

INFORMED CONSENT BILL

Consumer Protection for Vermonters

Vermont law needs to be improved to protect consumers.

1. The State should be protecting consumers.
2. Vaccines are pharmaceutical products. The manufacturers warn of possible side effects, so the State and health department should make sure consumers are well informed and given full disclosure
3. The drug and medical industry have no liability when it comes to vaccines.
4. Informed consent is the ethical foundation of medicine and is critical in a free society.

Increasing numbers of providers are giving vaccines. We need a standardized process to ensure that patients and parents give their consent after being given information about each vaccine in advance, and give their written consent.

Constituents routinely report that their children (or they themselves) have had bad reactions after vaccines—Rep. Vicki Strong has even had a constituent die after a flu vaccine.

Although rare, there are reactions to these products that we—the Vermont government—are recommending (maybe even mandating, without possibility of exemption).

The responsibility therefore lies with the legislature to ensure that there is a clear process for informed consent for these specific products.

“Informed Consent Prior to Immunization” would mean:

1. Documenting provision to patient or parent, the CDC VIS and the vaccine manufacturer’s package insert for each vaccine 24 hours prior to the procedure; and
2. Documenting having received the written consent/signature of adult, or parent if minor is under age 18; and
3. Documenting that adult, or parent is told that they can say no, without threat of punishment or coercion.

Today we hear parents who say—“I was never told this could happen” about vaccine reactions. And adults who go in for a booster shot find out they got three vaccines in one shot. “I only wanted tetanus”. Were they told what was in the shot? This Informed Consent bill would insure that consumers are properly informed.

This Informed Consent bill is simple and easy to implement in this digital age. Patients can receive the manufacturer inserts and VIS as PDF files emailed in the required timeframe. And a two-part form can easily be developed that allows for either digital or print signatures to document receipt of the required information and consent.

Formal Informed Consent prior to any vaccination is needed because:

1. Vaccines are not given for treatment of any disease.
2. Vaccines, acknowledged to be "unavoidably unsafe", are given to HEALTHY children and adults, and thus their administration requires the higher ethical bar of formal informed consent as set forth in the 1948 Nuremberg Code, the 2005 UNESCO Declaration, and the 2018 AMA code of Ethics—see below.
3. Public health agencies, health care personnel, and drug makers bear no liability in the event that a vaccine causes serious disability or death.
4. FDA states that "Until a vaccine is given to the general population, all potential adverse events cannot be anticipated." <https://www.fda.gov/biologicsbloodvaccines/developmentapprovalprocess/biologicslicenseapplicationsblaprocess/ucm133096.htm>

Note:

Informed consent to any medical treatment (and the right to refuse freely) is a crucial human right as set forth in the [1947 Nuremberg Code](#), and the [2005 Universal Declaration on Bioethics and Human Rights](#).

Even the American Medical Association respects informed consent when it comes to immunizations, allowing philosophical exemptions for its doctors, according to the [AMA 2018 Ethics-Policy on Routine Universal Immunization of Physicians](#).