Dear Chairman Weisz and members of the Human Services Committee,

I am a physician board certified in the disciplines of internal medicine and infectious diseases. Additionally, I am a professor in the public health graduate program and teach in the area of the management of infectious diseases in public health at North Dakota State University (NDSU). I am also a professor in the University of North Dakota (UND) School of Medicine and Health Sciences in the Department of Internal Medicine. Lastly, I am the founder and medical director at the Center for Immunization Research and Education within NDSU. I am writing in opposition to HB1200 on my own behalf, and not as a representative of either institution, but as someone with a broad range of experience and teaching about vaccines, communicable diseases and associated public health policies.

First, it is important to understand that all states within the U.S. and most developed countries around the world have established schools as the primary source of ensuring a vaccinated population for the prevention of communicable diseases. Through decades of legislation and litigation, schools have steadily been upheld for this oversight, and rightly so. This is because most of these diseases are acquired in childhood, school is for the most part a universal experience in the U.S., and schools congregate children into confined spaces for prolonged periods of time and are ideal settings for the spread of communicable diseases. These laws and policies have been tremendously successful, with the elimination or near elimination of diseases such as smallpox, polio, measles, mumps, diphtheria, and Haemophilus and meningococcal meningitis. It is worth noting that survey data still shows that the majority of parents in the U.S say healthy children should be required to get vaccinated for things like measles/mumps/rubella to assure a safe school environment for their children.

Although there are no school requirements for SARS-CoV-2 (COVID-19) vaccines in ND, and establishing that would require an act of the legislature, HB1200 goes well beyond just SARS-CoV-2 vaccines. It literally seeks to redefine the entire safety and regulatory process for establishing vaccine safety in the U.S., making North Dakota the only state in the U.S. that would redefine **all** existing vaccines as “experimental” and therefore ineligible as a requirement for school entry.

First, this bill states that for a vaccine to not be considered experimental, the pivotal clinical trials necessary for FDA approval must run for at least a year. While this does happen with some vaccines, most clinical trials are designed to occur in a window of time long enough to have enough disease cases to occur to be able to show efficacy, and long enough to detect major safety signals, which usually is less than a year. These are extremely expensive studies to conduct (typically billions of dollars), and running them longer than needed would add substantially to the overall cost of healthcare. No pharmaceutical company will take on the added enormous costs of re-running their clinical trials of their already FDA approved vaccines just to meet North Dakota’s re-definition of what the FDA approval process should be, thus assuring ND will never have most of our well-established vaccines approved as a school requirement.

I suspect that underlying this bill’s requirement for one year follow up belies a mistaken notion that such follow up is needed to detect rare or delayed serious adverse events. This notion is seriously misguided for several reasons. First, we already have surveillance systems in place to detect rare or late serious side effects. In the history of all licensed vaccines in the U.S., none has ever been found to have a causally associated serious adverse event appearing after 6-8 weeks following vaccination. This makes sense when one considers the biology behind side effects. Side effects, which can and do occur, happen most often from the direct effect of the vaccine contents itself. Vaccine ingredients are typically rapidly

cleared from the body over days to weeks, and if a side effect occurs, it is likely to occur in the time shortly following vaccination when the levels of the vaccine contents are the highest. Side effects may also occur from an auto-immune response from the vaccine, which typically peaks when antibodies rise to their highest levels at about four to six weeks post-vaccination, and then fade to lower levels. Additionally, this requirement would not help to detect very rare side effects. The number of subjects enrolled in vaccine clinical trials are typically in the thousands, occasionally the tens of thousands. Rare side effects and delayed reactions might not be evident until the vaccine is administered to millions of people (untenable for a clinical trial). Therefore, the federal government established the Vaccine Adverse Event Reporting System (VAERS), a surveillance system to monitor adverse events following vaccination. In addition, large-linked databases containing information on millions of individuals, such as the Vaccine Safety Datalink (VSD), have been created to study rare vaccine adverse events after vaccines are released to the broader population. These studies are ongoing, even for our older vaccines, and as mentioned, have never discovered a serious adverse event causally linked to a vaccine beyond 6-8 weeks.

Second, the bill will deem any vaccine "experimental" if the manufacturer does not bear liability for any death or injury from the vaccine. This, again, by the bill's own definition, makes **all** vaccines "experimental". Vaccine manufacturers are not held directly liable since 1986 when President Ronald Reagan and Congress passed the National Childhood Vaccine Injury Act (NCVIA) in response to a flurry of frivolous and erroneous lawsuits against vaccine manufacturers that led to the near disappearance of many vaccines. Furthermore, families suing the manufacturers were frustrated by the often long drawn out process of litigating cases of alleged vaccine injury, and desired a more expedient process. The NCVIA was established as a no-fault alternative to the traditional legal system for resolving petitions claiming injury after vaccination. This is called the Vaccine Injury Compensation Trust Fund and was put in place to assure prompt adjudication through a "vaccine court" of legitimate injuries and also assure an ongoing supply of vaccines. More information can be found here: https://www.immunize.org/catg.d/p2075.pdf . HB1200 would have North Dakota reject the NCVIA, and insist on going back to the pre-1986 method of adjudicating vaccine injuries, something that would literally require an act of congress to reverse itself. Thus, again, assuring ND will never have **any** vaccine approved as a school requirement.

Finally, the requirement that a school or higher education institution cannot "promote" a vaccine would be seriously problematic. Take the example of an outbreak of meningococcal meningitis on a university campus, something that happens almost every year in the U.S. A mainstay of controlling these outbreaks is "promoting" the meningitis vaccine to those who were exposed or put at risk. This bill's definition would deem the meningitis vaccine an "experimental vaccine", and therefore university officials could not "promote" the vaccine to exposed roommates or fellow classmates. The universities where I work would be stripped of one of the major tools to halt such an outbreak of a potentially devastating disease. Or take the example of human papillomavirus infection. Studies suggest that up to 50% of college students may acquire this potential cancer-causing infection by the time they graduate. The HPV vaccine is remarkably effective at preventing this infection and its associated cancers. Should student health services or campus education campaigns not have the ability to promote this vaccine to prevent unnecessary cancers in this population?

Please vote NO on this seriously misguided bill.