower priority group with more authority).

During priority vaccination only, a local vaccine broker may be used. A vaccine broker is a partner institution at the local level which has agreed to receive vaccine and administer it

according to state and federal guidance. Only local public health units (LPHU) and hospitals are designated as eligible vaccine brokers in current plans[12]. Only a vaccine broker would be designated as a ship-to site during priority vaccination.

The roles of the vaccine broker include:

- Receipt and storage of vaccine, including maintenance of cold chain;
- Security of the vaccine;
- Administration of the vaccine to those authorized to receive it;
- Maintaining documentation of administration and reason for vaccination priority, and providing that documentation on request;
- Ensuring that persons given their initial dose receive an appropriately timed second dose;
- Allocation of vaccine to end user organizations (duty of LPHU only);
- Establishing clinics or PODs for mass vaccination (duty of LPHU only), and;
- Splitting vials of vaccine among priority recipient groups (duty of LPHU only).

For additional details related to roles during priority vaccination, see Attachment C.

Vaccine Prioritization and Allocation during a Future Pandemic

The NDIIS can calculate where (provider) people routinely go to get vaccinated. This could provide a reasonable estimate of how much each destination should expect to receive, but would still have to be modified by provider input since the percentage of the vaccination burden that will be left to LPH or other vaccinators may vary from provider to provider. For instance, Hettinger Clinic would need to plan to vaccinate substantial portions of Bowman, Slope, Hettinger, Grant and Adams Counties, and could receive an allocation based on the percentage of people it normally vaccinated from each county in its catchment area. This might result in a substantially better algorithm than that based on provider estimates of coverage alone. An allocation module in the registry would have the potential to improve the allocation process, but creating it would likely be expensive and no funds have been identified for this at this time. Another possible resource is SAS code written in Tennessee intended to assist with the allocation process. This software has not been evaluated in North Dakota to date.

[12] One problem that has developed since the H1N1 vaccinations is the rapid population growth in Western North Dakota and shortfall in health and public health services for the population. In this area of the state at least, it may be necessary to encourage employers to register to receive and administer vaccination, if they have the capability to do that. Employer-based vaccination would still be required to follow risk-group prioritization requirements and would need to provide estimates of how many of each risk group they could vaccinate. Estimates from NDIIS would not be available to help allocate vaccine to employers.

To the extent possible, Disease Control would attempt to provide the same vaccine to a provider consistently rather than giving them whatever vaccine is available. If providers must track the indications of many different vaccines, they are likely to make errors and deliver vaccine to individuals for which the vaccine available is not approved. This effort to create some consistency for providers would have to be balanced with the need to fairly distribute vaccine to the entire population. That is, if no shipment of the vaccine which the provider previously received is expected soon, they would be allocated a different vaccine so that the patients served by that site could have access to vaccine.

The use of adjuvant would provide a new challenge to vaccine management. It will not be known whether one or more adjuvants will be used or how they will be managed or administered until the event. Some additional training will be required for providers, but that is not expected to pose a substantial problem. NDIIS is being setup to manage data related to adjuvant. This is discussed further in the section allocation of vaccine for second vaccination.

During H1N1, traditional vaccination providers (clinic-based) providing longitudinal care and local public health were given allocation priority over pharmacies or contract vaccine providers in the allocation process. Although this was felt to be advantageous at that time, it would be less likely to be advantageous in a situation in which outpatient care was being overwhelmed with sick patients. This would remain an incident command decision during a future pandemic. Allocation will also need to consider special destinations like state penitentiary and other custodial care institutions and cross border vaccinees in how vaccine will be allocated. Consideration may rest heavily on the epidemiology of the virus (e.g., susceptibility to serious disease outcomes). For instance, H1H1 has not had a propensity to cause epidemic illness in long term care facilities, so allocation to LTC was less urgent during the last pandemic. See section on vaccination of vulnerable population for additional discussion.

Example:
In county X with a population of 5,000 of which 1,000 are children, 50% of adults (2,500) and 50% of the child population (500) usually get an annual influenza vaccine, of which 30% of the vaccinations provided to children in the county are done by Clinic A (150), 50% by Clinic B (250), and 20% by LPH (100). For adults 50% are provided by Clinic B (1,250), 10% by Clinic C (250) and 40% by LPH (1,000). If Clinic A reports that it will attempt to vaccinate any children presenting for vaccination (guess maybe 40% of child population or 400 children) and Clinics B and C expect to only vaccinate the number of people they would normally vaccinate in a typical influenza season, that is B (250 + 1,250) and C (250 adults). If 90% of the population is expected to be vaccinated with pandemic vaccine, that leaves 250 children ((1,000*0.9) – 650=250) and 2,100 adults ((4,000*0.9)-2,500=2,100) that LPH or other non-traditional vaccinators would vaccinate in that county. If two doses are required, the total allocation to that provider for that county would be double the number of people that they would expect to vaccinate. Each provider would also receive an allocation for each of the other counties they served.

Communication to the Public and to Providers

During H1N1

On a single instance early in the vaccine delivery process, part of a shipment of vaccine was thought to have possibly frozen. The vaccine was administered before a determination was made that it should be discarded. NDDoH decided to report the vaccine loss in the media and ask that those who received the vaccine be re-vaccinated. Other states also froze some vaccine but NDDoH was the only one known to have reported it to the media. The NDDoH response was consistent with DOC policy of media transparency during a disaster.

Information about influenza and vaccination were communicated through the media by weekly press conferences, radio and TV ads. This was in addition to information which was coming from CDC through the media. The hotline was open and received calls, but many callers were looking for clinical information (e.g., about care of an individual) that the hotline was not able to provide.

Although the amount of information flowing to the public was large, misinformation remained a problem. For example, as the pandemic progressed it became increasingly difficult for the state to give a uniform message about who was eligible for vaccination. Initially all local providers were targeting the same high risk groups, and it was intended that local areas not progress to vaccinating new groups until the DOC notified them that the entire state would begin to vaccinate the same new groups. In part because vaccine availability and demand were uneven, some local areas began to run out of eligible and willing vaccinees before they ran out of vaccine, so they moved to new target groups without consulting the DOC. Rumors about low vaccine safety were also common nationwide although the extent to which that impacted vaccine uptake was not known.

Communicating local vaccine availability to the public during H1N1 was a challenge that was never fully solved. The vaccine delivered to a particular provider could be provided by NDDoH because NDDoH made the allocation decision, but local clinic-specific information which the public needed to know to seek out vaccination could not be updated by the state. This included eligibility, how many doses the clinic had for what age or risk groups and when vaccination clinics were being held. Although local providers (e.g., LPHU) may have used methods specific to their area, the primary method used by the state was the Flu-Finder website.

The intent was that each provider or clinic would update this information in Flu-Finder as the information changed, but this was not done consistently. The only incentive offered to providers was the ability to get information to their patients and to decrease the number of phone calls to the office. Substantial pressure was applied by the federal government to the states related to this issue, but that did nothing to alleviate the problem[13]. The website was adequate, but the updating was not, and NDDoH did not control the updating.

Communication during a Future Pandemic

[13] DHHS went so far as to call state governors to complain about problems with up-to-date vaccination information in Flu Finder without first consulting with state health agencies. This created a firestorm of protest.

The communication of general information about the pandemic and vaccine worked reasonably well, particularly with federal investments in nationwide education, and is unlikely to be greatly different in a future pandemic. However, communication about the specifics of vaccine availability at local sites needs to improve (see below).

During a moderate or severe pandemic, some issues will be difficult to communicate to the public such as declining quality of care and allocation of ventilators. Priority vaccination may be one of these issues since it may be viewed as inherently unfair by some persons. Priority vaccination is about valuing the protection of some people over others. This not likely to be as much a problem for vaccination of high risk group as it will be for vaccination of priority infrastructure, particularly those outside of health care. Since the recommendation for priority infrastructure vaccination will come from the federal level, the federal level is also likely to take the lead in justifying it to the public.

A couple of methods may be useful for getting provider offices to update the Flu-Finder website. A requirement to update Flu-Finder can be included in the initial registration agreement signed by the provider as a condition of receiving vaccine, as well as requiring contact information for one or more persons in each office who were assigned the responsibility for updating. Incentives may be helpful but have not been identified. Yet, as long as it is left to the providers' initiative to update this information, gaps will occur.

A more reliable approach would be for NDDoH to assume responsibility for updating the website. This would require incident command to collect this information from provider offices, probably by daily or every other day phone calls to all registered provider offices. This information would then be posted by NDDoH to the Flu-Finder website. Taking on this task would require additional personnel time, either by using additional NDDoH non-EPR staff in the response or by hiring temporary employees. In a moderate or severe pandemic, additional personnel time to make phone calls to provider offices may not be available due to high absentee rates.

Heavy dependence on a website to communicate the needed information may tend to limit access for some people to this information; however, the information is complex and changes often, so other easily accessible statewide alternatives are not apparent. Some alternatives include reverse 911, mass text messages through Amber Alert, large clinic reverse 911 systems or National Weather Service alerts. Problems with these systems include 1) triggering the use of several of these would require that the information had a substantially higher urgency than was the case in H1N1, and 2) complex information which is locally specific and changing frequently would be a barrier for these methods. Social media use may be successful but would have similar limitations to the Flu-Finder website. Local communications (newspaper, public access channels) can reach local populations with provider specific messages about availability and may be the best option, but one better employed by local public information providers. Local public health could be asked to be responsible for collecting and communicating vaccine availability within their jurisdiction, but many local public health units are small and may have very thin staff due absenteeism. Complete loss of public health services in some local jurisdictions is possible due to absenteeism since staff depth is so small.

No mechanism was in place to evaluate the success of communication systems in H1N1, but anecdotal information suggests a substantial problem. In a future pandemic, it would be helpful to determine if alternative communication strategies being employed were meeting the information need. Although not without bias, one simple approach would be the addition of a pop-up survey on the Flu-Finder website and questions asked of callers to the hotline. The BRFSS could be used with less bias, but is more difficult to alter and would have a substantial delay (e.g., one or more months until prior months data became available).

Warehouse Vaccine Processing

During H1N1

During H1N1, the warehouse received cases of vaccine which had to be split among multiple delivery points. These arrived in large Styrofoam containers delivered by commercial carrier. The vaccine was transferred into alarm-monitored, walk-in refrigerators. Allocation schedules were received as packing slips produced by NDIIS prior to actual receipt of the vaccine and faxed or emailed to the warehouse by Disease Control. All the designated sites were plotted on a map and eight cluster routes were defined for delivery[14]. The vaccine was sorted by provider and route and routing sheets were created. Vaccine for each route was put into a holding container (basket) in the refrigerator for loading at 6:00 am the next morning.

The next morning, all the vaccine in a single container was placed in a portable refrigerator, a glycerin thermometer with lead wire was placed among the vaccine and the lead wire was attached to the external temperature display of the thermometer. One route sheet was put on a clipboard with route instructions and another route sheet was attached to the top of the portable refrigerator. Each refrigerator was numbered and the number was added to the routing sheets.

The drivers would leave the warehouse in time to arrive at their first destination after the site had opened to receive it (usually 8:00am). The route driver called the recipient contact for each site a few minutes before arrival. If the contact could not be reached, the driver called the DOC and requested the DOC to make contact with the destination. On arrival at the site, all the vaccine for that site was removed from the refrigerator to a Styrofoam cooler and carried into the building, where it was transferred into the refrigerator. If the site had any coolers or shippers to return the warehouse, these were picked up by the driver. Routes were intended to be no longer than 12 hours. To keep the length of the routes down, far distant destinations (e.g., Divide County) received their allocation by certified shipper shipped by commercial carrier. The vaccine recipient shipped the certified shippers back to the warehouse once emptied.

It was not intended that the driver stay overnight with any vaccine, but return to the warehouse to report-in that same afternoon. If a driver had to stay overnight, the driver would take the vaccine refrigerator into the hotel room and plug it in. If the driver was unable to deliver all the vaccine (e.g., the recipient site refused the vaccine because they

[14] In large rural areas like North Dakota, cluster routing in which routes look like lollipops on a stick are more efficient that loop routes that look like a horseshoe.

had all they wanted), the vaccine was returned to the warehouse and reallocated for the next shipment.

Several problems had to be overcome (during and after the pandemic) until final procedures were established. These included:

- Non-certified shippers could not always maintain temperature during extreme weather. Shipping switched to controlled temperature refrigerators in temperature controlled vehicle cabins, and certified shippers.
- Refrigerators initially used were hard to set and did not reliably hold temperature. The refrigerator could be plugged into the cigarette lighter, but did not have battery backup. They were replaced with vaccine refrigerators with battery backup.
- Drivers were not initially instructed to carry vaccine into the destination building in coolers. This upset some recipients so procedures were changed.
- Attempts to use SNS software called TourSolver v. 2 were not successful. The faster way to route was by hand which proved to be quite adequate for this state. Many iterations of TourSolver have been released since then, but it may not be valuable for this purpose in this state.
- Disposable temperature monitors were not found to be reliable enough and could not be externally monitored. The disposable thermometers had a plus or minus two degree margin of error. Glycerin thermometers had a plus or minus one degree margin of error and could be externally monitored.
- DOT drivers "wore out" over the course the outbreak. The DOC switched to a contract service to transport the vaccine to its destination. This worked well.
- Certified shippers needed to be pre-cooled before loading to help them maintain the correct temperature. This resulted in a procedure change.
- Although no frozen vaccine was used during H1N1, it was used in other vaccination projects. Vaccine refrigerators can manage frozen vaccine. Packing frozen vaccine in shippers is problematic since there is no reliable source of dry ice in Bismarck.
- Two vaccine refrigerators can be run off the cigarette lighter of a truck, but not in a smaller vehicle due to insufficient amperage.
- If a refrigerator is unable to keep temperature and the time to route completion lengthy, the vaccine can be dropped off at a LPHU (if so directed by the DOC) until the problem is solved. I reality, the vaccine is not so sensitive to a modest temperature rise that that should be necessary, but the freeze-thaw threshold for that vaccine should not be crossed.

Communications between the warehouse, the DOC and Disease Control evolved over the course of the pandemic and seemed to work well during most of the course of the response. Communication from providers to the DOC or Disease Control did not always work as well. Often the first indication NDDoH got that a particular provider had all the vaccine that that clinic wanted was when the vaccine was refused at the door. Most clinics would make provisions to receive vaccine after hours if they were notified to expect it. After hour delivery was an occasional problem for private providers, but a bigger problem for some small local public health units. Communications from NDDoH to providers improved over the course of the H1N1 response. The next allocation of vaccine was posted on the FluFinder website for each provider including when to expect delivery. The only place substantial problems remained was in one of the areas which was managing vaccine allocation for its region. Substantial provider complaints were received from that region.

Warehouse Vaccine Processing during Future Pandemics

A future pandemic would follow the procedures outlined above except:

- Data loggers (with probe in glycol) which can be externally monitored and have an alarm (different from the refrigerator alarm) have replaced glycerin thermometers. These are periodically re-calibrated.
- Vaccine refrigerators do not need to be plugged in unless there is an overnight stay. They will hold temperature over the course of the delivery route. Batteries will re-charge overnight.
- During H1N1, NDDoH attempted to receive, route, pack and deliver vaccine it received within 24 hours of receiving it. Although the policy prevented vaccine from sitting in the warehouse when it was needed by vaccine providers, it placed considerable strain on resources both in Disease Control and the warehouse. Whether to continue this policy would be an incident command decisions. In a serious pandemic when personnel resources become stretched and tired, this may be unreasonable.
- Additional contacts other than the primary contact for each destination are held in NDIIS; this information needs to be transmitted to the DOC.
- For shipped vaccine, recipients have had a hard time learning how to read the temperature log. More training is required and is being undertaken by Disease Control. Recipients must look at the logger at the time of vaccine receipt to ensure the vaccine is still good.
- Transportation capacity may be impaired in a severe pandemic. This may result in less frequent shipments and possible use of a greater combination of transportation resources to move vaccine.
- Higher volume of vaccine may cause a problem for certified shippers, but portable vaccine refrigerator capacity should not be taxed.
- Having all vaccine for a single destination inside a single, breathable container (e.g., laundry mesh bag) inside the refrigerator would prevent driver errors in selecting vaccine for each destination. This was not perceived to be a serious problem during H1N1, but occasionally errors were made.
- Destination will sign for the vaccine when they receive it.
- Sites which may have difficulty having someone available after hours to receive the vaccine need to make arrangements with an alternate recipient such as hospital or LTC facility which would be able to store the vaccine until it could be picked up by the vaccine provider.

Vaccine Documentation

During H1N1

Data from the vaccine recipient (vaccinee) was collected at the clinic site on a form designed for that purpose. The form could be scanned using an appropriate fax machine which would upload it into NDIIS.

- Persons completing the form often made little effort to write into the designated scannable boxes on the form.
- The program reading the forms did not perform adequately. This lead to data being dropped or scanned in as gibberish, including some critical information.
- Information required before the data could go into NDIIS was often unreadable or unavailable. There was no way to ensure that all the information needed was collected

at the time of the encounter. Mandatory fields had to be removed in order for the data to go in.
- Form scanning was often delayed.
- It was not possible for the person scanning the form to know of the form had been successfully transmitted or not.
- Data going into the registry often duplicated individuals rather than merging with existing individuals, mostly due to the poor data quality from the scan.

Eventually data was redirected to the DOC where manual data correction occurred.

Vaccine Documentation during Future Pandemics

Collection of all vaccine administration data during a pandemic will be important, and data needs to be available as soon as possible to permit assessment of coverage and reminder recalls for second dose administration. Consequently, all providers must agree to submit the data into NDIIS if they wish to become vaccine providers. The Immunization Program will be responsible for training providers as to how to use the NDIIS.

With the adoption of electronic health records (EHRs) by many health systems, data from the EHR can automatically document the vaccine record in NDIIS in real time. As of the time of this writing, about 60% of records were going into NDIIS electronically by EHRs. One of the limitations of EHR is inflexibility of the systems that generate the data for NDIIS. That is, if a new field is wanted in NDIIS, the EHR cannot easily be altered to capture the information. Pharmacies and local public health account for most of the remaining vaccine that is not transferred by EHR. Few vaccinations given in LTC facilities are currently being entered into NDIIS so that data is being lost (a new grant has been received to bring LTC into NDIIS). Additionally, IHS is not yet electronically submitting immunization data to the NDIIS.

It is assumed that all or nearly all mass vaccination records will need to be collected on paper forms for later entry into NDIIS, and a very substantial portion of the vaccines given in a pandemic could take place in mass clinics. Those forms blanks would be created by Disease Control at the time of the pandemic with content adjusted to the specific pandemic situation. To encourage getting data into NDIIS, the proposed policy is not to ship additional vaccine to a site which does not account in NDIIS for administration of all the doses previously sent (that is, every dose is accounted for by administration to a specific individual). Failure to enter data into NDIIS would limit ability of that provider to receive more vaccine; the assumption will be if the data is not in NDIIS, the vaccine dose has not been delivered. This is already being done with Vaccines For Children (VFC) vaccine. (Whether this could actually be enforced during a pandemic would depend on the circumstances.) Another alternative to ensure timely entry of data into NDIIS would be for the paper records to be sent to NDDoH for entry here. Substantial numbers of temporary staff would be needed to accomplish this. Forms would be destroyed once the data is entered.

Entry of data into NDIIS from a paper record has not proven to be problematic; matching to the correct person for data updating appears to be quite good. Time requirements for data entry into NDDoH for persons without existing records is not expected to be a serious problem since about 80% of all North Dakotans already have a record in the system.

NDIIS can generate recall reminders for persons who received the initial dose of pandemic vaccine once the required time between doses had elapsed. The system can produce line lists to upload to an autodialer which could deliver a generic message to persons needing to return to the clinic[15]. A more specific message would be better, especially if it is determined that to be important that a person's second dose be exactly the same vaccine (e.g., type, manufacturer) as the first dose, or at least the same adjuvant. In that case, just because sufficient time had elapse for the person to receive the second dose would not mean the specific vaccine would be available in the community. It might prove difficult for the patient to show up at the right place and time to get the correct vaccine, even if they knew what vaccine and adjuvant they needed. A reminder letter could be generated when the vaccine the person needed was available to them locally, but this would be labor intensive and expensive, and likely impractical during a pandemic when hundreds of thousands of persons were receiving two doses of vaccine. Furthermore, by the time the letter was received, the vaccine the person needed might already have been used.

Adverse Event Reporting

Influenza vaccines are rarely associated with serious side effects, but any vaccine or drug given to enough people will cause serious adverse reactions in rare instances. The addition of adjuvant to the vaccine, even if very safe, will increase the risk of adverse reactions, although the risk profile of the vaccine will depend on specific adjuvant used with it. The NDDoH currently recommends that providers directly report adverse events using an on-line form to VAERS (www.vaers.org). Previously, providers reported adverse events using the NDIIS. Since these events are not able to be electronically submitted to VAERS, the immunization program changed this process. During a pandemic, VAERS reporting in NDIIS could be turned back on. During H1N1, CDC pushed states to receive adverse events and investigate those that were unexplained and serious. CDC is likely to do this again during the next pandemic. Not all vaccines are quite as safe as influenza vaccine, and some are substantially less safe.

Wasted and Recalled Vaccine

Some wastage of vaccine is inevitable. Currently this is reported to NDDoH through the NDIIS. The Immunization Program is responsible for training providers on how to use the NDIIS vaccine return/waste system. If vaccine is recalled, NDIIS will be able track who received the specific vaccine that was recalled in order to make contact with the provider to quit using the vaccine.

Security

In the event of a serious pandemic in which many otherwise healthy persons are dying because insufficient vaccine is available to protect them, vaccine security may become a substantial problem. In that event, security will be handled as outlined in the SNS for other types of materials distribution.

Mass Vaccination Clinics

Medical Waste

[15] Use of autodialers in North Dakota is currently against the law; however, this could be altered during a pandemic by executive order.

NDDoH has acquired the materials needed for safe containment of large amounts of medical waste. Individual public health units have their own local arrangements with providers of services for disposal or destruction of the waste material. During a pandemic it is expected that there will be some problems with managing large amounts of sharps generated by mass vaccination within the capacities of existing disposal companies. If necessary, LPHU will store the waste in sealed containers in locked rooms until the capacity of disposal companies is sufficient to receive and destroy the excess medical waste material.

Infection Control and Social Distancing

Public health workers routinely administer vaccines, including influenza, and are trained in universal and bloodborne pathogen precautions. It is possible that a public health worker shortage might lead to vaccine administration by some workers who are not normally allowed to administer vaccine, but could do so under circumstances of a Governor-declared disaster. Ensuring that these employees are adequately trained in infection control will be the responsibility of the vaccinating entity.

Prevention of transmission of influenza during a pandemic vaccination clinic is a serious concern, since presence in a pandemic vaccine clinic may increase the risk of exposure but receiving the vaccine will not provide immediate protection against disease. In other words, a vaccination clinic will have a potentially powerful anti-social distancing effect. There are several approaches that may be used to minimize the adverse social distancing:

- Universal covering of the nose and mouth – Masking appears to be at least somewhat effective a limiting the droplet spread of a person who is sneezing or coughing, even if its effectiveness at preventing another person from inhaling the droplets is less clear. Although sufficient surgical masks may not be available to put on every person, clinics may need to require every person to have their nose and mouth covered with a mask or a cloth at all times.
- Education – Continuous education of those who enter the clinic regarding respiratory etiquette, avoiding touching surfaces, frequent hand washing, not touching the face with one's hands, and maintaining a distance between families of at least three feet may be needed.
- Use of outdoor space or drive through clinics – Not all local sites have exercised drive through clinics which should more effectively limit spread between families, but many of the large jurisdictions in the state have exercised it. Throughput would likely be a problem for large scale vaccination is needed quickly.
- Clinic intensity – Lower clinic throughput may decrease the risk of transmission; if is not likely that if this will be known although if it permits greater distance between families coming in for vaccination, it should be partially effective. Lower than expected throughputs may also be necessary if an acute shortage of public health workers makes staffing large clinics impossible.

Logistics

Vaccination at the LPHU may be logistically easier than POD-based vaccination when the number of doses to be administered remains small. It will be the option of LPHU to determine when the number of doses is so large that transition to POD-based vaccination would be more efficient. The details of POD-based operations are contained within local POD planning documents which are part of the SNS documentation at the local level.

Local POD plans[16] encompass both drug distribution and mass vaccination. Initial plans were developed for antibiotic prophylaxis, but have been modified to address vaccine specific issues. Issues unique to vaccination, when compared to mass dispensing of oral medication include:

- Workforce vaccinators and person drawing up vaccine/adjuvant– Even though an executive order by the Governor made under the state disaster act would provide opportunity to use providers to give vaccines who don't normally give vaccinations, the availability of providers who will be capable of administering an injection will be limited. In addition the greater physical demand of the work compared to pill dispensing will place more limitation on the number of hours a vaccinator can work without rest.
- Cold chain – Mass vaccination sites may have limited refrigeration capacity which will require LPHU to transport the vaccine from the storage site to the mass vaccination site and maintain the vaccine within temperature at the clinic site. Requirement for cold chain maintenance may limit the amount of vaccine that can be brought to the vaccination site at any one time.
- Number of persons to be treated – Unlike antibiotic dispensing which provides multiple courses of medication to the head of household, vaccination clinic will have to reach all persons.

Vaccination of Special and Dependent Populations

The approach to vaccination of special and dependent populations will vary from one LPHU to another, but is similar to plans developed for SNS drug distribution.

- Homebound – Vaccination of homebound will take place after mass vaccination clinics have largely completed general population vaccination. This reflects the somewhat lower risk of infection of persons who are not mobile, but more especially the low efficiency of reaching the population compared to mass clinics. In most LPHU, this will involve home visits by public health personnel.
- Outreach to custodial institutions – Delivery of vaccine to institutions which have custodial responsibility for the health of their population, when health care personnel are not on-staff to provide the vaccine, will require a visit by public health vaccine providers. Generally, public health personnel will be dispatched to go on-site after mass vaccination is completed, but institutions may be prioritized for earlier vaccination based on risk assessment. Some institutions will be able to vaccinate their own residents. These would include hospitals and clinics, long term care, some schools (if operational at that time), state penitentiaries.
- Language barriers - North Dakota has a low percentage of non-English speaking persons generally, but substantially higher in some areas. Approaches vary depending on the percentage of the population which is not English speaking. In areas with relatively higher numbers of non-English speakers (e.g., Fargo area), interpreters will be available within clinics for common languages. For areas with low numbers of non-English speakers (as well as for languages which are spoken by few persons in all parts of the state) telephone-based interpretative services will be provided with the help of designated persons assigned to assist those with special needs in the clinic.

<u>Vaccination of Reservation Populations</u>

Some reservations have PODs which may be able to vaccinate. Otherwise, persons on reservation will need to seek vaccination at the nearest public venue off reservation. For both Spirit Lake and Turtle Mountain reservations, these venues are likely to be close. Fort

[16] Each of the 62 local POD plans includes an MOU and points of contact for both site command structure and building access including multiple access numbers. The plans are located in the secure document library of NDDoH.

Berthold is likely to be able to vaccinate locally since they have had the most stable POD structure. Standing Rock has not been able to sustain a POD in the past across changes in tribal leadership. Because of the large distance to the nearest substantial city (Mandan), and accessory transportation plan has been drafted and may need to be activated. Standing Rock is trying to re-establish a POD at this time. The NDIIS should provide the ability to track vaccine coverage among American Indians.

Emergency Use Authorization Vaccination

The provisions of an EUA requires that persons receiving the vaccine know that the vaccine has not completed full approval, but that it is being offered due to an emergency. Potential recipients would need to know the risks and benefits of receiving the vaccine or of refusing the vaccine, any alternatives that they have to the vaccine, and an assurance of their right to refuse the vaccine. In the event that NDDoH needed to administer vaccine under an EUA, the agency would expect to receive substantial information from DHHS detailing the following:

- Target recipients;
- FDA conditions for use;
- Information regarding risk and benefit of use;
- Additional information to be collected (in addition to contact information and information collected as part of the vaccination process for a non-EUA vaccine);
- Guidance regarding enhancements to adverse event reporting and case investigation which would need to implemented as additional safeguards.

NDDoH would provide training of all persons who would be administering vaccine under an EUA. Training would be provided using video conferencing over Stagenet and BTWAN (hospital network), as well as by web-casting if needed to reach additional entities not tied into the videoconferencing system.

Investigational New Drug Protocol

IND protocols require specific information collection, especially related to adverse events, a detailed consent signed by each recipient and patient follow-up. Because of its high burden of documentation, investigational new drug protocols would be impossible to implement on a mass scale; however, implementation within a narrowly targeted population could be feasible. Should IND vaccine use be necessary, NDDoH will look for additional guidance specific to the vaccine being used under IND including vaccine recipients to be targeted, additional documentation requirements and reporting. The NDDoH IRB would be prepared to review the protocol on a priority basis. Prior to use of the IND protocol, NDDoH would ensure that it had:

- FDA site approval for administration;
- IRB approval by the NDDoH IRB (or a CDC IRB which NDDoH has recognized as a substitute IRB);
- A designated principal investigator. Since the vaccine would be administered under the authority of NDDoH, the State Health Officer would likely be the PI.
- A research protocol which incorporated FDA requirements for data collection and patient follow-up and to which no changes would be made without IRB review and approval.
- A reporting pathway defined for adverse event communication back to DHHS.
- State training of all persons who would be administering vaccine under an IND protocol including informed consent requirements, record keeping and reporting. Training would be provided using video conference over the Stagenet (IT backbone for state) and BTWAN (hospital network), as well as by web-casting if needed to reach additional entities not

tied into the videoconferencing system. State software used to register for and track training would be used to confirm participation in training for each site before the IND protocol could be used.

Until the time of the event, it will not be known what the extent of the utilization of a vaccine would be under an IND protocol. Once this is known, vaccine would be allocated to specific sites and duplicated consent form/protocols (duplicated through central duplication services of the state) would be distributed through the SNS system along with POD materials for clinic setup.

ATTACHMENT A
HOSPITAL PREPAREDNESS PROPOSAL FOR PANDEMIC INFLUENZA VACCINE DISTRIBUTION PRIORITIES

At this time, NDDoH is expecting that direct care providers in hospitals will be first line recipients of pandemic influenza vaccine. It is likely that initial vaccine shipments will not be sufficient to vaccinate all direct care providers; consequently, establishing a priority system for vaccination pre-event is necessary. At this time, no guidance is available for development of such a system.

Hospital preparedness representatives to the four regional HPP meetings were asked to describe a priority system for allocating the expected small numbers of vaccine doses which would initially be available to distribute to health care workers. Prioritization does not include other personnel who may be assigned vaccine outside the health care sector such as critical community infrastructure and public health.

To divide health care personnel into priority groups, the hospital planning committees were asked to only consider prioritization based on their perceptions of the approach that would save the most lives. In keeping with that overarching goal, it was recommended that they consider 1) whether the person had specialized skills which were necessary for patient care and difficult to replace (e.g., ventilator management); and 2) the level of exposure that the employee would likely have to persons infected with the pandemic strain. Since in smaller hospitals, many of the staff serve multiple roles, it was decided that the prioritization level of any individual would be based upon their highest level of priority. For example, a nurse covering both the floor and the ER would be considered ER for purposes of prioritization, since it was at a higher priority level.

PRIORITIZATION RECOMMENDATION

The following prioritization schedule represents a consensus of the hospital preparedness representatives. Tier 1 is numerically ordered with each numerical group being completed with two doses before starting the next numerical group. Lower tiers are not subdivided. If insufficient doses are available to vaccinate an entire tier (e.g., Tier 2A) or category (Tier 1 Category 1) that was eligible for vaccination, it would be up to the health care institution to decide who within the tier or category would receive the vaccine. It is expected that facilities would attempt to vaccinate some persons from across the categories represented within a tier in order to maintain all functions to the degree possible.

Tier 1

1. Critical Care Staff [ICU, ER, and Specialty Physicians (ICU, ER, and Infectious Disease)
2. Hospital designated urgent care staff (walk-in/triage area to minimize traffic in ER)
3. Primary Care Nursing Staff (RN, LPN, CNA)
4. Emergency Medical Services staff
5. Incident Commanders
6. Radiology Staff
7. Respiratory Therapy staff
8. Primary care physicians
9. General Surgeons

10. Laboratory/phlebotomy staff
11. Anesthesia
12. Inpatient pharmacy

Tier 2A

- All other physicians, nurses, CNAs
- Admitting staff
- Housekeeping
- Bio-medical staff
- Dietary staff
- Laundry staff
- Incident Command staff
- Chaplain staff

Tier 2B

- Medical records staff/ward clerks
- Central Supply staff
- Long term care staff
- Home health staff
- Social Workers/Discharge/Case managers
- Psychiatry staff/mental health providers
- General Incident Command Staff
- Security staff

Tier 3

- Purchasing staff
- Maintenance staff
- Information technology staff
- Rehab Therapy
- Admin Support
- Finance staff

Tier 4

- Any other staff without direct patient contact
- Family members of Tier 1 hospital staff

ALLOCATION

It is expected that when NDDoH receives the first shipment of vaccine, the Department Operation Center (DOC) would determine the percentage of vaccine that would go to several different domains (e.g., local public health, state public health, health care, first responders, municipal workers, and disaster management). The relative allocations between these groups will be an incident command decision guided by the situation in the state when the initial vaccine is made available and any CDC requirements. It is expected that the vast majority of doses would be allocated to health care. Based on the number of doses of vaccine available for allocation to that domain, recipient institutions would be asked to supply the number of persons who fall into each Tier 1 category. Incident command would designate which categories were eligible for vaccination, and recipients would have to agree to abide by these eligibility criteria in order to receive vaccine. For the purposes of this discussion, community

health care staff (within minimum care facilities) will be considered for vaccination based on their assigned role, as if they were hospital staff.

The available doses would be divided proportionate to the number of personnel in each of the categories that could be covered. It is the intent of NDDoH that the vaccine would be sent to destinations within 24 hours of receipt by the state. Facilities receiving vaccine would be asked to provide the vaccine to staff within 24 hours of receipt, keeping careful records of who received the vaccine and why. The receiving facility would need to provide for the security and storage of the vaccine including maintenance of cold chain.

If insufficient vaccine is available to vaccinate an entire priority group (e.g., ICU and ER), the hospital would need to decide how to allocate the vaccine. The decision needs to be logical and ethical. It could be by lottery, epidemiological risk (e.g., age), professional risk (e.g., assignment to care for pandemic patients specifically), availability to work through the pandemic or any other defensible method. The method chosen should be documented and as each person is vaccinated, it should be documented why that person was vaccinated and not someone else. These records would be made available to NDDoH on request, which would only be likely if questions were raised about ethical allocation. Given that vaccine receipt may determine whether certain persons live or die, public inquiry may occur after the pandemic.

PUBLIC HEALTH PANDEMIC INFLUENZA VACCINE PRIORITIZATION

Once the world enters into pandemic influenza, an effective vaccine is not expected to be available for several months. Although it is not possible to know how the situation will unfold, we are expecting that as vaccine is produced, it will be released to states in small quantities, and into the public sector (NDDoH) rather than the private sector. Past experience suggests that it will be up to states to determine how the vaccine will be allocated within their states within broad guidelines supplied by CDC. At this time, it is anticipated that two doses would be required by each vaccine recipient in order to acquire any protective immunity. Persons who had received one dose would be given a second dose (assuming sufficient time had elapsed) before an unvaccinated person was given their first dose.

It is expected that when NDDoH receives the first shipment of vaccine, the Department Operation Center (DOC) would determine the percentage of vaccine that would go to each of six domains as follows: local public health, state public health, health care, first responders, municipal workers, and disaster managers (listed in no particular order) in addition to any risk categories designated as high priority by CDC. The relative allocations between these groups will be guided by the situation in the state when the initial vaccine is made available. That is, different shipments of vaccine might be divided among the domains differently based on the situational assessment. It is anticipated that the largest quantity of vaccine in each shipment would be allocated to the health care domain.

The NDDoH Department Operation Center would designate which categories were eligible for vaccination and potential recipient institutions would be asked to supply the number of persons who fall into each specific eligible category. Recipients would have to agree to abide by these eligibility criteria in order to receive vaccine.

Priority
The tier table below represents the recommendation of local public health for vaccine prioritization. The final decision on eligible categories would be made by the NDDoH Department Operation. In the recommendation below, each tier and each numbered category within each tier below represents a higher priority level than the tiers or categories below it. Vaccination would be completed in the highest level tier or category before moving on to a lower category or tier. Regardless of category or tier, provision of second dose to those already having received their first dose takes precedence over provision of any first dose, assuming sufficient time as elapsed since the first dose was given.

<u>TIER 1:</u>

1. Nursing Staff
2. Public Health Officer (with direct patient contact)
3. Field Surveillance Workers

<u>TIER 2:</u>

1. PH staff at-risk of exposure*
2. Incident Command Staff

- Incident Commander
- Business Manager
- PIO
- Community members filling these functions
- EPR Coordinators

4. IT Staff

TIER 3:

1. Program Staff
2. Janitor
3. Board of Health Members
4. Primary and secondary POD people/managers
5. Families of Tier 1

* Persons having direct patient contact other than those listed above.

Local Vaccine Brokers

A local vaccine broker is a partner institution at the local level, typically a local public health unit or hospital, which has agreed to receive vaccine and administer according to state guidance and federal guidance. The role of the vaccine broker would include:

- Receipt and storage of vaccine including maintenance of cold chain;
- Security of the vaccine;
- Administration of the vaccine;
- Allocation of vaccine to end user organizations;
- Maintaining documentation of administration and reason for vaccination priority and providing that documentation on request;
- Ensuring persons receiving their initial dose receive an appropriately timed second dose, and;
- Setting clinics or PODs for mass vaccination.

Only a vaccine broker would be eligible to receive and administer the vaccine for priority vaccination of infrastructure. This would not be true of priority vaccine for demographic risk groups. All domains which were allocated doses would have to report to the vaccine broker in order to have the vaccine administered. If both a hospital and local public health unit were designated vaccine brokers, it is expected that in most cases, the local public health unit would be the primary broker responsible for splitting vials among domains and administering those doses.

ATTACHMENT C

Vaccine Management and Administration Roles During Priority Vaccination

Local Public Health Roles

By its nature, vaccination is considered to be primarily a local public health function. Local public health assumes this duty under legislative mandate and contract with NDDoH. The following are the anticipated roles of local public health:

- Receiving vaccine and signing for receipt (chain of custody)[17];
- Administering vaccine to all non-hospital priority recipients;
- Ensuring that vials which need to be split between two different groups are appropriately divided. This includes splitting vials for hospital employees when only part of the vial is allocated to hospital personnel. Those hospital employees receiving vaccine from a split vial will need to go to the LPHU to be vaccinated, unless other arrangements have been made with the LPHU.
- Ensuring that vaccinees receive their second dose as soon as possible after they become eligible for the second dose;
- Maintaining records for all priority recipients which include the reason why the person was selected for priority vaccination;
- Providing whole vials to institutions which agree to 1) perform self-administration and 2) maintain required vaccination records. (See section on custodial care.)
- Maintaining the vaccine between 35°and 46° at all times, and provide documentation of cold chain records;
- Maintaining refrigeration space in excess of daily, non-pandemic requirements sufficient to hold a local allocation equivalent to one dose per person – Given the uncertainty of potency of the vaccine and hence the number of vials of vaccine which might be received at any time, it is difficult to know with certainty the amount of refrigeration space required.
- Maintaining cold chain transportation from vaccine storage sites to public health operated clinics. That is, vaccine will be received at the LPHU; however, POD sites, one or more per region, may be at a different location. This will require transporting the vaccine from the LPHU to the vaccination site and storage of the vaccine at the site. (Vaccine which is released to other institutions for self-vaccination will also have to be kept cool, but this is the responsibility of the receiving institution. LPH would need to take care that it does not release vaccine to an entity which is packaging it for cold chain transport;
- Setting up and operating vaccine clinics of sufficient capacity to administer expeditiously the quantity of vaccine ready for administration. When vaccine quantities are small, vaccinations will occur at LPHU offices with transition to POD sites for large volume administration. The point of transition from office to POD will be at the discretion of local public health;
- Establishing hotlines which can receive reports of vaccine adverse events and forwarding adverse event reports to NDDoH;
- Entering data into the North Dakota Immunization Information System (NDIIS);
- Providing public communication in cooperation with regional and state public information officers.

Hospital Roles

[17] The receiving agent for vaccine within each local public health unit is the designee of the incident commander for the institution. NDDoH will make direct contact with the agency operations center for notification of vaccine shipments and signing custody transfer forms.

- Receiving shipments of vaccine from manufacturer or shipping agent and maintaining security and cold chain[18];
- Administering vaccine to own employees and volunteers, unless arrangements have been made specifically with local public health to complete this;
- Selecting individuals for priority vaccine within the guidelines provided by the state;
- Ensuring that employees due a second dose receive it in a timely manner;
- Maintaining records for all employees given priority vaccination including the reason why the person was selected for priority vaccination;
- Entering data into the North Dakota Immunization Information System (NDIIS);
- Receiving reports of adverse reactions caused by the vaccine and reporting that to NDDoH.

NDDoH Roles

- Designating the priority recipient groups based on pre-determined state and federal guidelines provided (responsibility of incident command in the DOC);
- Determining shipment allocations;
- Providing to the federal shipping agent the list of ship-to sites and the quantities to be shipped to each destination for each shipment;
- Receiving shipments from the manufacturer or their shipping agents and re-packaging vaccine for shipment to smaller geographic areas as necessary.
- Approving redistribution of vaccine if indicated -- If all persons within the approved priority groups in the jurisdiction of a LPHU have been vaccinated, but vaccine remains, the LPHU will call the Department Operations Center (DOC) of NDDoH which will determine whether to permit use at the local site or to re-allocate vaccine to another LPHU jurisdiction for use with priority designees in the approved groups (unlikely unless quantity of vaccine remaining unused is large). NDDoH will coordinate the transfer of the vaccine between the public health units if this becomes necessary.
- Reviewing adverse reactions to identify those of high severity or of an unusual nature which require investigation to assess the likelihood that the reaction was vaccine-related, or identify any reasons why reaction occurred (e.g., presence of a relative contraindication or absolute contraindication to vaccination). See section on adverse event reporting for additional detail.
- Providing aggregate reports to CDC in the manner requested by CDC. NOTE: In some circumstances, shipment sites will differ from administration sites (e.g., multiple PODs within the jurisdiction of a single health unit);
- Providing oversight to the NDIIS system and coordinating system changes with Noridian (Blue Cross/Blue Shield of North Dakota) which administers the software;
- Analyzing results from the NDIIS system to provide estimates of coverage, identification of local areas which appear to be experiencing barriers to rapid completion of vaccination, identification of individuals substantially overdue for second dose vaccination and identification of number of persons ready for second dose vaccination (for purposes of vaccine allocation);
- Taking the lead in working with the PIO for public communications about priority vaccination. It is expected that not all persons will willingly understand why they or their family members were not selected for priority vaccination. NDDoH will attempt to provide transparency to the process through media messages.
- Ensuring staff at the state level who are to receive priority vaccination are vaccinated. (State personnel prioritized for vaccination will be vaccinated through their local public health unit in the same way as priority vaccinees of other infrastructure institutions.)

[18] The receiving agent for vaccine within each hospital is the designee of the incident commander of the institution. NDDoH will make direct contact with the agency operations center for notification of vaccine shipments and signing custody transfer forms.

ATTACHMENT D

Prioritization of Infrastructure

Summarizing information for critical infrastructure recommendations other than the above from The Prioritization of Critical Infrastructure for a Pandemic Outbreak in the United States Working Group

www.dhs.gov/xlibrary/assets/niac/niac-**pandemic**-wg_v8-011707.pdf.

:

Tier 1	Law enforcement personnel Fire services personnel Key government leaders
Tier 2	Electricity sector personnel Natural gas personnel Communications personnel Water sector personnel Critical government personnel Community suppt. & emergency mgt. (e.g. Red Cross
Tier 3	Transportation sector personnel Food and agriculture sector personnel Banking and finance personnel Pharmaceutical sector personnel Chemical sector personnel Oil sector personnel Postal and shipping personnel Other important government personnel

Sector	**Tier 1 Functions**	**Tier 2 Functions**	**Tier 3 Functions**
Financial	• Federal funds, foreign exchange, and commercial paper; • U.S. Government and agency securities; • Corporate debt and equity securities. • Sufficient critical personnel to operate and maintain minimum cash availability to the public through the ATM network (1 ATM per bank branch office).	• Obtain cash on a broader basis through the ATM network • Maintain electronic payment systems (checking, wire transfer, ACH, retail lockbox, credit/debit card) throughout a pandemic.	

Chemical	50% of critical • Production and plant first-line management; • Production, plant and system assemblers and operators; • Material recording, scheduling, dispatching, and distributing; • Industrial machinery mechanics and machinery maintenance workers; • Transportation and material moving workers; and • Healthcare and safety and occupational health providers	Other 50% of critical personnel	
Commercial facilities	50% of the most critical • Lodging • Real estate • Retail maintenance • Media	Other 50% of critical personnel	
Communications	% of criticals • Wireless service providers; • Wireline service providers; • Other communications service providers; • Manufacturers, suppliers and vendors; • Networking companies; • Information Technology companies that characterize themselves as having a communications infrastructure or provider-related role; • Communications-related system integrators; • Owners/operators of infrastructure used within the sector including cable systems, other operators and broadcasters; • Trade and other associations representing sector members; • Infrastructure owners who have national assets used in the Emergency Alerting Systems		
Emergency Services	• Fire • EMS • Law Enforcement • Emergency Management • Local Jail/Corrections Officers • Dispatch		

Electricity	• Transmission System Operators • Distribution System Operators • Power Plant Operators • Outage Response Line Mechanics • Substation Operators • Substation Technicians • SCADA Technicians	• Maintenance Line Mechanics • Power Plant Maintenance Mechanics • Customer Service Representatives • Substation Maintenance Mechanics • Material Handlers, Management, Finance and Accounting • Regulatory Affairs, Engineers	• All remaining power plant personnel • Line mechanics • Substation mechanics • Dispatchers • Supply chain • Customer service • Finance • Accounting
Oil and Natural Gas	Mission criticals for: • Oil and Natural Gas Extraction • Petroleum Manufacturing • Petroleum Merchant Wholesalers • Gasoline Stations • Pipeline Transportation (Natural Gas)	Business criticals for: • Oil and Natural Gas Extraction • Petroleum Manufacturing • Petroleum Merchant Wholesalers • Gasoline Stations • Pipeline Transportation (Natural Gas)	
Food and Agriculture	None identified		
Health Care	See Above		
IT	Those providing onsite presence to customer support.		
Nuclear			
Postal and Shipping (Public sector)	10% of critical employees in • Field processing • Movement and delivery	20% of criticals for maintenance of service	
Postal and Shipping (Private sector)	5% of criticals in • Aviation • Truck delivery • Warehouse and material management	15% of warehouse and management	

Transportation	Criticals in • Aviation air traffic controllers and critical specialty commercial pilots; • 50 percent of maritime crew members and the most critical port workers, such as crane operators; • Some critical skilled maintenance workers • 50 percent of the most critical railroad locomotive engineers, operators, and maintenance workers; • 50 percent of total drivers and support personnel for critical specialty cargos and vehicle types.	Remaining 50% of criticals	
Water and Waste Water	Not defined		

Support HB 1377

The current schedule has vaccines that used other vaccines as the placebo and not an actual inert substance. This is NOT the gold standard that pharmaceutical companies and the FDA talk about. I support the ND DOH website monitoring the injury and disease rate following or caused by vaccination and not just in lieu of vaccination. Proving that the death rate from the vaccination MUST be less than that of the disease is pertinent. The fact that there is no liability to the manufacturers, this has removed the will to be safe because they are going to make money no matter the outcome. Exemptions are in place for a reason and no pharmaceutical should be mandatory. There will always be a subset of the population that is susceptible to injury from any pharmaceutical and if you make something mandatory, then you are in turn giving those susceptible people a possible death sentence.

Amanda Saueressig

Strong support for HB 1377

I strongly support HB 1377 to provide transparency within the system and to truly allow informed consent with immunizations/vaccines. If the proposed criteria were required, then informed consent can truly happen. Those that strongly believe in their decisions will have a fair and just path to exemption.

I currently feel the ND Health Department, medical offices/clinics, media, CDC, WHO provide a very one-sided picture with immunizations/vaccines. This does not allow for full transparency for people to make the best decision for themselves and their children. These resources of information should be providing neutral information to allow the person to form their own opinion and make the best decision for themselves and their children.

I feel it is in the "common goods" best interest to be able to seek an exemption if important information is missing when making such an important decision. The decision to vaccine/immunize is not taken lightly. There is a "social norm" surrounding immunization that has prevailed which causes shame and fear. This is only because the information readily provided is one-sided verses neutral.

Passing this bill is a huge step in the right direction that shows how our incredible state of ND is challenging the country to demand transparency and neutral information to allow the best decision to be made for all people. Let's set the right standard!

Respectfully submitted in support of HB 1377,

Jennifer Vesey

1/24/2021

My name is Diane Kadrmas and I am in favor of HB 1377. I feel that every vaccination needs to be personal choice and not up to any employment, business, school or government entity to decide regardless of emergency status or non emergency status we may be in. We are finding that there are other treatments that can be given to prevent or treat certain diseases that may be more effective than a vaccination. Forced vaccination for the ability to work, education, shopping or any licenses would be an infringment on personal rights given to up by our forefathers and fought for by our veterans.

Greetings, my name is Jessica Kuntz, and I am writing to SUPPORT HB1377 regarding immunization exemptions. I believe this goes back to personal choice and responsibility. We should oversee our own heath choices. We should not have to worry about your jobs being in jeopardy or our kids' educations taken away for an immunization of any kind, but certainly, not for one that has not been through the proper testing protocols. An important part of this bill would be holding the manufacturer liable for any death or injury related to said immunization. Anyone who is manufacturing and distributing pharmaceuticals should be liable for ALL medicines they bring to the public.

Please support HB1377.

Thank you!

1/24/2021

My name is Curtis Kadrmas and I am in favor of HB 1377. I feel that every vaccination needs to be personal choice and not up to any employment, business, school or government entity to decide regardless of emergency status or non emergency status we may be in. We are finding that there are other treatments that can be given to prevent or treat certain diseases that may be more effective than a vaccination. Forced vaccination for the ability to work, education, shopping or any licenses would be an infringment on personal rights given to up by our forefathers and fought for by our veterans.

HB 1377 – HFND

STRONGLY SUPPORT – Please support this bill, as it will allow people to exempt out of a vaccine (school, job, license) if it does not meet certain criteria which includes placebo safety tests, liability with manufactures and risks of injury vs infection. Please people should have a right to choose without fear of repercussions to their education, license, or job.

Dear Members of the Human Services Committee,

My name is Dr. Paul Carson. I am a physician board certified in the specialties of internal medicine and infectious diseases, a Professor in the NDSU Dept. of Public Health, and the Medical Director of the NDSU Center for Immunization Research and Education. I have conducted clinical and public health research for over 25 years, and have no conflicts of interest to disclose in the matter of the current vaccination bills. My sole interest in this legislation is regarding the health of our citizens, and assuring we continue to do our best at preventing unnecessary illness and death from vaccine-preventable diseases.

I am writing in opposition to HB 1377. This bill, in essence, does an "end run" around all current vaccine laws, to create an impossibly high standard to ever be able to have a school or work-related vaccine requirement. It basically requires numerous added layers of bureaucracy and expense to "prove" vaccines are safe to an impossible standard. It requires that original vaccine licensing trials continue the formal trial for a full year before considering licensure. This would essentially place a cost burden on vaccine development that could never be met. Already, because of our stringent FDA approval process, the cost of typical vaccine development averages between $0.5-2.1 billion (The cost to develop a new vaccine) . Adding a full year of the intensive scrutiny of a full clinical trial would make this an astronomical cost, assuring no vaccine would ever meet these criteria. Vaccine companies will not take on that added cost and expense to meet some arbitrary regulatory standard from one small rural state. And we know from past experience that the overwhelming majority of serious adverse events related to vaccination occur within 6 weeks of receiving the vaccine. Furthermore, we already have a very robust safety and regulatory process that includes industry and federal review of post-licensure vaccine safety through a number of safety systems designed to detect rare events (Pre and post-licensure vaccine safety monitoring).

Other provisions in this bill would add layers of unneeded cost and bureaucracy, such as requiring the state dept. of health to track and report vaccine injuries and disability, something already done at the federal level. And the bill would require vaccine manufacturers to bear liability for any death or injury from a vaccine. Adjudicating the rare events of vaccine-related injuries has already been provided for by the *National Childhood Vaccine Injury Act of 1986* in order to assure a continued supply of vaccine distribution, while allowing for appropriate compensation for those rarely injured by vaccines (National Vaccine Injury Compensation Program) . This bill would be in direct opposition to that act raising legal challenges and likely federal state aid issues.

And finally, if this impossibly high standard were to pass, unlike any other in the rest of the country, it would essentially nullify any school or business-related vaccination requirements. Nearly all healthcare institutions in the sate have a variety of vaccine requirements, as do our schools. This bill would make those requirements invalid, and prevent our tried and true methods of assuring a safe work or school environment for our patients and schoolchildren.

Please vote do not pass on this bill.

I support HB1377. I like this bill because it mandates full disclosure so one can make an informed decision. May God guide you and bless you all!

Chairman Weisz and Members of the House Human Services Committee,

I want to briefly write to you all in support of HB1377, but before I give my testimony, I just want to thank the incredible representatives who have brought forth bills in the hearing today and also in hearings last week that promote medical freedom and personal choice. I am so grateful to you for your desire to protect and defend the Constitution of the United States and of North Dakota, as well as to represent the true wishes and needs of North Dakotans. I have a great deal of respect for the hard work you do and I recognize this can be a tiring and thankless job! I have written many testimonies, and I hope you have sensed my gratitude, but if not, I just want to reiterate that here. Thank you so much!

You may receive many passionate, sometimes even highly emotional testimonies. I hope you know that while we feel very strongly on the subject of medical freedom, we realize that the frustrations we feel are not your fault. We are merely trying to convey to you what has been weighing heavily on our hearts and minds over the past months, years, and for some of us, even decades.

A lot of freedom has been taken from us when it comes to health choices over the past year. People, including myself, feel as though they have had no voice. I have spent the last 10 months shedding many tears over decisions being made at the higher levels in regards to health that I completely disagree with. I watched as my view on health and wellness was completely ignored by the general public, and in many ways, still is being ignored. I spent much of the last year struggling with depression and hopelessness over the misinformation flooding the country when it comes to immune health, vaccines, and viruses. This is why so many of us are passionately sharing our thoughts, feelings, beliefs, and years of indepth research with you. We want you to be informed on these topics as well. We know it is important for the health of all, and we want to be a part of seeing things change for the better.

For all these reasons, I support HB1377. This is a bill that will help to expose the truth about how vaccines are approved in our country. They are rushed through the trials, never truly deemed safe, and when parents watch their children experience injuries, they are ignored by their doctors. The system has failed them. It has failed all of us. It is time for a change, and that can start right here in the great state of North Dakota!

We have the opportunity to be leaders in the march towards true bodily autonomy and health freedom, as well as supporting ways to become truly healthy through nutrition, exercise, and other positive lifestyle habits. I am so proud to be a North Dakotan and to watch as these amazing bills are introduced and heard. I wish I could be there in person, but distance, time, and commitments hinder me from doing so. In the future, I hope to be standing in the same room with you, testifying and hopefully chatting and getting to know you all. This is a cause that is near and dear to my heart, and I plan to continue supporting you all in the effort to allow people to have the freedom to pursue health in the way that they see fit. As one of my favorite mottos states: “Where there is RISK, there MUST be choice.”

Thank you again so very much for your time and efforts!

Sincerely,
Melyssa Howry

Committee members, my name is Jocelyn Backman and I am writing IN SUPPORT of HB 1377 relating to informed consent and notice of risks associated with vaccines; and to provide a penalty.

Where there is risk, there needs to be a choice. I am already hearing rumbling of Employers mandating the C-19 vaccine, and if they don't take it, they will lose their jobs. This is a slippery slope. Who would then be liable if the employee were to get sick or even worse, die from the vaccine? I have been watching the VAER's website since C-19 Vaccines have rolled out, and as of Friday there has been over 6,000 severe adverse reactions to the Vaccine.

It is important to keep in mind that everyone is different. Their genetics are different. Their diets are different. Their lifestyle is different. Vaccines are not a one sized fits all medical solution. Some healthy people that have rarely gotten sick in their lives have died from this vaccine, but they don't seem to investigate these deaths, and the Vaccine push has NOT slowed down at all. I see it picking up soon. We need to be able to use these exemptions to be able to retain our employment and keep our jobs. Vaccine status CANNOT ever be a requirement for a job or school.

Please render a DO PASS on HB1377.

Thank you for your leadership and service to our state.

HB 1377

Vaccination education involves presenting all benefits, risks, safety data, etc. If you only present one aspect, it is indoctrination and not education!!! This is a medical decision that the government should not be involved in, but if they are it is there responsibility to be impartial! The data should support the decision and if you have to force a decision on citizens, that is communism and not a republic. If the data is solid, then the individual will make the decision based on the data presented.

I support HB 1377

This bill gives the freedom to decline a required vaccine as a condition of employment, school attendance, or licensure if the following is not met:

- **The pivotal clinical trial the United States Food and Drug Administration relied upon to approve the vaccine evaluated the safety of the vaccine for at least one year after the vaccine was administered against a control group that received either a placebo or another vaccine that meets this criteria.**
- **The state department of health posts on the department's website the injuries or diseases caused by the vaccine and the rate at which the injury or disease occurs from the vaccine.**
- **The risk of permanent disability or death from the vaccine has been proven to be less than that caused by the infection the vaccine is intended to prevent.**
- **The vaccine's manufacturer has liability, including for design defect claims, for any death or injury caused by the vaccine.**

I like HB 1377 because it mandates full disclosure so one can make an informed decision.

Dear Chair and Committee members

Please support a do pass on HB 1377

Thank you,

Bea Streifel

Love the fact that this bill allows for a self-proclaimed exemption.

January 24, 2020

This is my written testimony for HB 1377. People should be allowed to exempt out of a vaccine in their place of employment if it does not meet certain criteria, which includes placebo safety tested, liability with manufactures and risks of injury vs. infection. Please vote yes for vaccine exemptions.

Thank You,
Rosemary Ames

Amy Thom

6480 Flickertail Drive

Bismarck, ND 58503

1/24/21

Representatives Hoverson, Simons, Skroch

HOUSE BILL NO. 1377

To Whom it May Concern,
I am providing written testimony in favor to this presented bill. I value our individual freedom and ability of autonomy when it comes to our health. I love that this bill would help to protect us from being required to have certain vaccines, without first presenting the risks and safety. I am so hopeful regarding this bill, thank you!
Thank you for your time.

Sincerely,
Amy Thom

I am writing in support of House Bill 1377. This bill will make data and information transparent. The studies that are done will have to show the risk and safety of each vaccine. People cannot then be required to get a vaccine unless there is valid risk/safety data and proven safety, among other things. This requires the health department to publicly show adverse events and all the data that tends to be manipulated and hidden. This also allows a self proclaimed exemption which is ideal. We are then in control of our own body and what we choose to do to it. Please vote YES on HB 1377.

Hi my name is Hilary Lund and I am testifying in support of bill HB1377. Individuals should absolutely be able to claim a vaccination exemption and if the USDA thinks otherwise then they should absolutely have to prove there's a risk, have valid safety data, and in the case of a death or injury the manufacturer should definitely be liable. I still cannot believe they have no liability for any vaccines. Just goes to show they don't actually care about the individual just the billions of dollars they make on these vaccines.

Rod & Linda Widicker
232 40th Ave NE
Bowdon, ND 58418

January 24, 2021

TO: District 14 Representatives: Robin Weisz and Jon O. Nelson

REGARDING: HOUSE BILL NO. 1377

We are providing written testimony in favor of HOUSE BILL NO. 1377.

We believe that every person should have the God-given right to make their own personal health care decisions, including whether to receive or decline vaccines. This right also belongs to parents, as they make informed decisions for their dependent children.

HOUSE BILL No. 1377 would help ensure that the safety and benefits, as well as the risks of vaccines are clearly defined. It would also help protect the rights of individuals and/or parents who wish to claim vaccine exemptions.

We are asking your support of HOUSE BILL NO. 1377. Thank you.

Respectfully,
Rod & Linda Widicker
District 14 Constituents

HB 1377

I beg you to vote “DO PASS” for this legislation.

It is very important to me that I have freedom to choose for myself and my family whether we take part in the controversial use of vaccinations. **The ability to have choice in regards to vaccines has affected where we live, where we work, and how we teach our kids.**

I am fully aware of the risks of vaccinating and the shortcuts that have been taken in creating these biologics. I understand that some people think they are safe, believe that their health provider has thoroughly researched them, and that if there were issues of safety that the manufacturers would quickly make the necessary changes to make them safe. These are unfortunately all false beliefs.

With biologics, otherwise called vaccines, the health provider gives the vaccine and then sometimes supplies a brief information sheet saying how “safe and effective” it is. I hear of no one being told of the side effects, allergies, and contraindications. If you have a question if the vaccine may be worse than what it treats, you are accused of being anti-vaccine. Some recipients are aware that vaccines cause injuries and that the Vaccine Injury Compensation Program has awarded over $4 billion dollars in funds due to injury (representing a tiny fraction of those that apply, as most cannot afford to fight or miss the window of submitting a claim because of not receiving informed consent). But most people are told incorrectly that any adverse reaction is “normal” and expected, even a “good sign” that it is working. We know that health providers report less than 1% of adverse events to the Vaccine Adverse Events Reporting System (VAERS) so they are not admitting the adverse events or they are not informed themselves enough to identify them. It is this same passive reporting system charged with determining if the vaccines are dangerous or causing too many injuries. This broken system has led to years of injuries before a vaccine is removed from use. A vaccine, once injected, cannot be “stopped” like a medication, so it is even more vital that informed consent be provided. Pharmaceutical companies are not held liable for any injuries or deaths resulting from their use. Neither is the health provider who did or did not offer informed consent before it was given.

I understand the common view that “vaccines are safe and effective.” In fact, I’m sure that you will hear pediatrician testimony claiming that as fact. This however is not fact.

Because governmental agencies both sell vaccines and choose which ones to add to the schedule, they are hardly unbiased in their research and recommendations. Health providers are fed this research and told not to question the “science.”

Because they are biologics, they are not required to be studied for years and against inert placebos.

Because there is no liability, no one is to blame or helps to cover medical and lifelong living costs due to injury.

Because they are accepted by most health providers as safe, adverse events are excused and injuries go unreported.

Because they are “required”, people don’t even know that they have a choice and don’t know there are exemptions.

We need to ensure we are leaving the decision to vaccinate or not to vaccinate up to the ones who will be left responsible.

We need to give informed consent so that health decisions can be made, not forced.

We need to allow people to make their own risk vs benefit analysis after being informed, not pressured.

Please pass this bill to show your support for protecting our most basic right, the right for health freedom.

Erin McSparron

Lisa Pulkrabek
4795 Co Rd 82
Mandan, ND 58554
Wadenlisa@aol.com
701-663-4294
701-595-4264

Dear Human Services Committee Members,

I am writing to you today about HB 1377, Relating to immunization exemptions. I am in FAVOR of this bill. Please DO PASS HB 1377.

We already have three vaccine exemptions for children attending school and that is wonderful. This bill will extend exemptions for adults whose employers are demanding vaccines in order for the employee to keep their job. Vaccines must be very safe and all risks must be laid out for the patient before the vaccine is given. Patients must have the choice of what is put into their bodies. This is called bodily autonomy. We need to keep the freedom to choose what is put into our bodies without fear of losing our jobs, or being kicked out of school.

Again, I am urging a DO PASS on HB 1377.
Thanks so much!
Lisa Pulkrabek

January 24, 2021

RE: SUPPORT - (HB 1377 - A BILL for an Act to create and enact a new section to chapter 23-07 of the North Dakota Century Code, relating to immunization exemptions.)

Dear Chairman Weisz and Committee Members: My name is Jennifer Kadrmas and I am a North Dakota resident who resides in district 7.

I am in SUPPORT for HB1377 - choosing what is best for one's or family's health is important. If a person chooses due to all information provided (informed consent) then a person does have a right not to include themselves in that activity. Why this bill is important for myself, my family and the state of North Dakota residents are because of the following:

A medical intervention should always be a choice of the individual by deciding the risk/benefits. Another person should not coerce someone with fear of losing a job or not being entered in a school, refusal of service nor to get a license. Especially if manufacturers have not done the proper safety studies and if they are not liable for their product. This is especially true in 2021 when there is pressure about the COVID vaccine, which is currently still in trials. No one should be forced to get the vaccine to live in society when there is no proof of safety or effectiveness.

Thank you and consider a DO PASS!

Sincerely,

Jennifer Kadrmas
District 7

My name is Linda Mittlestadt. I am a resident of Mandan, ND.
I am submitting written testimony in SUPPORT of HB 1377.

It has been proven that vaccines come with risks. Risks of permanent damage to an individual's health and can also result in death. It has also been proven that each individual has a unique set of health criteria to consider before an immunization. Therefore I believe it is necessary to present the person/parent/guardian with the option of exemption with respect to their individual health concerns and needs. Also, I do not feel that ANY individual should be "required" to receive a vaccine/immunization based on the fear of loss of employment, access to school, etc.

I am in support of HB 1377. This is a common sense bill.

I am in major support of HB 1377. All drugs have these standards. It is time that biologics have them as well. This is a common-sense bill for all North Dakotans.

2021 HB 1377
House Human Services Committee
Representative Robin Weisz, Chairman
January 25, 2021

Chairman Weisz and members of the House Human Services Committee, I am Tim Blasl, President of the North Dakota Hospital Association (NDHA). I am here to testify in opposition to House Bill 1377. I ask that you give this bill a **Do Not Pass** recommendation.

I am here on behalf of hospitals in opposition to the bill because it would allow anyone who is required to receive an immunization for any purpose, including as a condition of employment, school attendance, or licensure, to claim an exemption from the immunization requirement if there is not a vaccine approved by the Food and Drug Administration (FDA) which meets certain criteria. We are concerned that the criteria would rarely, if ever, be met, especially with certain vaccinations that are very important in the health care setting such as influenza vaccines. This bill will become an outright prohibition on mandatory vaccinations, which is very problematic in the health care setting.

In the healthcare setting, immunizations don't just protect vulnerable patients, they also protect employees. Healthcare workers are at risk for exposure to serious, and sometimes deadly, diseases. If they work directly with patients or handle material that could spread infection, they should get appropriate vaccines to reduce the chance that they will get or spread vaccine-preventable diseases. Even those workers not directly involved in patient care can potentially be exposed to infectious agents that can be transmitted to and from patients.

Patients who require hospitalization are often the most vulnerable and need more protection. Hospitals and health care workers have a shared responsibility to prevent occupationally acquired infections and avoid causing harm to patients by taking reasonable precautions to

prevent transmission of vaccine-preventable diseases. We are concerned that the bill would prohibit any healthcare provider from being able to require a vaccine as a condition of employment. It would mean that vaccination programs would no longer be an essential part of hospital infection prevention and control. Vulnerable patients would not be as protected as they could and should be.

The bill will allow an employee to claim an exemption from an immunization requirement unless:

- The pivotal clinical trial the FDA relied upon to approve the vaccine evaluated the safety of the vaccine for at least one year after the vaccine was administered against a control group that received either a placebo or another vaccine that meets this criteria.

- The state department of health posts on its website the injuries or diseases caused by the vaccine and the rate at which the injury or disease occurs from the vaccine.

- The risk of permanent disability or death from the vaccine has been proven to be less than that caused by the infection the vaccine is intended to prevent.

- The vaccine's manufacturer has liability, including for design defect claims, for any death or injury caused by the vaccine.

These requirements would be very difficult, if not impossible to meet. For example, influenza vaccines are updated each year to accommodate for different strains and changes in the virus from season to season. So, vaccines such as these will likely not be studied for at least one year after they were administered against a control group. Additionally, federal laws govern vaccine manufacturers' liability. These laws provide immunity from civil liability for certain vaccine manufacturers in order to ensure the manufacturers will be willing and able to produce vaccines. Injuries are dealt with under these laws much like workers compensation statutes with an injury compensation program operated by the government.

North Dakota should implement policies that are aimed at increasing immunization rates, not policies that undermine vaccination efforts. Failure to vaccinate not only puts the unvaccinated individual at risk, but also anyone they come into contact with — including those too young to be immunized and people who, for medical reasons, cannot be vaccinated. It is imperative that North Dakota continues to allow healthcare providers the ability to determine which immunizations are necessary to keep patients and employees safe.

Especially as the COVID-19 pandemic continues, we are reminded of the importance of vaccines and their ability to stop the spread of disease and save lives. Rather than telling employers what they cannot do, we see a need for greater engagement. The small (albeit vocal) minority of people who refuse vaccines outright rarely change their minds. The much larger hesitant population, however, does respond to information campaigns. Therefore, rather than prohibiting vaccination mandates outright, we would prefer to see greater investment in education and more efforts to facilitate meaningful conversations between concerned people and health-care professionals. We ask that health care providers be given the flexibility to determine appropriate immunization and infection control policies that are best for their patients and employees.

For these reasons, we urge you to oppose House Bill 1377 and give it a Do Not Pass recommendation. I would be happy to respond to any questions you may have. Thank you.

Respectfully Submitted,

Tim Blasl, President
North Dakota Hospital Association

HB1377

Thank you for taking the time to read my written testimony. My name is Janelle Anderson and I am from rural Alexander, ND in District 39. I am a mother of 4 children, ages 9 months to 16 years old. My husband and I ranch together, as well as own/run multiple other businesses.

I am writing this today in reference to House Bill 1377, which deals with Informed Consent. I want you to know that I **SUPPORT** HB1377.

There should never be any medical procedure, or vaccine requirement for anyone. If there is risk, there must be choice. This bill gives North Dakotans the ability to choose what is right for them and their families without the threat of being fired or discriminated against.

I ask you all as a committee, to give HB1377 a **PASS.** This bill is much needed.

Thank you committee members for your ears, your time serving your constituents, and being open to hear why our family fully **SUPPORTS** HB1377.

Sincerely,

Janelle Anderson
Rural Alexander, ND
District 39

HB1377

Thank you for taking the time to read my written testimony. My name is Paula Slow and I am from Arnegard, ND in District 39.

I am writing this today in reference to House Bill 1377, which deals with Immunization Exemptions. I want you to know that I **SUPPORT** HB1377.

I ask you all as a committee, to give HB1377 a **PASS.**

Sincerely,

Paula Slow
Arnegard, ND
District 39

1839 East Capitol Ave

Suite B

Bismarck, ND 58501

To whom it may concern…

In regards to HB 1377, I am in FULL SUPPORT if this bill.

A bill to protect individuals from medical procedures with the potential to do harm and the administering agent responsible for providing this information and held responsible for any damages….priceless.

Helping Create Health and Wellness,

Dr. Allen Rudolph

I STRONGLY support HB 1377 because we all have the right to make our own personal decisions for medical procedures of which vaccines are included. We should not be forced to receive vaccines in order to go to school, keep our jobs, or received licenses of any sort. When there is risk there NEEDS to be choice. Thanks for listening.

Hi my name is Brady Lund from Watford City, ND and I am testifying in support of HB1377.

Hello
My name is Marvin Lepp and I am writing to you today in regards to HB 1377.
I have dealt with the first hand pressure that is placed on individuals when it comes to vaccines and have dealt with the issues that arise after the fact.
My wife was convinced to receive the HPV vaccine in 2010 by her Doctor shortly before our marriage. It was when the vaccine first came out and she was told that it would help prevent all sorts of issues including cervical cancer and was pressured into taking the shots.

I cannot express how much I wish this never would have happened. What the vaccine actually did was make a very healthy young woman near infertile. We spent the better part of 6 years and thousands of dollars trying to conceive our little miracle. She developed Polycystic Ovary Syndrome, has had to endure surgeries for the pain related to it, and lasting emotional health issues as this “CURE” permanently damaged her body.

This same vaccine is now in our school systems and on the “required list”.

Moving forward after we finally had our little miracle we dealt with a ton of pressure from our pediatrician, “the best in the state” Kathy Anderson. She was the same doctor who led the CHI dr. revolt and the one that has been spearheading all the letters to the Governor regarding masks and vaccines. The amount of pressure being pushed onto parents who only want the best for their children is alarming. The Doctors, their nurses, everyone pushes this issue and it disgusting the tactics that are currently taken to convince us for the “appropriate” vaccines.

Why do you think the only people in opposition of this are doctors and members of the State Health Department. You know the same people who helped coordinate statewide lock downs, quarantine measures, and letters of encouragement to the governor.

The State Health Department has already created enough issues in our schools, our lives and our state over the last year with unelected officials dictating our lives, with zero accountability.

As far as I am concerned the state health officer and the director of human service should be an elected position just like the state superintendent so that they are held accountable for their actions.

There is no liability for vaccine damage. If there was it would not be a multi-billion dollar industry.

Vaccination should be an informed choice of the parents, not forced upon them by anyone.

Thank you for your time.

I am writing in support of HB1377. People deserved to not be discriminated against in the workforce with their decision to refuse vaccinations and use medical, religious, or philosophical exemptions to protect themselves and their beliefs. Vaccines are not tested for safety with a true placebo. Vaccine manufacturers have carried no liability for vaccines since the Vaccine Injury Act of 1986. Included in the Vaccine Injury Act of 1986, was a stipulation that the US Department of Health and Human Services was required to perform biannual safety studies on vaccinations. In 2018, it was revealed that the Health and Human Services had not done a SINGLE vaccination safety study in 32 years, resulting in a lawsuit over their breaking of federal law. Vaccines contain many heavy metals, neurotoxins, allergens, animal parts, and in some cases human diploid fibroblasts-all of which can react with people differently, cause more harm then good in some situations, and go against people's individual and religious beliefs. All of this considered, it should in no way be a requirement to receive vaccinations in order to work and provide for one's self and family. Thank you for your consideration.

To whom it may concern;

Good Morning, my name is Megan Martina and I have three beautiful kiddos that I would move mountains for. My oldest child, whom my husband tried for years to get pregnant with, was vaccine injured as an infant. She suffers from seizures, a tic disorder and brain damage that her neurologist has confirmed is a result of adverse effects from vaccines. I strongly encourage you to support HB 1377. I was never given information from her doctors office that warned me of the risks from vaccines. I always heard the line “safe and effective” and now I live with the heavy guilt of seeing my child suffer as a result of my ignorance. All vaccines carry risks, including death, and none have ever been tested for being carcinogenic or causing infertility. No one should ever be forced into a medical procedure that carries risks, and forced vaccination is a huge violation of our rights. No one should ever be told that they must receive a vaccine that carries risks in order to go to school, keep a job, etc. It is not right, period. I vaccinated my child and she was a sacrifice for “the greater good” and it makes me so angry that she has to suffer everyday. No child or person should be forced into a medical procedure, and no one should be forced into something that carries very real and serious risks. Please support HB 1377 for people like my daughter, because it could be your child, your grandchild, your spouse or best friend.

Thank you,

Megan Martina

HB1377

Malinda Weninger

701-527-8226

I support HB1377.

This is my written testimony for HB 1377.

We need to have the right to exempt out of a vaccine if we so choose after we have done our research.

There should not be restrictions in places of employment and education based on vaccine exemption or not. People are currently being bullied at doctor's offices when they refuse vaccines for themselves or their children. People are being restricted to daycares currently – even with the vaccine exemption in place. Because "they think they have the right to do that". Which they don't but the average person doesn't know that they can't be forced into vaccinating.

Vaccine manufacturer's are exempt from any lawsuits – WHY? There is a reason for that – there really are injuries out there. Proper testing protocols are being bypassed and injuries are happening.

This is an individual's freedom to choose what goes into their BODY – the one thing we all own.

Please vote yes for vaccine exemptions.

Thank you.

Malinda Weninger
701-527-8226

My name is Sara Williams, I am writing you today as a constituent of District 37 who supports HB1377. I believe where there is risk there must be choice, and this bill would give individuals who may not fall into the other vaccine exemption categories the opportunity to apply an exemption when they determine the risk outweighs the benefit to a particular vaccine. Thank you for your consideration.

Hello, my name is Kim Huebner. I am testifying in SUPPORT of HB1377. I believe there should be exemptions for vaccines. Thank you.

HB1377

Malinda Weninger

701-527-8226

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Please vote yes for vaccine exemptions.

Thank you.

Malinda Weninger
701-527-8226

Christine Miller
922 East Owens Ave Apt 8
Bismarck, ND 58501

January 25, 2021

Regarding: HOUSE BILL 1377 - A BILL for an Act to create and enact a new section to chapter 23-07 of the North DakotaCentury Code, relating to immunization exemptions.

Dear Committee Members,

To begin I'd like to tell a short story about my perspective as a North Dakota transplant. As you read this it may seem like I've forgotten that I am writing a testimony in support of a bill related to vaccine exemptions, but please hang in there till the end and you will see where I am going with this. Thank you.

I grew up in New York and have lived in handful of states, including Illinois, Indiana, and Wisconsin, as well as in Calgary, Canada before settling in North Dakota in September of 2000. I've reared three children here, one who is now a 19 year-old college graduate, and two teens whom I am homeschooling. My children were born in Jamestown and we moved to Bismarck in 2016. We chose the Capitol city because of the abundance of opportunity that we saw here – an affordable college, plenty of jobs, lovely parks, ample shopping, all within a small-town, friendly community. The quality of life we',ve experienced in Bismarck, and in North Dakota as a whole has been good. We have amazing friends, a fantastic hometown college, a comfortable home, ample work opportunities, and good old fashioned midwestern values. Overall, I have been pleased to call myself a North Dakotan these last twenties years, and until recently I've never considered leaving the state for any reason other than to be closer to my family in New York.

A few years ago I remember reading about a contest of sorts to come up with a new logo for the state of North Dakota. An idea came to me immediately, and I'd like to share my idea and why it occurred to me. Back in 2011 or so I was talking to a good friend of mine about the changes the Oil Boom was bringing to our state. My friend is a North Dakota native so his perspective comes with much more experience than mine. What he said that day is something I have never forgotten. He simply said, "The secret is out!" I remember a swell of emotions when I heard that. I felt proud to live in such a wonderful place. I felt grateful that I had chosen North Dakota as the place to rear my children. But I also felt a sting of fear – what if the influx of so many new people would end up changing our state – what if ND changed so much I would no longer be happy here? And change it did, but I still feel safe and happy to be here.

Now getting back to my idea for a North Dakota logo. My idea was profoundly simple but compelling. Here it is: *The SECRET is out... NORTH DAKOTA!* I smile inside every time I think of this. I smile because I love North Dakota and I smile because I remember what drew me here. I wondered what out-of-staters would think when they drive across out state line and saw: *The SECRET is out... North Dakota!* I'm guessing they would ask themselves, what secret? I am certain that those seeking what I was seeking when I moved here would have a sense of what it means without even asking anyone. So what is the "secret?" The secret is that North Dakota offers what most human beings, and especially families, crave and need. North Dakota offers safety. We have low crime rates, few if any poisonous species, no earthquakes, hurricanes, or mudslides. If you are not out on the Interstate during a blizzard, you don't have much to fear in North Dakota. What else does North Dakota have that people want? We have economic growth and low employment. If you want to work and are able to work, you can find a job in North Dakota. North Dakota has plenty of space for rural living, and recreation, but also offers several larger cities, technology, and opportunities for those who crave a faster

pace of life.

For a good long time, North Dakota was drawing newcomers. Today the states that are drawing the "weary masses" are Florida, and South Dakota. Why is that? The reason people are leaving states such as New York and California and fleeing to states like South Dakota and Florida is because as much as people need and long for safety from crime, ample economic opportunities, open spaces for play and recreation, and so much more that our state has to offer, what they seek and need most is something that many of us have taken for granted most of our lives. Freedom. We are fortunate and have taken for granted the privilege it is to live in a free country. But things are changing and people are sensing that freedom is dying in this country, and of all the freedoms people cherish and should be entitled to by God first and by their government next, is the freedom to **body autonomy**, including the right to receive or reject the injection of vaccines for any reasons including employment, school attendance, or state licnsure. People in states with oppressive governments are weary and scared, and they are fleeing to states that offer health freedom.

Prior to Covid-19 and all the mandates for masks and now the constant talk about vaccine passports and certain employers requiring the Covid vaccine, I never worried about the possibility of being forced to take a vaccine. I have not received a vaccine since 2001, and if I had had adequate information about vaccines at that time, I would not have received that one.

I am very fearful about losing my right to decide for myself if a vaccine is safe for my body. I have severe asthma and I have chosen up to this time to avoid vaccines because they made my mother so sick and because the one time I did get a flu vaccine in my adult life, I became very sick. Also, it is quite likely that I have the MTHRF genetic mutation that runs in my family which means I am at high risk of developing serious adverse reactions and even life long debilitating diseases or conditions if I take a vaccine.

I am even more concerned about my children one day being forced to take vaccines in order to work, attend school, or be licensed in the state of North Dakota. That is not freedom. That is medical tyranny. And that is why people South Dakota and Florida are becoming the new homes of the "free and the brave."

I cherish my right as an American to choose what goes into my body and what is done to my body by the medical community, and I hope and pray and I implore you to make sure that my children and grandchildren and all future generations in the state of North Dakota continue to have the right to health freedom for themselves and their children.

Please **do pass HB 1468. Y**our decision could make North Dakota a beacon of freedom for the worn out, stressed out, frightened masses who are fleeing from oppressive control and forced vaccinations in other states. Or your decision could add North Dakota to the list of states from which to flee.

Sincerely,

Christine Miller

HB 1377: YES, SUPPORT

Chairman Weisz and the House Human Services Committee;

My name is Whitney Jeske, a resident of McKenzie County, ND. I am testifying in SUPORT of HB1377.

Re: HB 1377 Testimony Human Services Committee
January 25, 2021 2:45 p.m.

Good afternoon, Chairman Weisz and members of the Human Services Committee. I am writing to testify to my support for HB 1377. I think it should go without saying that we should have the right to decide if we want to inject something into our body that has not been properly safety tested or that the manufacturer has no liability. My health is something I take very seriously and it should be between me and my doctor to make a decision about what is best for me. My school or job should have nothing to do with that decision. I urge you to vote yes on HB 1377.

Sincerely,

Melanie K Paape

Testimony to the House Human Services Committee on HB 1377
Testimony by Barbara Frydenlund Rolette County Public Health District Administrator

Good afternoon, Chairman Weisz and members of the House Human Services Committee. My name is Barbara Frydenlund, and I am the Nurse Administrator for Rolette County Public Health District. I am offering this testimony today in opposition of HB 1377.

The Importance of Vaccines CDC statistics demonstrate dramatic declines in vaccine-preventable diseases when compared with the pre-vaccine era. Immunizations are among the most cost-effective and successful public health interventions.

As you are aware, there are several vaccine preventable diseases. Many of these diseases have never been seen by today's healthcare providers and parents, in part because we have been actively educating parents and guardians and vaccinating children for several years.

Families who claim exemptions from immunization mandates for any reason are at increased risk of developing a vaccine-preventable disease. In fact, children in families who have been granted a vaccine exemption are more than 35 times likely to contract measles and nearly six times more likely to contract pertussis. In addition, persons who claim philosophical or religious exemptions create risk for their community because unvaccinated or under-vaccinated persons can transmit disease.

Currently 15 states allow personal belief exemptions to vaccination, but 45 states permit religious exemptions. Given the need to assure community herd immunity persists, having more families claim exemptions can jeopardize the safety of those who are immunocompromised and could enable outbreaks of preventable illnesses like measles to occur in this state and country. It is for this reason that vaccine champions like Dr. Richard Pan, who is both a pediatrician and legislator in California, has worked to remove both philosophical and religious exemptions in that state, leaving only medical exemptions in place. The question remains if a state should oversee the approval of medical exemptions to ensure their legitimacy. At the end of the day it is the responsibility of the trained medical community to complete their due diligence to ensure that children and adults do not succumb to life-threatening illnesses preventable by vaccines.

It has been my public health experience and my connection to local schools that the limited number of parents and guardians in my service area who sign the philosophical exemption do so strictly for convenience of avoiding a clinic appointment to enable their child to receive age-appropriate immunizations. **I am in no way against medical exemptions to vaccine,** but I am very much against false exemptions and exemptions of convenience.

Vaccinations not only help protect children, but also protect the broader community by minimizing the spread of disease. It is the responsibility of parents, guardians, and the healthcare providers to protect the health and safety of children. ALL CHILDREN, including those with bona fide medical exemptions, who attend public daycare facilities and schools have the right to be protected from vaccine preventable disease.

Thank you for allowing me to share my experience as a Registered Nurse and mother of two fully vaccinated children. Please follow the science of health and spare future generations from walking through cemeteries only to note the deaths of young children who lost their lives to vaccine preventable diseases.

I urge a **DO NOT PASS recommendation on HB 1377**.

Sincerely,

Barbara Frydenlund, RN
Nurse Administrator
Rolette County Public Health District

Please support House Bill 1377. There are people who legitimately cannot receive vaccines. This bill will protect their future.

Please support House Bill 1377. The it is widely recognized that vaccines are protective medical treatments. However, there are many who medically or morally cannot accept vaccination. Please support this bill to protect those who are most vulnerable.

HB1377

My name is Selenna Bolanos-Reyes , I am a resident of Williston,ND. I am testifying in support of HB1377. There has never been a true placebo safety study done of vaccinated vs not vaccinated children to really help show if vaccine are protecting against what it's claim to protect with out adding any new possible injury to; Or a study done on how the current schedule is infact safe to be administered at the times that they are; Or if multiple vaccines at one time interact with one another an dif it causes any harm

To add to that manufacturers are not liable for any type of injury cause by vaccine.

Therefore, until these studies are done, manufactures are liable for injury or even death, individuals should have the right to be exempt for any/and all medical procedures such as vaccines.

Dear Committee Members,

Please recommend a ‘Do Pass’ on HB1377.

Employers should not be allowed to jeopardize the financial stability of their employees by forcing them to violate their religious beliefs or force the employee to divulge private health information. Freedom of Religion and the right to privacy are Constitutional Rights.

Again, please recommend a ‘Do Pass’ on HB1377.

Sincerely,

McKenzie McCoy
Watford City, ND
District 39

HB 1377: YES, SUPPORT

Chairman Weisz and the House Human Services Committee;

My name is James Jeske, a resident of McKenzie County, ND. I am testifying in SUPORT of HB1377.

HB 1469

Dear Representatives of House Bill 1469,

I am writing in direct opposition to 23-07-17.1.3.b as well as 23-07-17.1.8

I am in full support of the 1468 bill proposed, as well as the 1377 bill.

As a practicing clinician in a chiropractic and health center where our focus is on health restoration, we are often the last resort for very sick children. I am trained in removing triggers that lead to malfunction of the human body (as opposed to using drugs and surgery to control function) and to help to restore homeostasis.

Upon consulting, we ask about vaccination history, and if relevant, inquire as to whether they have concerns about safety. Most have significant concerns however report they have been scared, intimidated, and were never told about their options to opt out or what risks are.

I get about 1-5 contacts per month asking if we write exemptions because they cannot find a doctor willing to write them for their children or for their work. We don't write them. Parents are afraid because of how they are treated. They are intimidated, told that there are no risks, and when they express concerns about prior inoculations causing harm, they are very often flippantly dismissed.

Unfortunately, in giving my patients the time they deserve, I have not had the opportunity to thoroughly express why I am directly opposed to forcing biased information onto patients.

The NDDOH has been shown to minimize publicity of adverse events. Frankly, I do not trust them to put out unbiased information free from Industry (drug company) influence.

I had previously submitted a research study comparing fully inoculated individuals, partially inoculated, and those that had not had inoculations, and their likelihood of being diagnosed with various health problems. There ARE physiological mechanisms that cause these problems. However parents are grossly undereducated on the risks. They are taught to never question.

In regards to 1377, I am in full support, as exemption should be available whenever the producers of said product are considered free from any liability for damages. Drug companies, hospitals, and prescribing/administrating doctors are all exempt from liability if and when damage occurs. For that reason alone, no one should be forced/coerced for not wanting it or penalized for denying being injected with said product. **I don't know of any other product in the world that is free from manufacturer liability and at the same time, people are coerced into using it or penalized for not using it. The same companies that are free from liability are often convicted felons, some even hiding research causing damage from medications (avandia) from the public eye to continue to profit.**

For this reason, I believe 1377 would PROTECT people from impending mandates by companies influenced by drug industry lobbyists and pressure.

Thank you for your time and I apologize that this is not better formulated. If you have questions or would like further explanation, you may call me or email.

Dr. Steve Nagel

180 Health Solutions

I STRONGLY support HB 1377 because we all have the right to make our own personal decisions for medical procedures of which vaccines are included. We should not be forced to receive vaccines in order to go to school, keep our jobs, or received licenses of any sort. When there is risk there NEEDS to be choice.

Thanks for listening.

Stephanie Becker

Please note , I tried sending this through the website and it would not send.

I would like to thank you for considering my letter today. I am Kim Sheldon from Washburn, ND and I am writing to you today as one who has had adverse reactions to various medications and the flu vaccine.

Regarding House Bill 1377 which deals with exemptions for vaccines., I am very much in favor of this Bill. My reason for supporting this bill is very important as a person who has many intolerances to medications and vaccines. Back in the late 19990's I worked for a clinic in which I had to receive various vaccines for my job. I had a neurological event immediately after the flu vaccine, and then developed environmental allergies, of which I had none before.

I have fought long and hard to regain my health , and do not wish to experience that with a vaccine ever again.

After doing years of studying vaccine inserts, the ingredients within vaccines, peer reviewed literature, history of communicable diseases , and hearing testimony of person after person who has had reactions and disabilities due to vaccines, I cannot agree to the idea of one size medicine fits all. What may not harm one person can do severe damage to another. I have friends and relatives who have had severe anaphylactic reactions due to the flu vaccine alone.

Whenever a medical intervention is available , it needs to be one of choice not mandate. If there is ANY chance of injury , it should never be mandated, no matter what disease it is designed to confront. If not, then we are no better than the Germans who inflicted many people with their scientific experiments and then were tried in the Nuremburg trials.

We should never be forced to receive a vaccine, and especially one that has not gone through the gold standards of regular medicine. The new covid vaccines have been rushed through without the years of testing that they should have. Regular medications have to go through years of trials before going to market. Placebos many times are replaced with another vaccine.

In particular , with this new vaccine, we have no idea of the long term effects that it can have on our health. Past vaccines failed for corona virus, failed when the animal vaccinated came into contact with the virus, it had a much more severe reaction. There is something called ADE - Antibody Dependent Enhancement that happens at that time. We have no idea if something like this can happen to us in the future after receiving this vaccine. We don't know long term affects of the fetus in utero, or upon fertility. These things cannot be gaged in a short term study.

Below is a link to a Dr.s explanation of ADE.

https://sciencewithdrdoug.com/2020/08/01/is-a-coronavirus-vaccine-a-ticking-time-bomb/?fbclid=IwAR1OZGwFj6l2u9-Ephw5ULipCsHNjcxdJEt_oX5kj2S2wODc6d1utUGzGJ4

Also, many of these vaccines are made with aborted human fetal tissue and cell lines. This a deep concern for any person of faith who believes in the sanctity of life . I also have loved ones in medical professions and schools and colleges, where they may be forced to take the vaccine to keep their job or attend school.

We must have exemptions to allow us freedom to choice, whether it be religious, philosophical, or medical.

In conclusion, this bill will provide protection for all those who wish to deny a vaccine on any of these concepts. It will protect those whose bodies , through genetic makeup or some other reason, such as my own, would not have to be subjected to more injury.

Thank you for taking the time to hear my concerns.

Kim Sheldon

2356 2nd St SW Washburn, ND 58577

701-462-3563

HB1377:

In Support of

I watched some amazing nurses and other medical staff be let go because they refused the flu shot. Tell me, how does that help the ones we were hired to care for?

I left that job and never looked back. NO place of employment will hold that over my head again.

And yes, all expense were on me. My employer did not care that I got sick, nor did they even offer an egg free option. I had to make my own appointment, pay my own co-pays and use my own vacation just to get an egg free flu shot because my employer did not deem it necessary to order any.

Wasn't the flu shot required during Obama Care era because facilities risked losing funding if 90% of their staff was not inoculated? I am pretty sure that is where my research led me, many years ago. If so, this really was never about health anyway but money...it is always about money.

Never, never again!

Hi my name is Hilary Lund and I am testifying in support of bill HB1377. Individuals should absolutely be able to claim a vaccination exemption and if the USDA thinks otherwise then they should absolutely have to prove there's a risk, have valid safety data, and in the case of a death or injury the manufacturer should definitely be liable. I still cannot believe they have no liability for any vaccines. Just goes to show they don't actually care about the individual just the billions of dollars they make on these vaccines.

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

HB 1377
2/1/2021

Relating to immunization exemptions

Chairman Weisz opened the hearing at 3:36 p.m.

Representatives	Attendance
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	A
Representative Matthew Ruby	P
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Exception expansion
- Religious, philosophical or moral belief opposition

Rep. Jeff Hoverson, District 3 (3:39) Amendment 21.0875.01001 was given to committee - #5921.

Rep. Kathy Skroch (3:54) moved for adoption of amendment 21.0875.01001. **No second.** Motion failed.

Rep. Gretchen Dobervich (3:54) moved for a Do Not Pass.

Rep. Mary Schneider (3:55) seconded the motion.

Representatives	Vote
Representative Robin Weisz	Y
Representative Karen M. Rohr	Y
Representative Mike Beltz	Y
Representative Chuck Damschen	N
Representative Bill Devlin	Y
Representative Gretchen Dobervich	Y
Representative Clayton Fegley	Y

Representative Dwight Kiefert	N
Representative Todd Porter	A
Representative Matthew Ruby	N
Representative Mary Schneider	Y
Representative Kathy Skroch	N
Representative Bill Tveit	N
Representative Greg Westlind	Y

Motion for a Do Not Pass carried 8-5-1

Bill Carrier: Rep. Gretchen Dobervich

Chairman Weisz adjourned at 4:02 p.m.

Tamara Krause, Committee Clerk

REPORT OF STANDING COMMITTEE

HB 1377: Human Services Committee (Rep. Weisz, Chairman) recommends **DO NOT PASS** (8 YEAS, 5 NAYS, 1 ABSENT AND NOT VOTING). HB 1377 was placed on the Eleventh order on the calendar.

21.0875.01001
Title.

Prepared by the Legislative Council staff for
Representative Hoverson
January 28, 2021

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1377

Page 1, line 2, after "exemptions" insert "; and to amend and reenact section 23-07-17.1 of the North Dakota Century Code, relating to immunization requirements for students"

Page 1, after line 3, insert:

"**SECTION 1. AMENDMENT.** Section 23-07-17.1 of the North Dakota Century Code is amended and reenacted as follows:

23-07-17.1. Inoculation required before admission to school.

1. A child may not be admitted to any public, private, or parochial school, or day care center, child care facility, head start program, or nursery school operating in this state or be supervised through home-based instruction unless the child's parent or guardian presents to the institution authorities a certification from a licensed physician or authorized representative of the state department of health that the child has received age-appropriate immunization against diphtheria, pertussis, tetanus, measles, rubella (German measles), mumps, hepatitis B, haemophilus influenza type b (Hib), varicella (chickenpox), poliomyelitis, pneumococcal disease, meningococcal disease, rotovirus, and hepatitis A. In the case of a child receiving home-based instruction, the child's parent or legal guardian shall file the certification with the public school district in which the child resides.

2. A child may enter an institution upon submitting written proof from a licensed physician or authorized representative of the state department of health stating that the child has started receiving the required immunization or has a written consent by the child's parent or guardian for a local health service or department to administer the needed immunization without charge or has complied with the requirements for certificate of exemption as provided for in subsection 3.

3. Any minor child, through the child's parent or guardian, may submit to the institution authorities either a certificate from a licensed physician stating that the physical condition of the child is such that immunization would endanger the life or health of the child or a certificate signed by the child's parent or guardian whose religious, philosophical, or moral beliefs are opposed to such immunization. The minor child is then exempt from the provisions of this section.

4. The enforcement of subsections 1, 2, and 3 is the responsibility of the designated institution authority.

5. The immunizations required, and the procedure for their administration, as prescribed by the state department of health, must conform to recognized standard medical practices in the state. The state department of health shall administer the provisions of this section and shall promulgate rules and regulations in the manner prescribed by chapter 28-32 for the purpose of administering this section.