Model State Vaccine Consumer Protection Act

In 2015, The Maine Vaccine Choice Coalition opposed two bills in Maine that would remove the rights of parents to make uncoerced vaccine decisions for their children and retain the right to attend public school. As in dozens of other states, vaccine industry supported bills that attempted to remove parental rights were promoted using arguments that insisted parents were uninformed and uneducated, so their choices must be limited.

This position is untenable, as all research into vaccine uptake shows that it is the mostly highly educated parents who are the ones choosing to opt out of vaccination.

The Maine Coalition for Vaccine Choice argued that the real divide between the medical establishment and vaccine hesitance parents was because the US National Immunization Program is broken, and smart parents know it full well. In turn, their Director, Ginger Taylor, drafted the Maine Vaccine Consumer Protection Act which addressed the true problems that are destroying trust in vaccination and driving a wedge between educated families and their physicians. It was introduced by Maine State House Representative Beth O'Connor, as LD 1076, An Act to Enact The Maine Vaccine Consumer Protection Program.

We present the following bill, and justifications for the state legislation, as model legislation to introduce into all states, to educate legislators on the true problems in the vaccine program that are leading to an increase in Americans opting out of the CDC recommended schedule, and to address the harm and injustice currently being created by the federal National Immunization Program:

The 1986 National Childhood Vaccine Injury Act, and the Supreme Court ruling Bruesewitz v Wyeth that sided with Pharma, removed the rights of individuals to sue in cases of vaccine injury and death, and closed the courthouse doors to families with vaccine injured loved ones. Vaccine injury claims were then moved to the HHS Vaccine Injury Compensation Program. As a result of this freedom from legal accountability, corruption has taken hold in the US vaccine program:

- The CDC recommended Childhood Vaccine schedule ramped up from 25 to a minimum of 70 doses with no safety testing of the current schedule as a whole.
- The Federal Vaccine Injury Compensation Program rejects the vast majority of claims made by families regardless of merit.
- States and families pay for vaccine injury cases that are the responsibility of the federal government.
- HHS has become a vaccine patent holder, while approving, regulating and recommending vaccines, and while and adjudicating vaccine injuries, without disclosing its serious conflicts of interests to consumers.
- Corruption in safety and efficacy claims are being uncovered on an increasing basis:
 - The current Congressional investigation into the #CDCwhistleblower Scandal, triggered when senior CDC vaccine scientist William Thompson admitted publicly that he and his research team had actively hidden vaccine autism links from the public.

- The DOJ indictment of CDC vaccine safety researcher Poul Thorsen on 21 counts of fraud and money laundering for embezzling more than a million dollars from CDC and his university, whose research CDC is still using to support vaccine safety claims.
- The current mumps outbreak coupled with the Merck Mumps Whistleblower Lawsuit in underway in federal court in which Merck's own scientists are suing the company for turning in fraudulent mumps efficacy data to the FDA in 2000 to gain re-approval for the MMR II.
- False vaccine safety claims made by MaineHealth both on their web site and on MPBN, that the public is unable to get removed or retracted.
- The Government Accounting Office, Stanford Law, American University/George Washington University School of Law and Associated Press/NYT investigations into the failures of the VICP to properly compensate families of vaccine victims according to the intent of the 1986 National Childhood Injury Act.
- Research showing that, although the federal government will not officially establish the vaccine/autism link, the Vaccine Injury Compensation Program has been quietly paying autism cases since 1991.

To remedy this, Maine needs a Vaccine Consumer Protection Act to counter the corruption, misinformation, and attack on families right to informed consent. The proposed act would:

- Require doctors to be educated on the full Vaccine Injury Compensation Table and able to properly screen for and diagnose vaccine adverse events
- Add VICP and the full, and soon to be revised, vaccine injury table to the Maine Immunization Program's Provider Reference Manual.
- Advertise the VICP in Maine, per recommendation of the 11/14 GAO VICP report.
- Require a Maine State Vaccine Information Sheet for each vaccine which includes all known side effects be given to patient, per vaccine package insert, table and VICP rulings, remind patients of their right to opt out, and offer step by step instructions on what to do if a vaccine injury is suspected.
- Remove the restrictions on which doctors would be able to write a medical exemption.
 Our understanding of vaccine adverse reactions grows as science progresses, such as our new understanding on what genetic variations will put someone at risk for a vaccine adverse event, and should not be codified into law.
- Establish a vaccine injury office in Maine DHHS separate from the Maine Immunization Program that will:
 - Act as an ombudsman for Maine vaccine injury families and clearing house for VICP case data
 - Evaluate vaccine injury claims
 - Provide guidance and a specific process for physicians to follow when a vaccine injury is suspected by their office, or by parents and caregivers
 - Provide referrals to doctors who are experienced and qualified in vaccine injury and will evaluate and treat

- Provide referrals to attorneys who will file in the VICP
- Recoup MaineCare funds that are spent on vaccine injury cases
- Establish a complaint and review process for families to ask specific vaccine questions, challenge false vaccine safety and efficacy claims as well as coercion by vaccine providers, and requires DHHS to respond and justify recommendations.

Parents who have known for years that the vaccine program is broken have had their position yet again confirmed by two different in-depth investigative reports into the Vaccine Injury Compensation Program by both the US General Accounting Office and by the Associated Press; that once you have a vaccine injured child, you are on your own.

It is time to stop blaming parents for walking away from a broken vaccine program, and to simply begin to fix the vaccine program.

The Maine Vaccine Consumer Protection Act

SUMMARY

This bill establishes the Vaccine Consumer Protection Program within the Department of Health and Human Services and describes the services provided under the program.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA 1067 is enacted to read:

1067. Vaccine Consumer Protection Program

- 1.Definitions, As used in this section, unless the context otherwise indicates, the following terms have the following meanings,
- A. "Health care 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 Compensation 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 department. 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 information about vaccine injuries and immunizations to health care providers and the public.

The office shall establish and implement procedures to:

A. Promote public awareness of the Vaccine Injury Table through development and implementation of an educational outreach program that provides, at a minimum, the

information contained in the Vaccine Injury Table or to any individual in the State who requests information related to vaccine injuries or immunizations;

- B. Educate health care providers on the contents of the Vaccine Injury Table to help providers better screen for and diagnose adverse events caused by vaccines;
- C. Require health care providers to use vaccine package inserts and the Vaccine Injury Table information that describes the warnings, precautions and adverse reactions potentially caused by a particular vaccine during the screening and diagnosing of an illness, disability, injury or adverse condition caused by vaccines to evaluate patients, or refer for an evaluation, when an individual or caregiver suspects and reports that a vaccine reaction may have taken place.
- D. Write and publicize a Maine Vaccine Information Statement. The statement must include evidence-based information about vaccines and their potentially adverse side effects, inform patients about their right to opt out of vaccine requirements based on religious and philosophical grounds and offer a step-by-step explanation about how to pursue legal recourse if an individual suspects a vaccine injury has occurred. When drafting the statement, the department shall consult with nationally recognized vaccine safety advocates as well as Maine vaccine injured individuals and Maine families with vaccine injured family members.
- E. Investigate potential vaccine injuries;
- F. Evaluate vaccine injury claims:
- G. Review instances of potential coercion by health care providers related to the issuance of a vaccine and require health care providers who are suspected of coercion to retract any inaccurate statements or face discipline by the applicable professional licensing entity:
- H. Educate health care providers about the process for handling vaccine injury reports made in their practices.
- I. Provide individuals with referrals to health care providers that treat vaccine injuries and to attorneys that handle claims related to vaccine injuries; and
- J. Recoup funds that are spent on vaccine injury cases under the MaineCare Program established under chapter 855.
- 4. Rules. The department shall adopt rules to implement this section. Rules adopted pursuant to this subsection are major substantive rules pursuant to Title 5, chapter 375, subchapter 2-A.
- 5. Repeal. Upon repeal of the National Childhood Vaccine Injury Act of 1986, 42 United States Code, Sections 300aa-1 to 300aa-34, the department shall submit legislation repealing this section.
- 6. Strike out 20-A MRSA §§6352-6358 3 B which specifies what may constitute a valid

medical exemption so that physicians may base exemptions on up to date scientific information.

Sec. 2 Reference Manual. The Department of Health and Human Services shall add the Vaccine Injury Compensation Program and the Vaccine Injury Table covered vaccines and associated injuries established by the 42 Code of Federal Regulations, Section 100.3 (2000) to the Maine Immunization Program's Provider Reference Manual created by the department's division of infectious disease within the Maine Center for Disease Control and Prevention.

The hearings on all three vaccine bills took place on the same day, and the strong showing from Maine parents who showed up to tell their stories of their vaccine injured children, for whom they were not able to receive compensation or adequate medical care, resulted in the committee unanimously voting down a bill like California's SB277 to remove vaccine exemptions, a veto on a bill like California's AB2109 to require parents have a physician sign off on exemptions, the passage of the Maine Vaccine Consumer Protection Act in a dramatically reduced form and the drafting of a letter from the Health and Human Services Committee of the Maine Legislature to Maine's Congressional delegation expressing concern over the problems they were hearing from Mainers concerning the HHS Vaccine Injury Compensation Program and asking them to investigate the pharmaceutical industry's blanket protection from liability.

But one of the most surprising outcomes of the process was the opposition to the consumer protection bill. 21 mainstream medical entities registered opposition to the bill, but their statements showed that they did not understand the federal programs that they would have been mandated to be educated on and to use if the legislation was passed.

The MCVC sent questions to the Maine Chapters of the AMA and AAP that had drafted and supported the bill to require families to talk to their members before being allowed to file a vaccine exemption, but they refused to respond.

Thus the following additional testimony was submitted to the health committee just before they voted on the bills restricting vaccine choice rights:

Additional testimony in opposition to LD 471 and LD 606 Ginger Taylor, MS, Maine Coalition for Vaccine Choice, Brunswick, Maine

Maine physicians are not qualified to guide patients on vaccination.

In 1986 Congress passed the National Childhood Vaccine Injury Act i. The law:

- Removed all liability from the medical/pharmaceutical industry for vaccine injury and death.
- Established the Vaccine Adverse Reporting Events System (VAERS), housed at CDC, to track potential vaccine safety problems.
- Established the Vaccine Injury Compensation Program ii (VICP), housed at HRSA, to compensate vaccine injury cases, which established the Vaccine Injury Table of basic vaccine injuries, and makes judgments on off table claims.
- Required an HHS prepared Vaccine Information Sheet be given to parents and patients before a vaccine is administered that notifies them of some potential adverse reactions they may experience, and of the existence of VAERS and VICP iii.

This is SUPPOSED to be the safety system to prevent, diagnose, treat and compensate vaccine injury. HOWEVER...

In the nearly 30 years since the Act was passed, the vaccine schedule has grown from 24 doses of vaccine to 70 for children today. (Appendix 1)

All investigations iv into the VICP show that it is not properly compensating familiesv, and that it is hidden from the public vi.

While the Maine Immunization Program Provider Reference Manual vii provides information on VAERS to doctors, NO INFORMATION ON THE VICP IS PROVIDED.

You have heard the testimony of patients and parents who have experienced serious vaccine reactions. They have reported that they were not given informed consent ahead of time, that they could not get their doctors to take their vaccine reaction claims seriously, that medical investigations of reactions and even deaths are not undertaken, that the were not told of the VICP, that they were mistreated in the VICP and that even when one claim was granted, they were abused by the VICP.

No substantive arguments have been offered yet as to why this legislation should not be enacted, on the contrary, the testimony offered on all sides of this bill support the need for its enactment.

Parents in these hearings have made the bold and difficult to believe claim that doctors are not qualified to counsel patients on the vaccine program and are ill informed. In fact, of the 21 entities that have offered testimony opposing this bill, only one shows any evidence that they read and understood the bill.

Of the 21 entities testifying in opposition to LD 1076 On whether or not they knew about or understood the VICP:

9 gave testimony that showed that they didn't understand the VICP (4 Medical Professionals Organizations, 3 Public Health Agencies, 2 Health Care Corporations)

11 gave testimony that was unclear on whether they understood the VICP or not (3 Pediatricians, 2 Medical Professional Organizations, 1 Health Care Corporation, 2 parents and 3 advocates.

1 Gave testimony that showed that she knew about the VICP, but that she believed that it "provides a swift, comprehensive alternative to litigation." (Pediatrician representing a Health Care Corporation)

On whether or not they could differentiate VICP from VAERS:

8 confused VICP with VAERS (4 Medical Professional Organizations, 3 Public Health Agencies, and 1 Health Care Corporation)

12 did not give enough information to tell if they were confusing VICP with VAERS (1 Medical Professional Organizations, 3 Pediatricians, 3 Advocates, 2 parents and a Health Care Corporations)

1 could differentiate between VICP and VAERS (Pediatrician representing a Health Care Corporation)

On their reasons for opposing the bill:

9 stated only that they were opposed to the bill, and gave no explanation as to why (3 Pediatricians, 1 Medical Professional Organization, 1 Health Care Corporation, 2 Advocates and 2 parents.)

8 reported that it was redundant to federal legislation (3 Medical Professional Organizations, 3 Public Health Officials, 2 Health Care Corporations)

1 reported that it was redundant and a scare tactic

1 reported that it was anti-vaccine (Health Educator)

1 reported that DHHS should not be encouraging malpractice claims (Medical Professional Organization)

1 reported that it would not use credible information (Health Care Corporation)

Of the 21 entities opposing the bill, only one attended the hearing.

Quotes:

Michaud, Maine Medical Association: When asked about VICP rulings, "I don't know. I've

never been involved in that system."

Austin, Maine Hospital Association: On vaccine package inserts: "People don't receive vaccines like they do other prescriptions... not sure there is a package here."

Pelletier, Maine AAP: "The Federal Vaccine Injury Program provides appropriate venue for reporting and tracking vaccine related side effects."

Belisle, Maine Quality Counts: "Many of the components of this bill are redundant to the Vaccine Adverse Events Reporting System and Efforts already performed by the Maine Immunization Program in collaboration with providers and physicians state wide."

Box, Maine Immunization Program/Former Asst. Dir: "Many of the components of this bill are redundant to the Vaccine Adverse Events Reporting System and Efforts already performed by the Maine Immunization Program in collaboration with providers and physicians state wide."

Losey, Maine Immunization Program/FAAP Advisor: "LD 1076 to establish the Consumer vaccine protection program would fragment efforts to monitor and improve vaccine safety. Our state's relatively small population makes the experience much more limited and the efforts for the most part duplicate actions the us Centers for Disease Control and Prevention is already involved in."

Soma, Portland Pubic Health Director: "LD 1076, which would establish a vaccine safety office in Maine, would be redundant, as one already exists at the federal level."

Michael, EMHS: "LD 1076 proposes to refocus the public's attention away from credible public health information about the risks and benefits of immunization to establish a new governmental unit, apparently focused on promoting fear of potential injury, coercion and litigation. LD 1076 places not just children, but all Maine citizens at increased risk of illness, disability and death."

L'Heureux, American Nurses Association Maine: "the work of a vaccine consumer protection program is redundant to the scientific public health research of our Centers for Disease Control."

Westhoff, Maine Osteopathic Association: "This already exists at the federal level. It is redundant and would create a new state agency and a new level of bureaucracy that doesn't need to exist and would do little more than scare parents from getting children immunized."

Deborah Hagler, Matins Point: "...measure to create a Maine Vaccine Consumer Protection Program. However, this task is already capably handled by the National Vaccine Injury Compensation Program which established a no-fault compensation program for those seeing redress from injuries from vaccines. This existing federal program already provides a swift, comprehensive alternative to litigation. Adding another bureaucracy to complicate matters would only frustrate and burden the state resources and would serve no purpose."

Note that LD 1076 had nothing to do with the Vaccine Adverse Events Reporting System.

In light of the testimony offered by Maine AAP and the Maine Medical Association, the Maine Coalition for Vaccine Choice has requested that the Joint Standing Committee on Health and Human Services ask the the following questions:

Questions for the Maine Medical Association

Questions for the Maine Chapter of the American Academy of Pediatrics

Following the hearings and vote on legislation, we presented the following questions to the Maine CDC.

Link to the written testimony submitted on Maine LD 1076

Link to the <u>oral testimony given on Maine LD 1076</u> (This was at the end of a full day of testimony on three vaccine bills, so video on LD 471 & LD 606, also available from the same YouTube user, offer more information on what was discussed before the Health Committee that day in Maine.)

i http://www.hrsa.gov/vaccinecompensation/authoringleg.pdf

ii http://www.hrsa.gov/vaccinecompensation/index.html

iii http://www.cdc.gov/vaccines/hcp/vis/current-vis.html#mce temp url#

iv Court Heaps Grief on Vaccine Victims, Makes Them Wait Years, by The Associated Press, New York Times, December 22, 2014, http://www.nytimes.com/aponline/2014/12/22/us/politics/ap-us-vaccine-court.html?_r=2

v Fixing the Flaws in the Federal Vaccine Injury Compensation Program, Peter H. Meyers, George Washington University Law School, Administrative Law Review, Vol. 63, No. 4, p. 785, 2011, GWU Legal Studies Research Paper No. 2012-20 vi VACCINE INJURY COMPENSATION:Most Claims Took Multiple Years and Many Were Settled through Negotiation, GAO-15-142: Published: Nov 21, 2014. Publicly Released: Nov 21, 2014.

vii https://www1.maine.gov/dhhs/mecdc/infectious-disease/immunization/providers/manual/index.shtml

We hope this resource is valuable to you in your work, and if you have any questions, please feel free to contact Ginger Taylor of the Maine Coalition for Vaccine Choice, and The Canary Party at GingerTaylor@CanaryParty.org or 818-402-9672.