

Health & Human Services

Good afternoon, Chairman Weisz and members of the House Human Services Committee. I am Molly Howell, the Immunization Director for the North Dakota Department of Health and Human Services (Department).

I am providing testimony in opposition to HB1502. The greatest concern with HB1502 is the definition of "experimental vaccination." If a vaccine does not meet all four criteria outlined in the bill, then it is considered an "experimental vaccination" which could have an unintended consequence for other routine wellness vaccines.

One of the criteria, Section 2, 3d states, "The vaccine's manufacturer has liability, including for design defect claims, for any death or injury caused by the vaccine."

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

Based on the definition of "experimental vaccination" in HB1502, this legislation would eliminate all routine immunization (i.e., hepatitis B, measles) requirements for hospitals and healthcare facilities because these vaccines are included in VICP, and therefore would meet the proposed definition of "experimental vaccination." Vaccination of healthcare workers is critical to employee safety and patient protection. All healthcare personnel (HCP) should receive hepatitis B vaccination and be tested for immunity, to ensure protection in the event of a needle stick. Laboratorians working with rabies or meningococcal specimens need to be vaccinated to ensure prevention when exposed. One study model suggests that if influenza vaccination rates in clinics where vaccination was not mandated had equaled those where vaccine was mandated, HCP influenza infections would have been reduced by 52.1%.<sup>i</sup>

Each year influenza causes outbreaks in long-term care (LTC) facilities. The impact of influenza on LTC facilities can be particularly devastating since influenza can be a serious health threat, especially for people vulnerable to influenza complications, including older adults and people living with certain long-term medical conditions. People older than age 65 are at the highest risk for hospitalization and complications from influenza and they account for the majority of influenza hospitalizations and deaths in the United States each year.<sup>ii</sup> Several studies have demonstrated that vaccination in healthcare settings decreases influenza transmission from HCP to patients, particularly in LTC settings.<sup>iii iv</sup> Studies in LTC facilities have shown that staff vaccination against influenza has been associated with reductions in all-cause mortality among residents, influenza-like illness (ILI), and hospitalizations of individuals with ILI." In addition, one LTC study suggested that although staff vaccination rates did not independently predict ILI outbreaks, high rates of vaccination among both staff and residents substantially reduced the rate and impact of influenza outbreaks.<sup>vi</sup> In addition to protecting patients, influenza vaccination reduces staff absentee rate rates and protects staff and their families.vii

An additional concern about HB1502 is the lack of a definition in Section 2, 1b of what it means to "promote" in the healthcare setting. For example, would education about vaccines to healthcare workers be considered promotion? Another concern lies in Section 2, 3a, where the requirements for "pivotal clinical trials" are generally in accordance with current vaccine clinical trials in the United States, but historical clinical trials for vaccines such as measles, may not meet this requirement and therefore would be unallowable.

In conclusion, the vaccination of healthcare personnel is an important way to ensure staff and patient protection from infectious diseases. Vaccination also reduces staff absenteeism, ensuring this critical workforce is able to provide care.

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

<sup>i</sup> Simberkoff MS, Rattigan SM, Gaydos CA, Gibert CL, Gorse GJ, Nyquist AC, Price CS, Reich N, Rodriguez-Barradas MC, Bessesen M, Brown A, Cummings DAT, Radonovich LJ, Perl TM; ResPECT Study Team. Impact of mandatory vaccination of healthcare personnel on rates of influenza and other viral respiratory pathogens. Infect Control Hosp Epidemiol. 2022 Sep;43(9):1216-1220. doi: 10.1017/ice.2021.324. Epub 2021 Aug 5. PMID: 34350820.

<sup>ii</sup>Havers F, Sokolow L, Shay DK, et al. Case-control study of vaccine effectiveness in preventing laboratory-confirmed influenza hospitalizations in older adults, United States, 2010-2011. Clin Infect Dis 2016; 63(10): 1304-11.

<sup>iii</sup> Carman WF, Elder AG, Wallace LA, et al. Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomised controlled trial. Lancet 2000; 355(9198): 93-7.

<sup>iv</sup> Potter J, Stott DJ, Roberts MA, et al. Influenza vaccination of health care workers in long-term-care hospitals reduces the mortality of elderly patients. J Infect Dis 1997; 175(1): 1-6.

<sup>v</sup> Hayward AC, Harling R, Wetten S, et al. Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. BMJ 2006; 333(7581): 1241.

<sup>vi</sup> Shugarman LR, Hales C, Setodji CM, Bardenheier B, Lynn J. The influence of staff and resident immunization rates on influenza-like illness outbreaks in nursing homes. Journal of the American Medical Directors Association 2006; 7(9): 562-7.

<sup>vii</sup> Miguel Pereira, Siân Williams, Louise Restrick, Paul Cullinan, Nicholas S Hopkinson Clinical Medicine Dec 2017, 17 (6) 484-489; DOI: 10.7861/clinmedicine.17-6-484