

Testimony in Opposition

HB 1468

Human Services Committee January 25, 2021

Good afternoon Chair Weisz, Vice Chair Rohr, and members of the Committee,

My name is Dr Parag Kumar, MD, FAAP and I am a pediatrician at Sanford, Bismarck since last 20 years. I am also Clinical Professor, Clerkship director(Pediatrics), University of North Dakota School of Medicine and Health sciences Southwest campus Bismarck and Chairman of the North Dakota medical Association socioeconomic commission. Thank you for the opportunity to testify in **opposition** to HB 1468. I am asking the committee to give this bill a Do Not Pass recommendation.

Childhood vaccination rates in our community are 85 -95 %. 94 % of children entering Kindergarten are vaccinated against MMR. The requirement of providing the package insert will be burdensome to maintain such high immunization rates. Certainly, every parent who brings questions about vaccines to a pediatrician deserves support in a non-judgmental way. But then they deserve actual answers based on the science.

Package Inserts have very serious drawbacks as informed consent. First, and very importantly, inserts by design do not include a vaccine's benefits. They do not tell parents why they should get the vaccine, or the risks of not getting it. That makes the insert irredeemably flawed as an informed consent document. It simply does not include a major aspect of the information parents need to make a decision.

Most physicians feel that package inserts are not required and are also not useful for informed consent. Making this a law will hinder immunization and is government intrusion in to physician patient relationship. Is the package insert a helpful document to achieve informed consent? Imagine the following scenario. A child has been diagnosed with type I diabetes. The parent sits with the doctor and learns that the child will need to use insulin. [The doctor pulls out a 24 page insert \(pdf\)](#), gives to the parent, and says "here is a document I need to give you for informed consent." This is not only intimidating but will also hinder patient care.

Informed consent is important. For vaccines, as it is for all other medical treatments. But there appears to be some misunderstandings about what constitutes informed consent in this context. Informed consent is already provided in the form of **Vaccine information Statements (VIS)** . The Vaccine information Statements (VIS) are short, accessible, and accurate. They are made after a regulatory process that includes a notice and comment process as required in §553 of the Administrative Procedures Act: the government publishes notice, gives opportunity for comments, and [then publishes an explanation for its final rule](#). Parents get an accessible, accurate document giving them the facts they need for informed consent – and additional facts, like information about what to do if there's an adverse reaction, including reporting to the Vaccine Adverse Events System and how to file a claim with the Vaccine Injury Compensation Program. All physicians go over this VIS, the patient gets this in time to peruse it, and has a chance to raise questions and complaints, thus meeting the requirements of informed consent.

The complications (autism, seizures, deaths) or events following vaccinations are spurious correlations and not causation. These reasonable observations have been looked at closely in multiple large studies which do **include a control group**. Hundreds of such huge studies, in many countries, with millions of dollars spent, have not found any association or causation.

Unpublished and anecdotal experience of witnessing children injured from vaccines by physicians are misleading. Many have conflict of interest in promoting their anti-vaccination books or agenda. It is important to understand the difference between correlation and causation. There is a very tight correlations with U.S. cell phone cells, or organic food sales and autism. Whenever sales of ice cream go up there is increase in drowning. These are some examples of correlation and not causation. Vaccines don't cause autism. Vaccines, instead, prevent disease. Vaccines have wiped out a score of formerly deadly childhood diseases. Vaccine skepticism has helped to bring some of those diseases back from near extinction. I fear this HB 1468 (requirement of package insert) will be burdensome, unnecessary and may bring back diseases from near extinction.

I strongly urge do not pass recommendation for the HB 1468.

Sincerely,
Parag Kumar, MD, FAAP.