

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 state 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.