CO SENATE BILL 18-XXX

BY SENATOR(S):

THE COLORADO VACCINE CONSUMER PROTECTION ACT

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. Legislative declaration. The Colorado Senate hereby finds and declares:

(A) Colorado is a State with a strong tradition of protecting the health and safety of its citizens;

(B) As a precaution for the health of Colorado citizens, it is necessary to track the safety and adverse outcomes from vaccines on a state level;

(1) In an extracted report from the CDC's Vaccine Adverse Event Reporting System (VAERS), there are documented adverse vaccine outcomes from members of our Colorado population. This report shows that there were 633 serious injuries reported from vaccination in Colorado over the last three years. (See attached VAERS report for Colorado 2012-2015.)

(2) Most adverse vaccine reactions are not reported to the government. It is estimated that only one to ten percent of all serious health problems, hospitalizations, injuries and deaths that occur after vaccinations given to children or adults are ever reported to the Vaccine Adverse Events Reporting System (VAERS). Instead of reporting to federal health agencies responsible for monitoring vaccine safety, most pediatricians and vaccine providers are either not reporting at all or sending vaccine reaction reports directly to vaccine manufacturers. (Reference: Rosenthal S, Chen R. The reporting sensitivities of two passive surveillance systems for vaccine adverse events. *Am J Public Health* 1995; 85: pp. 1706-9. Braun M. Vaccine adverse event reporting system (VAERS): usefulness and limitations. Johns Hopkins Bloomberg School of Public Health.)

(3) The Colorado Department of Public Health and Environment (CDPHE) does not review and disclose the frequency and severity of Colorado vaccine injuries reported to VAERS with the public. Colorado needs an ongoing report of adverse events that have occurred in Colorado annually to keep its citizens informed. This report will also serve as a basis to monitor the safety of vaccines on a state level and potentially identify any problematic vaccine lots.

(C) In 1986, Congress passed the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. §§ 300aa-1 to 300aa-34, NCVIA) in response to the pharmaceutical industry and the American Academy of Pediatrics (AAP) requests to shield both vaccine manufacturers and doctors from civil product liability and malpractice lawsuits for injuries and deaths caused by federally recommended and state mandated vaccines. NCVIA acknowledged that vaccines can cause harm, and created a federal program to review vaccine injury claims called the Vaccine Injury Compensation Program (VICP);

(1) Vaccine providers need to be educated on NCVIA that established that they are not subject to lawsuits for injuries which result from vaccines they administer, to prevent fear of liability and avoidance of reporting adverse reactions to VAERS and avoidance of submitting claims to VICP. The aforementioned references establish that only ten percent of injuries are reported to VAERS.

(2) Vaccine providers need to be educated on the process of reporting to VAERS and submitting claims to VICP. Vaccine providers should be required to explain the VAERS process and VICP claim requirements to vaccine consumers.

(3) The VCIP rejects a vast majority of claims. Therefore Colorado needs to assess and monitor the financial impact of vaccine injuries on Colorado families on the state level.

(D) Vaccine Information Statements (VIS) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain both the benefits and risks of a vaccine. Federal law requires that vaccine providers supply VIS copies to consumers when vaccinations are given per informed consent;

(1) There is no office or agency in Colorado that enforces that vaccine providers systematically provide the VIS to patients, parents or guardians before each vaccination is given.

(2) Currently, the CDPHE website provides a link to the CDC VIS sheets. The VIS information only lists limited statements of mild risks like "redness, fever, pain and swelling at site." But the 1986 NCVIA requires vaccine providers to fully inform on risks and benefits. Since the CDC VIS information is abbreviated to one page, the vaccine consumer is not informed of the ingredients, contraindications, and severe adverse reactions. According to the Vaccine Injury Table in NCVIA, adverse reactions include: anaphylaxis, encephalopathy, seizure disorder, convulsions, shock-collapse, partial or complete paralysis, narcolepsy, cardiovascular and respiratory arrest, disability, and death. The omission of severe reactions from the CDPHE resources and from the

CDC VIS information creates a lower standard of informed consent for vaccines compared to all other prescribed pharmaceutical drugs. Therefore, vaccine providers need to provide the existing vaccine manufacturer's product insert for each vaccine to correct this disparity in informed consent.

(3) CDPHE provides incomplete information regarding the ingredients of vaccines to include adjuvants, excipients, and allergens. CDPHE selectively lists a few ingredients in their vaccine education module such as aluminum and thimerosal, and fails to disclose that those ingredients are known neurotoxins. Many vaccines contain ingredients which cause a variety of reactions and poor health outcomes for individuals and sub-populations who are susceptible to these known toxins such as aluminum, ethyl mercury, formaldehyde, and squalene. (Reference: CDC Vaccine Excipient Summary for exhaustive list) Therefore, vaccine providers need to provide the existing vaccine manufacturer's product insert for each vaccine for consumers to review the ingredients and potential allergens.

(E) The vaccine schedule has expanded from 25 to 70 doses from 1986 to 2015. Since there is no published safety research on the cumulative effect of the current vaccine schedule, vaccine providers need to inform consumers on their exemption rights. According to Institute of Medicine (2013), "Most vaccine-related research focuses on the outcomes of single immunizations or combinations of vaccines administered at a single visit. Although each new vaccine is evaluated in the context of the overall immunization schedule that existed at the time of review of that vaccine, elements of the schedule are not evaluated once it is adjusted to accommodate a new vaccine. Thus, key elements of the entire schedule – the number, frequency, timing, order and age at administration of vaccines – have not been systematically examined in research studies."

(F) There is no office or agency in Colorado that ensures that vaccine providers screen consumers for known contraindications for vaccines. "Both epidemiologic and mechanistic research suggests that most individuals who experience an adverse reaction to vaccines have a pre-existing susceptibility. These predispositions can exist for a number of reasons – genetic variants (in human or microbiome DNA), environmental exposures, behaviors, illness or developmental stage, to name just a few, all of which can interact. Some of these adverse reactions are specific to the particular vaccines, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine; others, at least with current technology and practice, are not." (Reference: Institute of Medicine (2012) Evaluating Biological Mechanisms of Adverse Events: Increased Susceptibility)

(G) There is a need for a state level office to monitor vaccine providers and advise vaccine consumers. Since the CDC approves, regulates, and recommends the US vaccine

schedule, then the CDC cannot also function as the watchdog for the safety of the vaccine schedule due to an unavoidable conflict of interest. Vaccine providers profit from vaccines and also have a conflict of interest and bias when providing safety information to consumers. Colorado needs an ombudsman for vaccine consumers since all pharmaceutical products have inherent risks and federal health agencies for compensation are disreputably difficult to access for the common person. In summary, Colorado currently does not have a system for monitoring vaccine injuries and compensation for its citizens.

SECTION 2. In Colorado Revised Statutes, XX-X-XXX ADD a new provision as follows:

This bill establishes the Vaccine Consumer Protection Program within the Colorado Department Public Health and Environment (CDPHE) and describes the services provided under the program.

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings:

A. "Vaccine provider" means a physician, nurse, clinic, hospital or other entity licensed by this State to provide health care services that administers vaccines. B. "Office" means the Vaccine Consumer Protection Office established in this section. C. "Program" means the Vaccine Consumer Protection Program established in this section. D. "Vaccine Injury Table" means the Vaccine Injury Table of covered vaccines and associated injuries established by 42 Code of Federal Regulations, Section 100.3 (2000).

2. Program established. The Vaccine Consumer Protection Program is established within the CDPHE. The Vaccine Consumer Protection Office is established within the department to carry out the purposes of the program.

3. Services. Under the program, the office must provide complete information about the benefits and risks of vaccines to health care providers and the public.

The office shall establish and implement procedures to:

A. In accordance with the legal requirements in the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. §§ 300aa-1 to 300aa-34);

(1) Require that vaccine providers give parents and consumers the complete vaccine benefit and risk information before vaccination per informed consent. CDPHE and vaccine providers will make available the existing vaccine manufacturers' product inserts which contain information on ingredients, contraindications, severe adverse reactions,

safety testing results, and effectiveness data which are lacking in the CDC VIS information.

(2) Assist and educate vaccine providers, parents, and adult vaccine consumers in reporting health problems following vaccination to the federal Vaccine Adverse Events Reporting System (VAERS). This education will be accomplished through an online education module similar to the required "Vaccine Storage and Handling Module."

(3) Require that vaccine providers keep written records of vaccine manufacturer names and lot numbers for each vaccination given because that information is necessary for reporting adverse events to VAERS and for identifying problematic vaccine lots.

(4) Require that vaccine providers record health problems, injuries, hospitalizations and deaths following vaccination into a consumer's permanent medical record.

(5) Require vaccine providers to counsel consumers prior to vaccination on VAERS and the Vaccine Injury Compensation Program (VICP), a specialized federal court handling vaccine claims through the US Department of Health and Human Services.

B. Along with the extensive vaccine benefit information in the CDPHE literature, website, and modules for the public and providers, include the corresponding vaccine risk information according to the Vaccine Injury Table which includes: anaphylaxis, encephalopathy, seizure disorder, convulsions, shock-collapse, partial or complete paralysis, narcolepsy, cardio vascular and respiratory arrest, disability, and death. Replace all risk information that uses subjective qualitative terms such as "rare" with objective quantitative risk data from the vaccine manufacturers' product inserts. Provide information on ingredients including all adjuvants, excipients, and allergens contained in vaccines.

C. Educate vaccine providers on the aforementioned contents of the Vaccine Injury Table and the adverse reaction section of the vaccine manufacturers' product inserts to help providers better diagnose adverse health events caused by vaccines.

D. Require vaccine providers to reference the list of contraindications in the vaccine manufacturers' product inserts for specific contraindications for each vaccine when counseling a parent. Require vaccine providers to utilize the screening form and screening guidance in the Colorado Immunization Manual (2011, page 6-7, 6-8) to screen patients for general contraindication for vaccination. Require vaccine providers to follow the guidance in the Colorado Immunization Manual (2011) in Section 12 Special Situations and Conditions for people with conditions who cannot be vaccinated. Require

vaccine providers to follow the guidance in Colorado Immunization Manual (2011) Section 13 Contraindications indicating that a reaction to a previous vaccine is a contraindication for future vaccines.

E. Since the vaccine schedule has grown from 25 to 70 doses of vaccines from 1986 to the 2015, require vaccine providers to educate consumers that a blood test result for positive antibodies to a virus can be provided as proof of not needing a booster vaccine and acceptable in lieu of taking an additional booster vaccine according to the vaccine schedule.

F. Write and publicize an annual report on the adverse vaccine reactions reported to VAERS from Colorado citizens. Make available on the CDPHE website the Colorado surveillance data concerning incidence of diseases that require vaccination for school, including data on vaccination status of those contracting a disease.

G. Inform consumers about their right to opt out of vaccine requirements based on religious and philosophical grounds. Inform consumers about their right to opt-out of their medical information being included in the Colorado Immunization Information System (CIIS) vaccine tracking database. Establish a complaint procedure and investigate any cases of coercion, discrimination, or sanctions against consumers who choose to exercise their exemption rights.

H. Require the Board of Health to include a vaccine-injured adult and parent of a vaccine-injured child as stakeholders on all rules committees for vaccine policy.

4. Rules. The department shall adopt rules to implement this section.

5. Repeal. Upon repeal of the National Childhood Vaccine Injury Act of 1986, 42 United States Code, Sections 300aa-1 to 300aa-34, this new section is repealed.

SECTION 3. Reference Manual. The CDPHE shall update the Colorado Immunization Manual for Providers and the Immunization department website with the provisions of the Colorado Vaccine Consumer Protection Act.

Bill drafted by Pam Long, mother of a vaccine injured child.

Highlights of the Report of the Colorado Autism Commission for Senate Bill 08-163 provided to Joint Legislative Committee on the Health and Human Services: Excerpted by Francis Sincere, Lakewood CO, Jan. 3, 2018

Introduction of Report

"In 2008, the Colorado General Assembly created the Colorado Autism Commission (SB08-163) in order to obtain additional information on people with Autism Spectrum Disorders (ASD) in the State. The Commission was tasked with identifying existing services and the gaps in these services as experienced by the Autism Spectrum Disorders community, and to determine appropriate actions to remedy these shortcomings through the preparation of a Ten-Year Strategic Plan for the State of Colorado. The legislation that authorized the Autism Commission is included in Appendix A.

Report cited an URGENT NEED...

"There is an urgent need to improve systems of care. Due to the dramatic increase in the incidence of ASD, the service systems for people with neurodevelopmental disabilities are unable to respond to the current need. Immediate and proactive steps must be taken to improve systems and services. The State of Colorado must focus on what steps must be taken to respond rapidly and efficiently to the needs and challenges of individuals and families affected by ASD. The sooner treatment begins in the life of a person with ASD, the better the outcomes.

Epidemic was Recognized 9 years ago!

"As the epidemic of ASD has grown, so has the media coverage of the truths and myths surrounding these conditions. This coverage has left the general public and those affected by ASD in a state of flux and confusion. There are unprecedented rifts in the community about causes, the appropriate treatments, and how to educate and support people with ASD. Testimony revealed that some families are using complementary and alternative treatments with anecdotal success. To decrease the general confusion surrounding the treatment of ASD, more research is needed to develop and substantiate effective and affordable treatments.

Information Systems Needed

"Significant amounts of data do exist but are often inaccessible and inaccurate. The virtual explosion of ASD in Colorado renders accurate data difficult to obtain. Until the State can accurately account for the numbers of individuals with ASD, the severity of the disorder among individuals, and the geographic distribution

and needs, development of effective systems for prevention, treatment, and recovery will be difficult. It is essential that accurate data be accumulated and used to inform planning.

Research

"A goal of the Commission is to encourage the various State departments to follow developments in research into the causes and treatment of Autism Spectrum Disorders. Dramatic increases in ASD may indicate a combination of genetic pre-dispositions coupled with environmental triggers (Eigsti & Shaprio, 2003). Implementation of recommendations arising from sound research on the risk factors and the environmental triggers for ASD ultimately may allow prevention of ASD in some at-risk children, or ameliorate the most serious disabilities in those affected.

Conclusion of this Report!

"In conclusion, The Colorado Autism Commission believes all Coloradans affected by Autism Spectrum Disorders deserve to have ready access to the services and supports they need to be safe, educated, healthy, productive, and able to pursue happy and fulfilling lives. To that end, we have developed this Ten-Year Strategic Plan to promote, integrate, coordinate, and expand services to all Coloradans affected by Autism Spectrum Disorders, including the creation of new programs as the science around the causes and treatment of ASDs expand. We believe a formal and sustainable mechanism to implement the recommendations within this report should be considered as a significant pathway towards these ends. Thank you for the opportunity to serve the Citizens of Colorado, and we hope to see these recommendations enacted in the coming years.

Betty Lehman
Chair, Colorado Autism Commission, 2009

http://www.jfkpartners.org/documents/Colorado%20Autism%20Commission%20Report_final.pdf