UNIVERSITY OF HAWAIʻI SYSTEM
Legislative Testimony

Testimony Presented Before the
House Committee on Health and Human Services
March 22, 2018 at 9:00 a.m.
By
Carolyn Ma, PharmD, BCOP
DEAN
UH Hilo - Daniel K. Inouye College of Pharmacy

HCR 157 / HR 107 – REQUESTING THE DEPARTMENT OF HEALTH AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION TO CONDUCT A STUDY ON THE INCIDENCES OF ADVERSE EFFECTS TO VACCINES IN HAWAII.

Chair Mizuno, Vice Chair Kobayashi, and members of the committee:

My name is Carolyn Ma, and I am the Dean for the UH Hilo Daniel K. Inouye College of Pharmacy (DKICP). As designated lead for UH Hilo and on behalf of Interim Chancellor Marcia Sakai, the University of Hawai‘i at Hilo opposes HCR 157 / HR 107.

Adverse drug reaction (ADR) reporting is a complex and incomplete method to capture the side effects of drugs or vaccines. Institutions from hospitals, clinics, long term care and nursing homes, even when required, have difficulty in mandating reporting and rely on all medical staff to report. Whichever system is utilized, it still relies on an individual reporting the incident, and this inherently has flaws. Thus, data can often be incomplete or inaccurate. The accreditation body of these types of organizations, namely The Joint Commission, follows and requires reporting of ADRs, as well as requires intervention, monitoring and follow up in an acceptable quality assurance or improvement process. This type of oversight has improved ADR reporting and clinical intervention, however, the process continues with improvements and refinement.

For any ADR system to be accurate, all reported ADRs need direct assessment of the reaction, inventory of all medications and diseases, and laboratory parameters, if necessary, to ascertain direct causal relationship. These steps require tremendous human resources and expertise.

The college has great trust in DOH and its abilities but without first examining the means of reporting and assurance of quality reporting, outcomes from such a study could lead to inaccurate information and outcomes. In addition, the resolution does not specify how the data will be utilized and for what purpose.

Mahalo for the opportunity to testify in opposition of HCR 157 / HR 107.

DAVID Y. IGE
GOVERNOR OF HAWAII

VIRGINIA PRESSLER, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P. O. Box 3378
Honolulu, HI 96801-3378
doh.testimony@doh.hawaii.gov

Testimony in OPPOSITION to H.C.R. 157
REQUESTING THE DEPARTMENT OF HEALTH AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION TO CONDUCT A STUDY ON THE INCIDENCES OF ADVERSE EFFECTS TO VACCINES IN HAWAII.
REPRESENTATIVE JOHN M. MIZUNO, CHAIR
HOUSE COMMITTEE ON HEALTH AND HUMAN SERVICES
Hearing Date: 3/22/2018 Room Number: 329

Fiscal Implications: If the Department of Health is required to fulfill the requirements of H.C.R. 157, increased funding and dedicated staff would be necessary to conduct investigations and follow-up reports, organize and maintain data in an appropriate database, and analyze and interpret the data.

Department Testimony: DOH strongly opposes this measure. The requirements of H.C.R. 157 are duplicative of extensive vaccine safety monitoring and communication efforts coordinated at the Federal level. The population of Hawaii is also not of sufficient size to conduct a vaccine safety study. Any signals (reports) or findings would be skewed and not generalizable—i.e., could not be used to reliably interpret whether there is an issue with a vaccine or not. Information gained by a study of adverse events in Hawaii would not provide information on whether or not adverse events were actually caused by vaccines, i.e., whether "vaccine injury" has truly occurred.

The Centers for Disease Control and Prevention (CDC) Immunization Safety Office is responsible for identification of possible vaccine side effects and conducts studies to determine whether health problems may have been caused by vaccines. Critical components of U.S. vaccine safety monitoring activities include:

Vaccine Adverse Event Reporting System (VAERS)**:** VAERS is a national vaccine safety surveillance program run by CDC and the Food and Drug Administration (FDA). VAERS serves as an early warning system to detect possible safety issues with U.S. vaccines by collecting

information about adverse events (possible side effects or health problems) that occur after vaccination.

In addition to the Federal requirement for providers to report adverse evnets to VAERS, CDC encourages providers to report any clinically significant adverse event that occurs in a patient following a vaccination, even if they are unsure whether a vaccine caused the event. Recommendations for healthcare professionals to report to VAERS are a part of the Standards for Pediatric Immunization Practices, which are endorsed by multiple professional organizations, including the American Academy of Pediatrics. In addition, each CDC-developed Vaccine Information Statement (VIS) provides information on reporting to VAERS.

Vaccine Safety Datalink (VSD): While VAERS is a passive reporting system, the VSD is an active surveillance system that allows for evaluating concerns in a scientific, or controlled, manner. The CDC has partnered with eight health care organizations across the country to collect data on vaccines given as well as illnesses that have been reported, urgent care visits, emergency department visits, and hospital stays. The VSD can then conduct safety studies based on questions or concerns raised through VAERS or by the medical community. The system also closely monitors any newly introduced vaccines.

Clinical Immunization Safety Assessment (CISA): The CISA project is an active surveillance system in which CDC partners with medical centers to study vaccines in particular groups of people. This system allows CDC to study rare potential side effects in vulnerable populations. CISA addresses vaccine safety issues, conducts high quality clinical research, and assesses complex clinical adverse events following vaccination. CISA facilitates CDC's collaboration with vaccine safety experts at leading academic medical centers and strengthens national capacity for vaccine safety monitoring. The CISA Project provides consultation to US clinicians who have vaccine safety questions about a specific patient residing in the U.S. In addition, CISA provides consultation to U.S. healthcare providers and public health partners on vaccine safety issues, and reviews clinical adverse events following immunization involving U.S.-licensed vaccines.

In addition, the FDA also has its own active surveillance system called the **Post-licensure Rapid Immunization Safety Monitoring System (PRISM)**. PRISM is a powerful, computer-based system that separates critical bits of information from vast streams of healthcare data to investigate adverse events and determine if there is a connection to a specific vaccine. Unlike passive surveillance systems such as VAERS, PRISM's active surveillance lets FDA initiate its own studies using existing electronic healthcare data in a timely manner.

H.C.R. 157 emphasizes provider reporting to VAERS, which is important as passive surveillance systems depend on industry, consumers, patients, and healthcare professionals to recognize and report suspected adverse events. However, VAERS is utilized ***in conjunction with*** active surveillance mechanisms. Active surveillance mechanisms such as the VSD, CISA and PRISM are also critical to timely identification and investigation of possible vaccine safety issues.

H.C.R. 157's public and provider educational requirements are also duplicative of existing Federally-mandated vaccine risk/benefit communication requirements. Currently, as required under the National Childhood Vaccine Injury Act [NCVIA] (42 U.S.C. §300aa-26, specified in the measure), all health care providers in the United States who administer, to any child or adult, any of the following vaccines—diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox)—shall, prior to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials produced by CDC to the parent or legal representative of any child to whom the provider intends to administer such vaccine, or to any adult to whom the provider intends to administer such vaccine.

CDC-developed Vaccine Information Statements (VIS) serve as these vaccine information materials and provide individuals with information on the benefit of vaccination ("Why get vaccinated?"), who should be vaccinated, contraindications to vaccination, risks associated with the vaccination (i.e., adverse events associated with the vaccination), what to do

in the event of an adverse reaction, information regarding reporting adverse reactions to the Vaccine Adverse Event Reporting System (VAERS), information regarding the National Vaccine Injury Compensation Program, as well as who to contact if individuals are interested in obtaining additional information about the vaccine. VISs provide individuals with current, relevant information regarding vaccinations in an accessible format and have been translated into over 40 languages to ensure important information related to vaccination is available to most persons. While VISs are written to fulfill the information requirements of the National Childhood Vaccine Injury Act of 1986 and not as informed consent forms, they cover both benefits and risks associated with vaccinations to assure persons are adequately informed about possible adverse effects of vaccination and how parents and providers may report to VAERS, if needed.

This measure requires Department of Health personnel and resources not currently available and may serve to discourage vaccination. On an individual level, decisions regarding vaccinations can have both immediate and lifelong ramifications, affecting children in infancy as well as years later, should exposure to disease occur. On the community level, most vaccine-preventable diseases are transmitted from person-to-person. When a sufficiently large proportion of individuals in a community are immunized, those persons serve as a protective barrier against the likelihood of transmission of the disease in the community, thus indirectly protecting those who are unable to be immunized (i.e., persons unable to receive immunizations because of age, medical condition, immunosuppressive therapy, etc.) and those who received the vaccine but have not responded and therefore have no antibodies or protection (vaccine failures). This phenomenon is referred to as "herd immunity." With the threat of vaccine-preventable infectious disease ever-present, including a severe nationwide influenza season and our ongoing statewide mumps outbreak, this measure jeopardizes the health of our community and places undue burden on the Department of Health and Hawaii healthcare providers.

Thank you for the opportunity to testify.

HAWAII MEDICAL ASSOCIATION
1360 S. Beretania Street, Suite 200, Honolulu, Hawaii 96814
Phone (808) 536-7702 Fax (808) 528-2376
www.hawaiimedicalassociation.org

TO:
COMMITTEE ON HEALTH & HUMAN SERVICES
Rep. John M. Mizuno, Chair
Rep. Bertrand Kobayashi, Vice Chair

DATE: Thursday, March 22, 2018
TIME: 9:00 a.m.
PLACE: Conference Room 329

FROM: Hawaii Medical Association
Dr. Christopher Flanders, DO, Executive Director
Lauren Zirbel, Government and Community Relations

Re: HCR 157

Position: OPPOSE

The United States' long-standing vaccine safety program closely and constantly monitors the safety of vaccines. A critical part of the program, CDC's Immunization Safety Office identifies possible vaccine side effects and conducts studies to determine whether health problems are caused by vaccines. Data show that the current U.S. vaccine supply is the safest in history.

There is no link between vaccines and autism.[1]

Some people have had concerns that ASD might be linked to the vaccines children receive, but studies have shown that there is no link between receiving vaccines and developing ASD. In 2011, an Institute of Medicine (IOM) report on eight vaccines given to children and adults found that with rare exceptions, these vaccines are very safe. A 2013 CDC study [PDF – 204 KB] added to the research showing that vaccines do not cause ASD. The study looked at the number of antigens (substances in vaccines that cause the body's immune system to produce disease-fighting antibodies) from vaccines during the first two years of life. The results showed that the total amount of antigen from vaccines received was the same between children with ASD and those that did not have ASD.

Vaccine ingredients do not cause autism.[2]

[1] https://www.cdc.gov/vaccinesafety/concerns/autism.html
[2] https://www.cdc.gov/vaccinesafety/concerns/autism.html

HAWAII MEDICAL ASSOCIATION
1360 S. Beretania Street, Suite 200, Honolulu, Hawaii 96814
Phone (808) 536-7702 Fax (808) 528-2376
www.hawaiimedicalassociation.org

One vaccine ingredient that has been studied specifically is thimerosal, a mercury-based preservative used to prevent contamination of multidose vials of vaccines.

Research shows that thimerosal does not cause ASD. In fact, a 2004 scientific review by the IOM concluded that "the evidence favors rejection of a causal relationship between thimerosal–containing vaccines and autism." Since 2003, there have been nine CDC-funded or conducted studies[PDF – 357 KB] that have found no link between thimerosal-containing vaccines and ASD, as well as no link between the measles, mumps, and rubella (MMR) vaccine and ASD in children.

Between 1999 and 2001, thimerosal was removed or reduced to trace amounts in all childhood vaccines except for some flu vaccines. This was done as part of a broader national effort to reduce all types of mercury exposure in children before studies were conducted that determined that thimerosal was not harmful. It was done as a precaution. Currently, the only childhood vaccines that contain thimerosal are flu vaccines packaged in multidose vials. Thimerosal-free alternatives are also available for flu vaccine. For more information, see the Timeline for Thimerosal in Vaccines. Besides thimerosal, some people have had concerns about other vaccine ingredients in relation to ASD as well. However, no links have been found between any vaccine ingredients and ASD.

VISs are updated only when they need to be. For instance, a VIS would be updated if there were a change in ACIP recommendations that affects the vaccine's adverse event profile, indications, or contraindications. Knowing that VISs posted on CDC's VIS website are always current should help alleviate any concern. Annually changing the dates on VISs that haven't changed otherwise could be confusing too, because there could be multiple VISs in circulation that are identical but have different dates. Providers using paper VISs shouldn't be required to renew their stocks each year because the date changed.[3]

Thank you for the opportunity to provide testimony.

[3] https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html

HCR-157
Submitted on: 3/21/2018 8:40:06 AM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Patrick Uyemoto	Hawaii Pharmacists Association	Oppose	Yes

Comments:

Chair, Vice Chair, and committee members, thank you for this opportunity to provide testimony on HCR157 and HR107.

As a concerned resident of Hawaii and parent, I oppose these resolutions as unnecessary, costly, and dangerous. These resolutions would required the use of limited state time and resources to investigate vaccine adverse events, even though the evidence clearly demonstrates vaccine effectiveness, safety, and importance for health. Please consider the following points:

- An "adverse event" is any health problem that happens after vaccination. It may or may not have been caused by the vaccine.
- The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) closely monitor vaccine safety using a collection of passive and active surveillance systems:
    - Vaccine Adverse Event Reporting System (VAERS)
    - Vaccine Safety Datalink (VSD)
    - Post-Licensure Rapid Immunization Safety Monitoring (PRISM)
    - Clinical Immunization Safety Assessment Project (CISA)
- These systems have the funding, resources, and expertise to monitor vaccines currently in use. Requesting the Department of Health and CDC to conduct additional studies is duplicative and unnecessary.
- The National Childhood Vaccine Injury Act (NCVIA) requires providers to report adverse events to VAERS. In addition, recommendations for healthcare professionals to report to VAERS are a part of the Standards for Pediatric Immunization Practices, which are endorsed by multiple professional organizations, including the American Academy of Pediatrics.
- "Informed consent" is a legal term under the purview of the Hawaii Medical Board (HRS §671-3) and applies to a "proposed medical or surgical treatment or a diagnostic or therapeutic procedure" – none of which accurately describe immunizations (or other medications such as antibiotics).
- Currently, healthcare providers are required by federal mandate to provide CDC-developed Vaccine Information Statements (VISs) to individuals or in the case of a minor, their parent/legal guardian prior to vaccination. VISs provide individuals with current, relevant information regarding vaccinations in an accessible format,

and include information regarding possible side effects of vaccination and how parents and providers may report adverse effects to VAERS, should they occur.

- The wording of each VIS is carefully written to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of The Patient Protection and Affordable Care Act of 2010.
- The VIS are then reviewed and approved by the Advisory Committee on Childhood Vaccines (ACCV) which includes:
- Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury; and
- Three members who are attorneys, including at least one who represents individuals who have been vaccine-injured.
- The VIS have been translated into over 40 languages, ensuring important information related to vaccination is available to and accessible by most persons.
- Requesting healthcare providers to obtain informed consent prior to vaccination is unnecessary and discourages vaccination, placing individuals and communities at-risk for outbreaks of vaccine-preventable diseases.

I urge you to stop these unnecessary and harmful resolutions from passing, so that we can focus on keeping our families healthy in Hawaii.

Mahalo for your consideration.

March 22, 2018 at 9:00 AM
Conference Room 329

House Committee on Health and Human Services

To: Chair John M. Mizuno
Vice Chair Bertrand Kobayashi

From: Paige Heckathorn
Senior Manager, Legislative Affairs
Healthcare Association of Hawaii

Re: Testimony in Opposition
HCR 157 and HR 107, Requesting the Department of Health and the Centers for Disease Control and Prevention to Conduct a Study on the Incidences of Adverse Effects to Vaccines in Hawaii

The Healthcare Association of Hawaii (HAH), established in 1939, serves as the leading voice of healthcare on behalf of 170 member organizations who represent almost every aspect of the health care continuum in Hawaii. Members include acute care hospitals, skilled nursing facilities, home health agencies, hospices, assisted living facilities and durable medical equipment suppliers. In addition to providing access to appropriate, affordable, high quality care to all of Hawaii's residents, our members contribute significantly to Hawaii's economy by employing over 20,000 people statewide.

Thank you for the opportunity to provide testimony **opposing** HCR 157 and HR 107. Patients should be informed decision-makers when it comes to their healthcare choices—however, the report requested by this resolution would not achieve that aim. We have three main concerns. First, we believe that following "adverse events" can be confusing for consumers since it would include any incident post-vaccination. For example, a broken arm could be listed as an adverse event even if that injury was sustained riding a bike, rather than from the vaccination.

Second, we would note that there are currently a number of surveillance systems in place to help monitor the safety of vaccines, including the Vaccine Adverse Event Reporting System. We believe those systems provide accurate statistics on this matter. Lastly, we would oppose the use of informed consent for vaccines. Under federal law, all providers are required to give patients a Vaccine Information Statement (VIS). The VIS is produced by the Centers for Disease Control and Prevention and serves to inform all recipients of vaccines about the benefits and risks of a vaccine they will receive. The VIS must be given prior to the vaccination, and prior to each dose of a multi-series dose. According to the CDC, because VIS forms "cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed." This practice meets the spirit of the proposed resolution on making information prior to making a decision on a vaccination.

Thank you for the opportunity to testify on this matter.

THE QUEEN'S HEALTH SYSTEMS

LATE

To: The Honorable John M. Mizuno, Chair
The Honorable Bertrand Kobayashi, Vice Chair
Members, Committee on Health and Human Services

From: Paula Yoshioka, Vice President of Government Relations and External Affairs, The Queen's Health Systems

Date: March 21, 2018

Hrg: House Committee on Health and Human Services; Thursday, March 22, 2018 at 9AM in Room 329

Re: **Oppose HCR 157 and HR 107, Requesting the Department of Health and the Centers for Disease Control and Prevention to Conduct a Study on the Incidents of Adverse Effects to Vaccines in Hawaii**

My name is Paula Yoshioka and I am the Vice President of Government Relations and External Affairs at The Queen's Health Systems (Queen's). We appreciate the opportunity to provide testimony in opposition of HCR 157 and HR 107, which requests that the Department of Health (DOH) and the Centers for Disease Control and Prevention (CDC) conduct a study on the incidents of adverse effects to vaccines and immunizations in the State of Hawaii.

Queen's believes that these resolutions are not necessary and duplicative because there are a number of surveillance systems in place to assist in monitoring the safety of vaccines. Healthcare providers are already required by federal regulations to provide CDC-developed Vaccine Information Statements (VISs) to individuals or in the case of a minor, their parent/legal guardian prior to vaccination. VISs provide individuals with current, relevant information regarding vaccinations and include information on potential side effects of vaccinations and how parents and providers may report adverse effects to the Vaccine Adverse Event Reporting System (VAERS), should they occur.

Thank you for the opportunity to testify on this measure.

House Committee on Health and Human Services
Rep. John M. Mizuno, Chair
Rep. Bertrand Kobayashi, Vice Chair
Conference Room 329

Thursday, March 22, 2018 at 9:00am

Testimony IN SUPPORT of House Resolution No. 107/House Concurrent Resolution No. 157.

"Any possible doubts, whether or not well founded, about the safety of the [polio] vaccine, cannot be allowed to exist in view of the need to assure that the vaccine will continue to be used to the maximum extent….."

-Federal Register, Friday, June 1, 1984
Vol. 49, No. 107, Page 23007
Rules and Regulation

Hawaii for Informed Consent, an organization with over 1,200 members, STRONGLY SUPPORTS HR 107/HCR 157.

We believe informed consent allows a healthy individual make an informed decision prior to receiving a VOLUNTARY medical procedure such as a vaccine, which carries inherent risks. Vaccines have been documented to cause an array of medical conditions, including paralysis, chronic autoimmune conditions, neurological conditions and death despite claims that vaccines are safe and effective.

Hawaii's healthcare providers do not seem to support discussing vaccine risks and this should be concerning to all current and potential patients. Testimonies from HB2622 that led to HR 107/HCR 157 showed that healthcare providers and organizations including the Hawaii Public Health Association, Healthcare Association of Hawaii, Hawaii Pacific Health Hospitals, the American Academy of Pediatrics, Hawaii Immunization Coalition, and Hawaii Medical Association who fervently believe in the benefits of vaccines, were not willing to provide additional information to their patients, answer questions and have meaningful discussions about the concerns patients may have. Instead, efforts to inform patients would be too costly, time-consuming, redundant, and unnecessary even to the point where some members have been kicked out of medical practices.

The intent of HR 107/HCR 157 is to encourage open, honest, dialogues between Hawaii's providers and their patients, not to discourage individuals from vaccinating as these organizations have argued. All individuals should be able to preserve their individual autonomy by taking an active role in managing

their own health and wellness based on individual circumstances. We do not and will not, fit into the same cookie cutter.

Vaccines contain specific antigens as well as vaccine excipients[1] including aborted fetal tissue (live-virus vaccines), retroviruses, stray strands of DNA, MSG(many vaccines), antibiotics (Vaqta, Havrix), acetone, heavy metals including thimerosal (multi-dose Afluria, Fluvirin), aluminum compounds (Gardasil 9 with the highest content), formaldehyde(flu vaccines), VERO monkey cells (polio), bovine cells (many vaccines), calf serum (many vaccines), borax (Vaqta), and squalene (Fluad), just to name a few. Anyone can sustain an adverse event from any vaccine, including death. If an individual feels that there are risks to his health based on the information presented on a package insert, then that individual should be allowed to make a decision most suited for his own well-being.

Adverse reactions can occur with any drug including prescriptions, over-the-counter products, vaccines, intravenous admixtures, vitamins and supplements. Any individual can experience a vaccine-induced adverse reaction. The problem is that neither the physician nor the patient has the tools to identify who is susceptible or vulnerable. Every individual has a different level of susceptibility due to differences in prescribed medications, genetic make-up, toxic-load, and different health issues, diagnosed or not. Nothing, FDA approved or not, is 100 percent safe with 0 percent risk. This is why patients should be allowed to discuss any potential vaccine injuries and risks PRIOR to receiving any vaccine.

Consider the following:

1. The FDA admits that "until a vaccine is given to the general population, all potential adverse events cannot be anticipated."[2] Therefore, safety and efficacy are not necessarily known as a general rule.

Vaccines undergo fewer clinical trials compared to drugs. The FDA will approve a drug only after clinical data and studies collected from Phase 1, Phase 2, Phase 3 and Phase 4 clinical trials have been conducted and completed. This can take several years, involve up to tens of thousands of volunteers, be extremely costly, and very complex.[3] However, the majority of drugs are approved through this common FDA process.

In contrast, vaccines only undergo Phase 1, Phase 2, and Phase 3 clinical trials and then they can become FDA licensed. According to the FDA, "many vaccines undergo Phase 4 studies ONCE on the market"[4] meaning that the public may be unwilling participants in a grand experiment for identifying the adverse effects of a particular vaccine.

2. The FDA and CDC collect data on vaccine injuries and deaths through the Vaccine Adverse Event Reporting System (VAERS). VAERS is a passive surveillance system that relies primarily on healthcare providers to VOLUNTARILY submit the mandatory information to this system after a suspected vaccine injury. The National Childhood Vaccine Injury Act of 1986 (NCVIA) requires healthcare providers to submit a report to the Secretary of the Department of Health and Human Services on every vaccine-induced adverse event to VAERS within seven days.[5]

Although reporting to VAERS is mandated by federal law, the majority of healthcare providers do not report adverse reactions. Most providers do not believe vaccines have any risks, are unaware of the VAERS system, and do not have the time.[6] Providers who do not report to VAERS do not suffer consequences for non-reporting since enforcement of this law does not exist.[7]

Whether the information gathered in VAERS is useful to the public ultimately depends on the reports submitted by doctors, nurses, family members or vaccine manufacturers and the quality of information provided.[8] Many times information is inaccurate, incomplete or delayed.[9]

3. Since 1990, VAERS has logged over 607,202 documented adverse event reports observed in the marketplace[10] with an average of 40,588 VAERS reports filed every year.[11] However, due to under-reporting by healthcare providers, 40,588 may actually represent less than one percent of vaccine adverse events reported to the FDA.[12] Further, as the majority of healthcare providers continually fail to report vaccine injuries to VAERS, vaccines are more than likely to carry a much higher risk of adverse events and death than reported by any surveillance system.

4. The Vaccine Injury Compensation Program (VICP) established by NCVIA, has paid approximately $3.8 billion dollars since 1987 to compensate vaccine-injured individuals, including deaths.[13] Despite the existence of the CDC/FDA's vaccine safety surveillance systems such as the Vaccine Safety Datalink (VSD), Post-Licensure Rapid Immunization Safety Monitoring (PRISM), and Clinical Immunization Safety Assessment Project (CISA), vaccine injuries DO occur and they are not as rare as healthcare providers represent them to be.

5. Vaccine Information Statements (VIS) are documents produced by the CDC offering a selective summary of information for vaccine recipients to review just prior to a vaccination. The VIS offers information about the vaccine and the disease it is intended to prevent, some common side effects, risks and benefits and information about the Vaccine Injury Compensation program.

Even though a VIS is supposed to be provided to a patient before vaccine administration, the CDC acknowledges the following:[14]

1) VIS' provided by the healthcare provider may be outdated.
2) The information on a VIS is based on recommendations from the Advisory Committee on Immunization Practices (ACIP) which only includes adverse events that the ACIP believes are causally linked to the vaccine. Therefore, a VIS does not fully present the adverse events as identified by the manufacturer during clinical trials.
3) Not all combination vaccines administered have an associated VIS thus pediatricians who use various vaccine combinations all of the time may not providing the appropriate VIS as required by NCVIA under 42 USCS § 300aa-26.
4) If a VIS is unavailable from the CDC, the FDA suggests the use of a Manufacturer's Package insert as a substitute for a VIS or other print materials.

Further, the CDC states that NCVIA requires providers to do the following:[15]

1) Make a notation in the patient's medical record or permanent office log regarding the provision of a VIS or the parent must acknowledge receipt in writing,

2) Make a notation of the edition date of the VIS provided, and date provided,

3) Provide patients with a current VIS PRIOR to vaccination, not afterwards.

Given that Hawaii's healthcare providers are admittedly extremely busy, how can there be any assurances that these steps take place on any regular basis?

6. According to the CDC, vaccinations are considered medical procedures. Yet, there are claims that HRS § 671-3 regarding informed consent does not apply to vaccinations. There are two problems to this claim.

First, under HR§ 671-1, the terms "medical or surgical treatment" or "diagnostic or therapeutic procedure" are not defined. Thus, to claim that the act of vaccinations do require informed consent under HRS § 671-3, is inaccurate and unsubstantiated and may need to be challenged in a court of law.

Second, the information on a VIS contains all of the elements of Informed Consent as required in HRS § 671-3 (b):

(b) The following information shall be supplied to the patient or the patient's guardian or legal surrogate prior to obtaining consent to a proposed medical or surgical treatment or a diagnostic or therapeutic procedure:

- **(1)** The condition to be treated;
- **(2)** A description of the proposed treatment or procedure;
- **(3)** The intended and anticipated results of the proposed treatment or procedure;
- **(4)** The recognized alternative treatments or procedures, including the option of not providing these treatments or procedures;
- **(5)** The recognized material risks of serious complications or mortality associated with:
  - **(A)** The proposed treatment or procedure;
  - **(B)** The recognized alternative treatments or procedures; and
  - **(C)** Not undergoing any treatment or procedure; and
- **(6)** The recognized benefits of the recognized alternative treatments or procedures.

One of the major reasons why the VIS does not constitute informed consent is that the information on the VIS does not accurately reflect the adverse events the manufacturer reported in clinical trials. As noted earlier, the ACIP makes recommendations on the information included on the VIS and clearly, this selectivity of information is not the same as informed consent. Lastly, many severe or unobserved vaccine events will not be observed until the vaccine is in the market and reported to VAERS and thus is not part of the VIS.

If HRS § 671-3, does not apply to vaccines where protections from informed consent would reduce vaccine injuries in Hawaii, then supporting HR 107/HCR 157 must be seriously considered since a great number of physicians and other recognized healthcare providers regularly recommend vaccinations as a medical intervention for health purposes.

7. NCVIA of 1986 was enacted as an administrative process intended to quickly address and facilitate the vaccine-injured[16] while preserving the U.S. immunization program. The NCVIA created a National Vaccine Injury Compensation Program (VICP) to compensate individuals for vaccine-related injuries or death[17] resulting from CDC recommended vaccines.[18] In exchange, vaccine manufacturers and medical professionals are exempted from all civil liability associated with vaccine injury claims.[19]

As a result of NCVIA, vaccine injured families can languish in the "Vaccine Court" up to five years seeking compensation for their vaccine injuries. [20] In contrast, vaccine market will be worth $61

billion dollars by 2020[21] and vaccine manufacturers will not be liable for a single vaccine injury or death.

Conclusion:

Patients have the right to refuse any medical procedure including vaccination. The risks from a vaccination may outweigh the benefits of protection from disease especially since many adverse events are not disclosed on the VIS or the package insert. Vaccine-induced adverse events that would normally be collected during a Phase 4 clinical trial are instead collected through VAERS, a passive-surveillance system where the majority of healthcare providers are not compelled to report vaccine related adverse events. If individuals considering a vaccination cannot rely on the VIS or their healthcare provider to provide relevant and necessary information to make an informed decision and if healthcare providers fail to report vaccine-induced adverse events to VAERS designed for this purpose, then how would any individual receive the necessary information required for true Informed Consent?

The argument should not be that providing additional information would confuse the patient, make the experience difficult, inconvenient, time-consuming or dissuade the patient from vaccination. The argument should be that any additional information about vaccine safety, adverse events, side effects and other risks should be provided to all patients prior to vaccination to allow patients to participate in their own medical decisions.

If vaccines had 0 risk, Congress would not have enacted the National Childhood Vaccine Injury Act of 1986. Congress would also not have created the VAERS system to collect adverse event reports and most of all, the Vaccine Injury Compensation Program would not have been created 32 years ago to compensate the vaccine-injured. To its credit, Congress recognized that CDC recommended vaccines can and do cause vaccine injuries, of which $3.8 billion dollars to date, has been paid as compensation.

We urge you to adopt HR 107/HCR 157 to review the adverse events in Hawaii that occur from vaccines so that there is transparency in the Hawaii immunization program where our children and families are truly protected.

Mahalo,

Sincerely,

T. Ocampo

Hawaii For Informed Consent

---

[1] https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. (See Appendix I).
[2] https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm.
[3] https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm.
[4] https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm.
[5] 42 USCS § 300aa-25 (b) (2017).

[6] David A. Kessler, “Introducing MED Watch. A New Approach to Reporting Medication and Device Adverse Effects and Product Problems." JAMA. 269 (21) 2765-2768, 2765, (1993) doi:10.1001/jama.269.21.2765.
[7] 42 USCS § 300aa-25 (b) (2017)
[8]"Surveillance Manual | Vaccine Adverse Event Reporting System | VPDS | CDC." Cdc.Gov, https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html.
[9] Miles M. Braun, "Institute for Vaccine Safety - Vaccine Adverse Event Reporting System (VAERS), Usefulness and Limitations."Vaccinesafety.Edu, http://www.vaccinesafety.edu/VAERS-Braun.htm.
[10] United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - last month, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html at 10:00:52 PM (accessed 22 October 2017).
[11]"Surveillance Manual | Vaccine Adverse Event Reporting System | VPDS | CDC." Cdc.Gov, https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html.
[12] R. Lazarus- Electronic Support for Public Health - Vaccine Adverse Event Reporting System (ESP: VAERS) - Final Report. (Prepared by Harvard Pilgrim Health Care, Inc. under Grant No. R18 HS017045). Rockville, MD: Agency for Healthcare Research and Quality, 1-7, 6 (2010). (PDF, 96.19 KB).
[13] https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/monthly-website-stats-2-01-18.pdf.
[14] https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html.
[15] https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html
[16] 42 USCS § 300aa-12 (d) (2) (2017).
[17] Id. § 300aa-10(a).
[18] Id. § 300aa-11(a) (3).
[19] Id.
[20] *GAO Report 15-142: Vaccine Injury Compensation - Most Claims Took Multiple Years And Many Were Settled Through Negotiation*. 30 (2014), http://www.gao.gov/assets/670/667136.pdf (accessed 1 October 2017).
[21] "Big Pharma And Big Profits: The Multibillion Dollar Vaccine Market | Global Research - Centre for Research on Globalization." Globalresearch.Ca, 2016, https://www.globalresearch.ca/big-pharma-and-big-profits-the-multibillion-dollar-vaccine-market/5503945. (14 October 2017).

Date: March 20, 2018

To: Chair Representative John Mizuno, Vice-Chair Bertrand Kobayashi and the Members of the House Health and Human Services Committee
From: Cheryl Toyofuku,

Re: **Support for HCR 157 / HR 107** REQUESTING THE DEPARTMENT OF HEALTH AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION TO CONDUCT A STUDY ON THE INCIDENCES OF ADVERSE EFFECTS TO VACCINES IN HAWAII.

Scheduled Hearing: Thursday, March 22, 2019 at 9:00 a.m., Hawaii State Capitol Room 329

As a mother, grandmother, registered nurse and health advocate, I am appalled at the numbers of escalating vaccine injuries and death. This has convinced many in Hawaii that **increased awareness, education and informed consents should be foundational and paramount in health care decisions.** Serious concerns are arising about the vaccine ingredients, the safety and effectiveness of each vaccine and the numerous adverse effects that we are seeing in many who receive these toxic inoculations. Please view the following:

CDC's Vaccine Excipient & Media Summary
This table lists all components, other than antigens, shown in the manufacturers' package insert (PI) for each vaccine.
https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf

Do You Know What Is In a Vaccine? (aluminum, antibiotics, formaldehyde, human & animal cells, mercury, poysorbate 80, genetically modified yeast, animal, bacterial and viral DNA, etc)
https://www.learntherisk.org/wp-content/uploads/2016/02/LTR_VaccineIngredients_White1.pdf

Vaccine Doses for U.S. Children (more than 72 dpses of 16 different vaccines are given by age 18)
https://www.learntherisk.org/wp-content/uploads/2016/03/Doses_v2.pdf

The actual reporting of adverse vaccine reactions to our federal health agencies is less than 10 percent. Since there is a law to report vaccine injury to a national reporting system, recommendations should require local health professionals to comply with this law. Doctors, nurses, pharmacists, other health care providers, parents and the general public should be educated on recognizing vaccine adverse reactions and consequently knowing the process of accurately reporting these events.

Below is information taken from the federal VAERS website, followed by MedAlerts searchable database to view the reports from VAERS.

> The **VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)** https://vaers.hhs.gov/
>
> Established in 1990, the Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences to CDC and FDA. https://vaers.hhs.gov/about.html
>
> Although this law requires doctors and other vaccine providers to *report* hospitalizations, injuries, deaths and serious health problems following vaccination to *VAERS*, it is *estimated* that less than 10 percent, of all vaccine-related health problems are ever *reported to VAERS*. https://www.nvic.org/reportreaction.aspx

MedAlerts (http://www.medalerts.org/) is a searchable database that makes it easy to view tens of thousand of reports of vaccine reactions, injuries and deaths made to the federal Vaccine Adverse Events Reporting System (VAERS) by doctors, nurses, patients and parents.

The following are examples of searches done on adverse reactions of 3 different vaccines:

- Using the MedAlerts search engine, as of October 31, 2017, there have been more than 148,088 reports of **influenza vaccine reactions**, hospitalizations, injuries and deaths following influenza vaccinations made to the federal Vaccine Adverse Events Reporting System (VAERS), including 1,399 related deaths, 11,008 hospitalizations, and 2, 802 related disabilities. Moderate reactions reported include fever, local reactions (pain, redness, swelling at the site of the injection), headache, fatigue, sore throat, nasal congestion, cough, joint and muscle pain, and nausea. Serious vaccine complications include brain inflammation and neurological damage, convulsions, Bell's palsy, limb paralysis, neuropathy, shock, wheezing/asthma and other breathing problems, and death. Influenza vaccinations can cause Guillain Barre Syndrome (GBS), a painful and disabling immune and neurological disorder of the peripheral nervous system that can cause temporary or permanent paralysis and death.

- Using the MedAlerts search engine, as of October 31, 2017, there have been more than 55,239 reports of **HPV vaccine reactions**, hospitalizations, injuries and deaths following HPV vaccinations made to the federal Vaccine Adverse Events Reporting System (VAERS), including 397 related deaths, 4,949hospitalizations, and 2,397 related disabilities. Over 35% of those serious HPV vaccine-related adverse events occurred in children and teens 12-17 years of age.

- Using the MedAlerts search engine, as of October 31, 2017, there have been more than 85,549 reports of **hepatitis b containing vaccine reactions**, hospitalizations, injuries and deaths following hepatitis b containing vaccinations made to the federal Vaccine Adverse Events Reporting System (VAERS), including 1,920related deaths, 11,541 hospitalizations, and 3,142 related disabilities. 63,030 of the adverse events were associated with hepatitis B vaccine alone (not combined with other vaccines). Approximately 5% of those serious Hepatitis B vaccine-related adverse events occurred in children under 3 years old, with approximately 1,562 deaths occurring in children under three years of age. Mild side effects such as redness, warmth, or swelling at the injection site where the shot was given have been reported in connection with administration of hepatitis B vaccines. Fever over 99.9 degrees F may occur, and can last one to two days. Systemic reactions include irritability, diarrhea, fatigue, weakness, diminished appetite and rhinitis. However, more severe reactions have also been reported in both clinical trials with all of the vaccines as well as to the Vaccine Adverse Events Reporting System (VAERS).

Please recall that the above statistics represent less than 10 percent of the actual numbers of adverse effects to vaccines. This should not be acceptable.

Improved education, informed consent and accurate reporting of adverse vaccine events will assist in decreasing vaccine injuries and death. Our keiki and ohana deserve this needed service from our local and national health agencies. Mahalo for supporting HCR 157 and HR 107.

HCR-157
Submitted on: 3/20/2018 4:45:08 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Heather Lusk	The CHOW Project	Support	No

Comments:

Chair, Vice Chair, and committee members, thank you for this opportunity to provide testimony on HCR157 and HR107.

As a concerned resident of Hawaii and parent, I oppose these resolutions as unnecessary, costly, and dangerous. These resolutions would required the use of limited state time and resources to investigate vaccine adverse events, even though the evidence clearly demonstrates vaccine effectiveness, safety, and importance for health. Please consider the following points:

- An “adverse event” is any health problem that happens after vaccination. It may or may not have been caused by the vaccine.
- The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) closely monitor vaccine safety using a collection of passive and active surveillance systems:
  - Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine Safety Datalink (VSD)
  - Post-Licensure Rapid Immunization Safety Monitoring (PRISM)
  - Clinical Immunization Safety Assessment Project (CISA)
- These systems have the funding, resources, and expertise to monitor vaccines currently in use. Requesting the Department of Health and CDC to conduct additional studies is duplicative and unnecessary.
- The National Childhood Vaccine Injury Act (NCVIA) requires providers to report adverse events to VAERS. In addition, recommendations for healthcare professionals to report to VAERS are a part of the Standards for Pediatric Immunization Practices, which are endorsed by multiple professional organizations, including the American Academy of Pediatrics.
- “Informed consent” is a legal term under the purview of the Hawaii Medical Board (HRS §671-3) and applies to a “proposed medical or surgical treatment or a diagnostic or therapeutic procedure” – none of which accurately describe immunizations (or other medications such as antibiotics).
- Currently, healthcare providers are required by federal mandate to provide CDC-developed Vaccine Information Statements (VISs) to individuals or in the case of a minor, their parent/legal guardian prior to vaccination. VISs provide individuals with current, relevant information regarding vaccinations in an accessible format,

and include information regarding possible side effects of vaccination and how parents and providers may report adverse effects to VAERS, should they occur.

- The wording of each VIS is carefully written to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of The Patient Protection and Affordable Care Act of 2010.
- The VIS are then reviewed and approved by the Advisory Committee on Childhood Vaccines (ACCV) which includes:
- Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury; and
- Three members who are attorneys, including at least one who represents individuals who have been vaccine-injured.
- The VIS have been translated into over 40 languages, ensuring important information related to vaccination is available to and accessible by most persons.
- Requesting healthcare providers to obtain informed consent prior to vaccination is unnecessary and discourages vaccination, placing individuals and communities at-risk for outbreaks of vaccine-preventable diseases.

I urge you to stop these unnecessary and harmful resolutions from passing, so that we can focus on keeping our families healthy in Hawaii.

Mahalo for your consideration.

HCR-157
Submitted on: 3/21/2018 5:08:40 AM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Melodie Aduja	Oahu County Committee on Legislative Priorities of the Democratic Party of Hawai'i	Support	No

Comments:

Fax

Fax:+1 808-586-6311 **From:** Hawaii for Informed Consent

To: House HHS Committee Phone: 8083430120

Subject: Group Testimony E-Mail: lwest402@hotmail.com

Date: Mar 21, 2018 Pages: 7

Comments:

☐ Urgent ☑ For Review

☐ Please Reply ☐ Please Recycle

☐ Please Comment

House Committee on Health and Human Services
Rep. John M. Mizuno, Chair
Rep. Bertrand Kobayashi, Vice Chair
Conference Room 329

Thursday, March 22, 2018 at 9:00am

Testimony IN SUPPORT of House Resolution No. 107/House Concurrent Resolution No. 157.

"Any possible doubts, whether or not well founded, about the safety of the [polio] vaccine, cannot be allowed to exist in view of the need to assure that the vaccine will continue to be used to the maximum extent....."

-Federal Register, Friday, June 1, 1984
Vol. 49, No. 107, Page 23007
Rules and Regulation

Hawaii for Informed Consent, an organization with over 1,200 members, STRONGLY SUPPORTS HR 107/HCR 157.

We believe informed consent allows a healthy individual make an informed decision prior to receiving a VOLUNTARY medical procedure such as a vaccine, which carries inherent risks. Vaccines have been documented to cause an array of medical conditions, including paralysis, chronic autoimmune conditions, neurological conditions and death despite claims that vaccines are safe and effective.

Hawaii's healthcare providers do not seem to support discussing vaccine risks and this should be concerning to all current and potential patients. Testimonies from HB2622 that led to HR 107/HCR 157 showed that healthcare providers and organizations including the Hawaii Public Health Association, Healthcare Association of Hawaii, Hawaii Pacific Health Hospitals, the American Academy of Pediatrics, Hawaii Immunization Coalition, and Hawaii Medical Association who fervently believe in the benefits of vaccines, were not willing to provide additional information to their patients, answer questions and have meaningful discussions about the concerns patients may have. Instead, efforts to inform patients would be too costly, time-consuming, redundant, and unnecessary even to the point where some members have been kicked out of medical practices.

The intent of HR 107/HCR 157 is to encourage open, honest, dialogues between Hawaii's providers and their patients, not to discourage individuals from vaccinating as these organizations have argued. All individuals should be able to preserve their individual autonomy by taking an active role in managing their own health and wellness based on individual circumstances. We do not and will not, fit into the same cookie cutter.

Vaccines contain specific antigens as well as vaccine excipients[1] including aborted fetal tissue (live-virus vaccines), retroviruses, stray strands of DNA, MSG(many vaccines), antibiotics (Vaqta, Havrix), acetone, heavy metals including thimerosal (multi-dose Afluria, Fluvirin), aluminum compounds (Gardasil 9 with the highest content), formaldehyde(flu vaccines), VERO monkey cells (polio), bovine cells (many vaccines), calf serum (many vaccines), borax (Vaqta), and squalene (Fluad), just to name a few. Anyone can sustain an adverse event from any vaccine, including death. If an individual feels that there are risks to his health based on the information presented on a package insert, then that individual should be allowed to make a decision most suited for his own well-being.

Adverse reactions can occur with any drug including prescriptions, over-the-counter products, vaccines, intravenous admixtures, vitamins and supplements. Any individual can experience a vaccine-induced adverse reaction. The problem is that neither the physician nor the patient has the tools to identify who is susceptible or vulnerable. Every individual has a different level of susceptibility due to differences in prescribed medications, genetic make-up, toxic-load, and different health issues, diagnosed or not. Nothing, FDA approved or not, is 100 percent safe with 0 percent risk. This is why patients should be allowed to discuss any potential vaccine injuries and risks PRIOR to receiving any vaccine.

Consider the following:

1. The FDA admits that "until a vaccine is given to the general population, all potential adverse events cannot be anticipated."[2] Therefore, safety and efficacy are not necessarily known as a general rule.

   Vaccines undergo fewer clinical trials compared to drugs. The FDA will approve a drug only after clinical data and studies collected from Phase 1, Phase 2, Phase 3 and Phase 4 clinical trials have been conducted and completed. This can take several years, involve up to tens of thousands of volunteers, be extremely costly, and very complex.[3] However, the majority of drugs are approved through this common FDA process.

   In contrast, vaccines only undergo Phase 1, Phase 2, and Phase 3 clinical trials and then they can become FDA licensed. According to the FDA, "many vaccines undergo Phase 4 studies ONCE on the market"[4] meaning that the public may be unwilling participants in a grand experiment for identifying the adverse effects of a particular vaccine.

2. The FDA and CDC collect data on vaccine injuries and deaths through the Vaccine Adverse Event Reporting System (VAERS). VAERS is a passive surveillance system that relies primarily on healthcare providers to VOLUNTARILY submit the mandatory information to this system after a suspected vaccine injury. The National Childhood Vaccine Injury Act of 1986 (NCVIA) requires healthcare providers to submit a report to the Secretary of the Department of Health and Human Services on every vaccine-induced adverse event to VAERS within seven days.[5]

   Although reporting to VAERS is mandated by federal law, the majority of healthcare providers do not report adverse reactions. Most providers do not believe vaccines have any risks, are unaware of the VAERS system, and do not have the time.[6] Providers who do not report to VAERS do not suffer consequences for non-reporting since enforcement of this law does not exist.[7]

   Whether the information gathered in VAERS is useful to the public ultimately depends on the reports submitted by doctors, nurses, family members or vaccine manufacturers and the quality of information provided.[8] Many times information is inaccurate, incomplete or delayed.[9]

3. Since 1990, VAERS has logged over 607,202 documented adverse event reports observed in the marketplace[10] with an average of 40,588 VAERS reports filed every year.[11] However, due to under-reporting by healthcare providers, 40,588 may actually represent less than one percent of vaccine adverse events reported to the FDA.[12] Further, as the majority of healthcare providers continually fail to report vaccine injuries to VAERS, vaccines are more than likely to carry a much higher risk of adverse events and death than reported by any surveillance system.

4. The Vaccine Injury Compensation Program (VICP) established by NCVIA, has paid approximately $3.8 billion dollars since 1987 to compensate vaccine-injured individuals, including deaths.[13] Despite the existence of the CDC/FDA's vaccine safety surveillance systems such as the Vaccine Safety Datalink (VSD), Post-Licensure Rapid Immunization Safety Monitoring (PRISM), and Clinical Immunization Safety Assessment Project (CISA), vaccine injuries DO occur and they are not as rare as healthcare providers represent them to be.

5. Vaccine Information Statements (VIS) are documents produced by the CDC offering a selective summary of information for vaccine recipients to review just prior to a vaccination. The VIS offers information about the vaccine and the disease it is intended to prevent, some common side effects, risks and benefits and information about the Vaccine Injury Compensation program.

   Even though a VIS is supposed to be provided to a patient before vaccine administration, the CDC acknowledges the following:[14]

   1) VIS' provided by the healthcare provider may be outdated.
   2) The information on a VIS is based on recommendations from the Advisory Committee on Immunization Practices (ACIP) which only includes adverse events that the ACIP believes are causally linked to the vaccine. Therefore, a VIS does not fully present the adverse events as identified by the manufacturer during clinical trials.
   3) Not all combination vaccines administered have an associated VIS thus pediatricians who use various vaccine combinations all of the time may not providing the appropriate VIS as required by NCVIA under 42 USCS § 300aa-26.
   4) If a VIS is unavailable from the CDC, the FDA suggests the use of a Manufacturer's Package Insert as a substitute for a VIS or other print materials.

   Further, the CDC states that NCVIA requires providers to do the following:[15]

   1) Make a notation in the patient's medical record or permanent office log regarding the provision of a VIS or the parent must acknowledge receipt in writing,

   2) Make a notation of the edition date of the VIS provided, and date provided,

   3) Provide patients with a current VIS PRIOR to vaccination, not afterwards.

   Given that Hawaii's healthcare providers are admittedly extremely busy, how can there be any assurances that these steps take place on any regular basis?

6. According to the CDC, vaccinations are considered medical procedures. Yet, there are claims that HRS § 671-3 regarding informed consent does not apply to vaccinations. There are two problems to this claim.

First, under HR§ 671-1, the terms "medical or surgical treatment" or "diagnostic or therapeutic procedure" are not defined. Thus, to claim that the act of vaccinations do require informed consent under HRS § 671-3, is inaccurate and unsubstantiated and may need to be challenged in a court of law.

Second, the information on a VIS contains all of the elements of Informed Consent as required in HRS § 671-3 (b):

(b) The following information shall be supplied to the patient or the patient's guardian or legal surrogate prior to obtaining consent to a proposed medical or surgical treatment or a diagnostic or therapeutic procedure:

- **(1)** The condition to be treated;
- **(2)** A description of the proposed treatment or procedure;
- **(3)** The intended and anticipated results of the proposed treatment or procedure;
- **(4)** The recognized alternative treatments or procedures, including the option of not providing these treatments or procedures;
- **(5)** The recognized material risks of serious complications or mortality associated with:
  - **(A)** The proposed treatment or procedure;
  - **(B)** The recognized alternative treatments or procedures; and
  - **(C)** Not undergoing any treatment or procedure; and
- **(6)** The recognized benefits of the recognized alternative treatments or procedures.

One of the major reasons why the VIS does not constitute informed consent is that the information on the VIS does not accurately reflect the adverse events the manufacturer reported in clinical trials. As noted earlier, the ACIP makes recommendations on the information included on the VIS and clearly, this selectivity of information is not the same as informed consent. Lastly, many severe or unobserved vaccine events will not be observed until the vaccine is in the market and reported to VAERS and thus is not part of the VIS.

If HRS § 671-3, does not apply to vaccines where protections from informed consent would reduce vaccine injuries in Hawaii, then supporting HR 107/HCR 157 must be seriously considered since a great number of physicians and other recognized healthcare providers regularly recommend vaccinations as a medical intervention for health purposes.

7. NCVIA of 1986 was enacted as an administrative process intended to quickly address and facilitate the vaccine-injured[16] while preserving the U.S. immunization program. The NCVIA created a National Vaccine Injury Compensation Program (VICP) to compensate individuals for vaccine-related injuries or death[17] resulting from CDC recommended vaccines.[18] In exchange, vaccine manufacturers and medical professionals are exempted from all civil liability associated with vaccine injury claims.[19]

As a result of NCVIA, vaccine injured families can languish in the "Vaccine Court" up to five years seeking compensation for their vaccine injuries. [20] In contrast, vaccine market will be worth $61 billion dollars by 2020[21] and vaccine manufacturers will not be liable for a single vaccine injury or death.

Conclusion:

Patients have the right to refuse any medical procedure including vaccination. The risks from a vaccination may outweigh the benefits of protection from disease especially since many adverse events are not disclosed on the VIS or the package insert. Vaccine-induced adverse events that would normally be collected during a Phase 4 clinical trial are instead collected through VAERS, a passive-surveillance system where the majority of healthcare providers are not compelled to report vaccine related adverse events. If individuals considering a vaccination cannot rely on the VIS or their healthcare provider to provide relevant and necessary information to make an informed decision and if healthcare providers fail to report vaccine-induced adverse events to VAERS designed for this purpose, then how would any individual receive the necessary information required for true Informed Consent?

The argument should not be that providing additional information would confuse the patient, make the experience difficult, inconvenient, time-consuming or dissuade the patient from vaccination. The argument should be that any additional information about vaccine safety, adverse events, side effects and other risks should be provided to all patients prior to vaccination to allow patients to participate in their own medical decisions.

If vaccines had 0 risk, Congress would not have enacted the National Childhood Vaccine Injury Act of 1986. Congress would also not have created the VAERS system to collect adverse event reports and most of all, the Vaccine Injury Compensation Program would not have been created 32 years ago to compensate the vaccine-injured. To its credit, Congress recognized that CDC recommended vaccines can and do cause vaccine injuries, of which $3.8 billion dollars to date, has been paid as compensation.

We urge you to adopt HR 107/HCR 157 to review the adverse events in Hawaii that occur from vaccines so that there is transparency in the Hawaii immunization program where our children and families are truly protected.

Mahalo,

Sincerely,

T. Ocampo

Hawaii For Informed Consent

---

[1]https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. (See Appendix I).
[2]https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm.

[3] https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm.
[4]https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm.
[5] 42 USCS § 300aa-25 (b) (2017).
[6] David A. Kessler, "Introducing MED Watch. A New Approach to Reporting Medication and Device Adverse Effects and Product Problems." JAMA. 269 (21) 2765-2768, 2765, (1993) doi:10.1001/jama.269.21.2765.
[7] 42 USCS § 300aa-25 (b) (2017)
[8]"Surveillance Manual | Vaccine Adverse Event Reporting System | VPDS | CDC." Cdc.Gov, https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html.
[9] Miles M. Braun, "Institute for Vaccine Safety - Vaccine Adverse Event Reporting System (VAERS), Usefulness and Limitations."Vaccinesafety.Edu, http://www.vaccinesafety.edu/VAERS-Braun.htm.
[10] United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - last month, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html at 10:00:52 PM (accessed 22 October 2017).
[11]"Surveillance Manual | Vaccine Adverse Event Reporting System | VPDS | CDC." Cdc.Gov, https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html.
[12] R. Lazarus- Electronic Support for Public Health - Vaccine Adverse Event Reporting System (ESP: VAERS) - Final Report. (Prepared by Harvard Pilgrim Health Care, Inc. under Grant No. R18 HS017045). Rockville, MD: Agency for Healthcare Research and Quality, 1-7, 6 (2010). (PDF, 96.19 KB).
[13] https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/monthly-website-stats-2-01-18.pdf.
[14] https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html.
[15] https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html
[16] 42 USCS § 300aa-12 (d) (2) (2017).
[17] Id. § 300aa-10(a).
[18] Id. § 300aa-11(a) (3).
[19] Id.
[20] *GAO Report 15-142: Vaccine Injury Compensation - Most Claims Took Multiple Years And Many Were Settled Through Negotiation.* 30 (2014), http://www.gao.gov/assets/670/667136.pdf (accessed 1 October 2017).
[21] "Big Pharma And Big Profits: The Multibillion Dollar Vaccine Market | Global Research - Centre for Research on Globalization." Globalresearch.Ca, 2016, https://www.globalresearch.ca/big-pharma-and-big-profits-the-multibillion-dollar-vaccine-market/5503945. (14 October 2017).

Fax

Fax:+1 808-586-6311 **From:** Hawaii for Informed Consent

To: House HHS Committee Phone: 8083430120

Subject: Group Testimony E-Mail: lwest402@hotmail.com

Date: Mar 21, 2018 Pages: 7

Comments:

- [ ] Urgent
- [x] For Review
- [ ] Please Reply
- [ ] Please Recycle
- [ ] Please Comment

House Committee on Health and Human Services
Rep. John M. Mizuno, Chair
Rep. Bertrand Kobayashi, Vice Chair
Conference Room 329

Thursday, March 22, 2018 at 9:00am

Testimony IN SUPPORT of House Resolution No. 107/House Concurrent Resolution No. 157.

"Any possible doubts, whether or not well founded, about the safety of the [polio] vaccine, cannot be allowed to exist in view of the need to assure that the vaccine will continue to be used to the maximum extent....."

-Federal Register, Friday, June 1, 1984
Vol. 49, No. 107, Page 23007
Rules and Regulation

Hawaii for Informed Consent, an organization with over 1,200 members, STRONGLY SUPPORTS HR 107/HCR 157.

We believe informed consent allows a healthy individual make an informed decision prior to receiving a VOLUNTARY medical procedure such as a vaccine, which carries inherent risks. Vaccines have been documented to cause an array of medical conditions, including paralysis, chronic autoimmune conditions, neurological conditions and death despite claims that vaccines are safe and effective.

Hawaii's healthcare providers do not seem to support discussing vaccine risks and this should be concerning to all current and potential patients. Testimonies from HB2622 that led to HR 107/HCR 157 showed that healthcare providers and organizations including the Hawaii Public Health Association, Healthcare Association of Hawaii, Hawaii Pacific Health Hospitals, the American Academy of Pediatrics, Hawaii Immunization Coalition, and Hawaii Medical Association who fervently believe in the benefits of vaccines, were not willing to provide additional information to their patients, answer questions and have meaningful discussions about the concerns patients may have. Instead, efforts to inform patients would be too costly, time-consuming, redundant, and unnecessary even to the point where some members have been kicked out of medical practices.

The intent of HR 107/HCR 157 is to encourage open, honest, dialogues between Hawaii's providers and their patients, not to discourage individuals from vaccinating as these organizations have argued. All individuals should be able to preserve their individual autonomy by taking an active role in managing their own health and wellness based on individual circumstances. We do not and will not, fit into the same cookie cutter.

Vaccines contain specific antigens as well as vaccine excipients[1] including aborted fetal tissue (live-virus vaccines), retroviruses, stray strands of DNA, MSG(many vaccines), antibiotics (Vaqta, Havrix), acetone, heavy metals including thimerosal (multi-dose Afluria, Fluvirin), aluminum compounds (Gardasil 9 with the highest content), formaldehyde(flu vaccines), VERO monkey cells (polio), bovine cells (many vaccines), calf serum (many vaccines), borax (Vaqta), and squalene (Fluad), just to name a few. Anyone can sustain an adverse event from any vaccine, including death. If an individual feels that there are risks to his health based on the information presented on a package insert, then that individual should be allowed to make a decision most suited for his own well-being.

Adverse reactions can occur with any drug including prescriptions, over-the-counter products, vaccines, intravenous admixtures, vitamins and supplements. Any individual can experience a vaccine-induced adverse reaction. The problem is that neither the physician nor the patient has the tools to identify who is susceptible or vulnerable. Every individual has a different level of susceptibility due to differences in prescribed medications, genetic make-up, toxic-load, and different health issues, diagnosed or not. Nothing, FDA approved or not, is 100 percent safe with 0 percent risk. This is why patients should be allowed to discuss any potential vaccine injuries and risks PRIOR to receiving any vaccine.

Consider the following:

1. The FDA admits that "until a vaccine is given to the general population, all potential adverse events cannot be anticipated."[2] Therefore, safety and efficacy are not necessarily known as a general rule.

   Vaccines undergo fewer clinical trials compared to drugs. The FDA will approve a drug only after clinical data and studies collected from Phase 1, Phase 2, Phase 3 and Phase 4 clinical trials have been conducted and completed. This can take several years, involve up to tens of thousands of volunteers, be extremely costly, and very complex.[3] However, the majority of drugs are approved through this common FDA process.

   In contrast, vaccines only undergo Phase 1, Phase 2, and Phase 3 clinical trials and then they can become FDA licensed. According to the FDA, "many vaccines undergo Phase 4 studies ONCE on the market"[4] meaning that the public may be unwilling participants in a grand experiment for identifying the adverse effects of a particular vaccine.

2. The FDA and CDC collect data on vaccine injuries and deaths through the Vaccine Adverse Event Reporting System (VAERS). VAERS is a passive surveillance system that relies primarily on healthcare providers to VOLUNTARILY submit the mandatory information to this system after a suspected vaccine injury. The National Childhood Vaccine Injury Act of 1986 (NCVIA) requires healthcare providers to submit a report to the Secretary of the Department of Health and Human Services on every vaccine-induced adverse event to VAERS within seven days.[5]

   Although reporting to VAERS is mandated by federal law, the majority of healthcare providers do not report adverse reactions. Most providers do not believe vaccines have any risks, are unaware of the VAERS system, and do not have the time.[6] Providers who do not report to VAERS do not suffer consequences for non-reporting since enforcement of this law does not exist.[7]

   Whether the information gathered in VAERS is useful to the public ultimately depends on the reports submitted by doctors, nurses, family members or vaccine manufacturers and the quality of information provided.[8] Many times information is inaccurate, incomplete or delayed.[9]

3. Since 1990, VAERS has logged over 607,202 documented adverse event reports observed in the marketplace[10] with an average of 40,588 VAERS reports filed every year.[11] However, due to under-reporting by healthcare providers, 40,588 may actually represent less than one percent of vaccine adverse events reported to the FDA.[12] Further, as the majority of healthcare providers continually fail to report vaccine injuries to VAERS, vaccines are more than likely to carry a much higher risk of adverse events and death than reported by any surveillance system.

4. The Vaccine Injury Compensation Program (VICP) established by NCVIA, has paid approximately $3.8 billion dollars since 1987 to compensate vaccine-injured individuals, including deaths.[13] Despite the existence of the CDC/FDA's vaccine safety surveillance systems such as the Vaccine Safety Datalink (VSD), Post-Licensure Rapid Immunization Safety Monitoring (PRISM), and Clinical Immunization Safety Assessment Project (CISA), vaccine injuries DO occur and they are not as rare as healthcare providers represent them to be.

5. Vaccine Information Statements (VIS) are documents produced by the CDC offering a selective summary of information for vaccine recipients to review just prior to a vaccination. The VIS offers information about the vaccine and the disease it is intended to prevent, some common side effects, risks and benefits and information about the Vaccine Injury Compensation program.

   Even though a VIS is supposed to be provided to a patient before vaccine administration, the CDC acknowledges the following:[14]

   1) VIS' provided by the healthcare provider may be outdated.
   2) The information on a VIS is based on recommendations from the Advisory Committee on Immunization Practices (ACIP) which only includes adverse events that the ACIP believes are causally linked to the vaccine. Therefore, a VIS does not fully present the adverse events as identified by the manufacturer during clinical trials.
   3) Not all combination vaccines administered have an associated VIS thus pediatricians who use various vaccine combinations all of the time may not providing the appropriate VIS as required by NCVIA under 42 USCS § 300aa-26.
   4) If a VIS is unavailable from the CDC, the FDA suggests the use of a Manufacturer's Package Insert as a substitute for a VIS or other print materials.

   Further, the CDC states that NCVIA requires providers to do the following:[15]

   1) Make a notation in the patient's medical record or permanent office log regarding the provision of a VIS or the parent must acknowledge receipt in writing,

   2) Make a notation of the edition date of the VIS provided, and date provided,

   3) Provide patients with a current VIS PRIOR to vaccination, not afterwards.

   Given that Hawaii's healthcare providers are admittedly extremely busy, how can there be any assurances that these steps take place on any regular basis?

6. According to the CDC, vaccinations are considered medical procedures. Yet, there are claims that HRS § 671-3 regarding informed consent does not apply to vaccinations. There are two problems to this claim.

First, under HR§ 671-1, the terms "medical or surgical treatment" or "diagnostic or therapeutic procedure" are not defined. Thus, to claim that the act of vaccinations do require informed consent under HRS § 671-3, is inaccurate and unsubstantiated and may need to be challenged in a court of law.

Second, the information on a VIS contains all of the elements of Informed Consent as required in HRS § 671-3 (b):

(b) The following information shall be supplied to the patient or the patient's guardian or legal surrogate prior to obtaining consent to a proposed medical or surgical treatment or a diagnostic or therapeutic procedure:

- **(1)** The condition to be treated;
- **(2)** A description of the proposed treatment or procedure;
- **(3)** The intended and anticipated results of the proposed treatment or procedure;
- **(4)** The recognized alternative treatments or procedures, including the option of not providing these treatments or procedures;
- **(5)** The recognized material risks of serious complications or mortality associated with:
  - **(A)** The proposed treatment or procedure;
  - **(B)** The recognized alternative treatments or procedures; and
  - **(C)** Not undergoing any treatment or procedure; and
- **(6)** The recognized benefits of the recognized alternative treatments or procedures.

One of the major reasons why the VIS does not constitute informed consent is that the information on the VIS does not accurately reflect the adverse events the manufacturer reported in clinical trials. As noted earlier, the ACIP makes recommendations on the information included on the VIS and clearly, this selectivity of information is not the same as informed consent. Lastly, many severe or unobserved vaccine events will not be observed until the vaccine is in the market and reported to VAERS and thus is not part of the VIS.

If HRS § 671-3, does not apply to vaccines where protections from informed consent would reduce vaccine injuries in Hawaii, then supporting HR 107/HCR 157 must be seriously considered since a great number of physicians and other recognized healthcare providers regularly recommend vaccinations as a medical intervention for health purposes.

7. NCVIA of 1986 was enacted as an administrative process intended to quickly address and facilitate the vaccine-injured[16] while preserving the U.S. immunization program. The NCVIA created a National Vaccine Injury Compensation Program (VICP) to compensate individuals for vaccine-related injuries or death[17] resulting from CDC recommended vaccines.[18] In exchange, vaccine manufacturers and medical professionals are exempted from all civil liability associated with vaccine injury claims.[19]

As a result of NCVIA, vaccine injured families can languish in the "Vaccine Court" up to five years seeking compensation for their vaccine injuries. [20] In contrast, vaccine market will be worth $61 billion dollars by 2020[21] and vaccine manufacturers will not be liable for a single vaccine injury or death.

Conclusion:

Patients have the right to refuse any medical procedure including vaccination. The risks from a vaccination may outweigh the benefits of protection from disease especially since many adverse events are not disclosed on the VIS or the package insert. Vaccine-induced adverse events that would normally be collected during a Phase 4 clinical trial are instead collected through VAERS, a passive-surveillance system where the majority of healthcare providers are not compelled to report vaccine related adverse events. If individuals considering a vaccination cannot rely on the VIS or their healthcare provider to provide relevant and necessary information to make an informed decision and if healthcare providers fail to report vaccine-induced adverse events to VAERS designed for this purpose, then how would any individual receive the necessary information required for true Informed Consent?

The argument should not be that providing additional information would confuse the patient, make the experience difficult, inconvenient, time-consuming or dissuade the patient from vaccination. The argument should be that any additional information about vaccine safety, adverse events, side effects and other risks should be provided to all patients prior to vaccination to allow patients to participate in their own medical decisions.

If vaccines had 0 risk, Congress would not have enacted the National Childhood Vaccine Injury Act of 1986. Congress would also not have created the VAERS system to collect adverse event reports and most of all, the Vaccine Injury Compensation Program would not have been created 32 years ago to compensate the vaccine-injured. To its credit, Congress recognized that CDC recommended vaccines can and do cause vaccine injuries, of which $3.8 billion dollars to date, has been paid as compensation.

We urge you to adopt HR 107/HCR 157 to review the adverse events in Hawaii that occur from vaccines so that there is transparency in the Hawaii immunization program where our children and families are truly protected.

Mahalo,

Sincerely,

T. Ocampo

Hawaii For Informed Consent

---

[1]https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. (See Appendix I).
[2]https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm.

[3] https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm.
[4]https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm.
[5] 42 USCS § 300aa-25 (b) (2017).
[6] David A. Kessler, "Introducing MED Watch. A New Approach to Reporting Medication and Device Adverse Effects and Product Problems." JAMA. 269 (21) 2765-2768, 2765, (1993) doi:10.1001/jama.269.21.2765.
[7] 42 USCS § 300aa-25 (b) (2017)
[8]"Surveillance Manual | Vaccine Adverse Event Reporting System | VPDS | CDC." Cdc.Gov, https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html.
[9] Miles M. Braun, "Institute for Vaccine Safety - Vaccine Adverse Event Reporting System (VAERS), Usefulness and Limitations."Vaccinesafety.Edu, http://www.vaccinesafety.edu/VAERS-Braun.htm.
[10] United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - last month, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html at 10:00:52 PM (accessed 22 October 2017).
[11]"Surveillance Manual | Vaccine Adverse Event Reporting System | VPDS | CDC." Cdc.Gov, https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html.
[12] R. Lazarus- Electronic Support for Public Health - Vaccine Adverse Event Reporting System (ESP: VAERS) - Final Report. (Prepared by Harvard Pilgrim Health Care, Inc. under Grant No. R18 HS017045). Rockville, MD: Agency for Healthcare Research and Quality, 1-7, 6 (2010). (PDF, 96.19 KB).
[13] https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/monthly-website-stats-2-01-18.pdf.
[14] https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html.
[15] https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html
[16] 42 USCS § 300aa-12 (d) (2) (2017).
[17] Id. § 300aa-10(a).
[18] Id. § 300aa-11(a) (3).
[19] Id.
[20] *GAO Report 15-142: Vaccine Injury Compensation - Most Claims Took Multiple Years And Many Were Settled Through Negotiation.* 30 (2014), http://www.gao.gov/assets/670/667136.pdf (accessed 1 October 2017).
[21] "Big Pharma And Big Profits: The Multibillion Dollar Vaccine Market | Global Research - Centre for Research on Globalization." Globalresearch.Ca, 2016, https://www.globalresearch.ca/big-pharma-and-big-profits-the-multibillion-dollar-vaccine-market/5503945. (14 October 2017).

HCR-157
Submitted on: 3/21/2018 8:33:21 AM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Kalma Wong	Individual	Support	No

Comments:

I am asking you to vote yes on HCR 157, requesting a study on the incidences of adverse effects of vaccines. Many vaccines contain toxic materials such as formaldehyde, mercury, aluminum, and even aborted baby fetal cells. Each day there are more and more reports of vaccine injury in America. Many adverse reactions include encephalitis, vasculitis, meningitis, anaphylactic reaction, and even death. This is a serious issue that must be addressed before we continue to be poisoned by these vaccines. Thank you.

Quentin Whitehurst

HCR-157
Submitted on: 3/21/2018 4:37:44 AM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
renee kawelo	Individual	Support	No

Comments:

We NEED transparency. If vaccines are safe and affective then we should demand studies proving this. Why would we not keep data to see how things affect the health of our keiki especially with the growing bills that have come up trying to push people towards mandatory vaccines.

I am asking you to vote yes on HR 107, requesting a study on the incidences of adverse effects of vaccines. Many vaccines contain toxic materials such as formaldehyde, mercury, aluminum, and even aborted baby fetal cells. Each day there are more and more reports of vaccine injury in America. Many adverse reactions include encephalitis, vasculitis, meningitis, anaphylactic reaction, and even death. This is a serious issue that must be addressed before we continue to be poisoned by these vaccines. Thank you.

Tracey Whitehurst

HAWAIʻI PACIFIC HEALTH | KAPIʻOLANI PALI MOMI STRAUB WILCOX

Thursday, March 22, 2018 at 8:30 am
Conference Room 329

House Committee on Health & Human Services

To: Representative John Mizuno, Chair
Representative Bertrand Kobayashi, Vice Chair

From: Melinda Ashton, MD.
Executive Vice President, Chief Quality Officer

Re: Testimony In Opposition for HCR 157/HR 107

Requesting the Department of Health and the Centers for Disease Control and Prevention to conduct a study on the incidences of adverse effects to vaccines in Hawaii.

My name is Melinda Ashton, MD and I am the Executive Vice President and Chief Quality Officer at Hawaiʻi Pacific Health. Hawaiʻi Pacific Health is a not-for-profit health care system with over 70 locations statewide including medical centers, clinics, physicians and other caregivers serving Hawaiʻi and the Pacific Region with high quality, compassionate care. Its four medical centers – Kapiʻolani, Pali Momi, Straub and Wilcox.

I write in opposition to HCR 157/HR 107 which requests that the Department of Health and Centers for Disease Control and Prevention conduct a study on the incidences of adverse effects to vaccines in the state. While we appreciate the intent of the measures and understand the concerns some may have about the safety of vaccines, there are already safety systems in place to monitor vaccine administration as well as reactions.

Under federal law, all providers are required to give patients a Vaccine Information Statement (VIS). The VIS is produced by the Centers for Disease Control and Prevention and serves to inform all recipients of vaccines about the benefits and risks of a vaccine they will receive. The VIS must be given prior to the vaccination, and prior to each dose of a multi-series dose. According to the CDC, because VIS forms "cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed." This practice meets the spirit of the proposed resolution on making information prior to making a decision on a vaccination.

"Informed consent" is a legal term under the purview of the Hawaii Medical Board (HRS §671-3) and applies to a "proposed medical or surgical treatment or a diagnostic or therapeutic procedure" – none of which accurately describe immunizations (or other medications such as antibiotics). Thus, the purposes of the resolutions are already met.

Thank you for the opportunity to provide testimony on this bill.

Testimony of
Hawaii Immunization Coalition (HIC)

Before:
Committee on Health and Human Services
Representative John Mizuno, Chair
Representative Bertrand Kobayashi, Vice Chair

March 22, 2018
9:00 am
Conference Room 329

Re: HCR 157/HR107 REQUESTING THE DEPARTMENT OF HEALTH AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION TO CONDUCT A STUDY ON THE INCIDENCES OF ADVERSE EFFECTS TO VACCINES IN HAWAII

Chair, Vice Chair, and committee members, thank you for this opportunity to provide testimony on HCR157 and HR107.

The Hawaii Immunization Coalition (HIC) **strongly opposes these resolutions** and urges the Committee to stop both resolutions from passing. These resolutions would require the use of limited state time and resources to investigate vaccine adverse events, even though the evidence clearly demonstrates vaccine effectiveness, safety, and importance for health. As such, they will lead to avoidable costs for the state as well as increased harm for families in Hawaii. There are some reasons why these resolutions are unnecessary:

- An "adverse event" is any health problem that happens after vaccination. It may or may not have been caused by the vaccine.
- The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) closely monitor vaccine safety using a collection of passive and active surveillance systems:
  - Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine Safety Datalink (VSD)
  - Post-Licensure Rapid Immunization Safety Monitoring (PRISM)
  - Clinical Immunization Safety Assessment Project (CISA)
- These systems have the funding, resources, and expertise to monitor vaccines currently in use. Requesting the Department of Health and CDC to conduct additional studies is duplicative and unnecessary.
- The National Childhood Vaccine Injury Act (NCVIA) requires providers to report adverse events to VAERS. In addition, recommendations for healthcare professionals to report to VAERS are a part of the Standards for Pediatric Immunization Practices, which are endorsed by multiple professional organizations, including the American Academy of Pediatrics.
- "Informed consent" is a legal term under the purview of the Hawaii Medical Board (HRS §671-3) and applies to a "proposed medical or surgical treatment or a diagnostic or therapeutic procedure" – none of which accurately describe immunizations (or other medications such as antibiotics).
- Currently, healthcare providers are required by federal mandate to provide CDC-developed Vaccine Information Statements (VISs) to individuals or in the case of a minor, their parent/legal guardian prior to vaccination. VISs provide individuals with current, relevant information regarding vaccinations in an accessible format, and include information regarding possible side effects of vaccination and how parents and providers may report adverse effects to VAERS, should they occur.
- The wording of each VIS is carefully written to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of The Patient Protection and Affordable Care Act of 2010.
- The VIS are then reviewed and approved by the Advisory Committee on Childhood Vaccines (ACCV) which includes:

    - Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury; and
    - Three members who are attorneys, including at least one who represents individuals who have been vaccine-injured.
- The VIS have been translated into over 40 languages, ensuring important information related to vaccination is available to and accessible by most persons.

Barriers to proven health interventions like vaccines will result in sicker families and communities. We implore you to oppose these unnecessary and harmful resolutions to not only save valuable state time and resources but also to keep our families healthy.

HIC is a statewide, community-based non-profit 501(c)3 coalition of public and private organizations and concerned individuals whose mission is to promote effective strategies to ensure that all Hawaii's families are appropriately vaccinated against vaccine-preventable diseases. Focus: Immunizations across the lifespan. The coalition has been active in Hawaii since the early 1980's and has more than four hundred immunization supporters.

Thank you for your consideration.

Date: March 20, 2018

To: The Honorable John Mizuno, Chair
The Honorable Bertrand Kobayashi, Vice Chair
Members of the House Committee on Health & Human Services

Re: **Strong Opposition of HCR157 and HR107**

Hrg: March 22, 2018 at 9:00am at Capitol Room 329

Respected Members of the House Committee on Health & Human Services,

As a concerned resident of Hawai'i and parent, **I strongly oppose HCR157 and HR107** as unnecessary, costly, and dangerous. These resolutions would required the use of limited state time and resources to investigate vaccine adverse events, even though the evidence clearly demonstrates vaccine effectiveness, safety, and importance for health. Please consider the following points:

An "adverse event" is any health problem that happens after vaccination. It may or may not have been caused by the vaccine.

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) closely monitor vaccine safety using a collection of passive and active surveillance systems, including:

- Vaccine Adverse Event Reporting System (VAERS)
- Vaccine Safety Datalink (VSD)
- Post-Licensure Rapid Immunization Safety Monitoring (PRISM)
- Clinical Immunization Safety Assessment Project (CISA)

These surveillance systems have the funding, resources, and expertise to monitor vaccines currently in use. Requesting the Department of Health and CDC to conduct additional studies is duplicative and unnecessary.

The National Childhood Vaccine Injury Act (NCVIA) requires providers to report adverse events to VAERS. In addition, recommendations for healthcare professionals to report to VAERS are a part of the Standards for Pediatric Immunization Practices, which are endorsed by multiple professional organizations, including the American Academy of Pediatrics.

"Informed consent" is a legal term under the purview of the Hawaii Medical Board (HRS §671-3) and applies to a "proposed medical or surgical treatment or a diagnostic or therapeutic procedure" – none of which accurately describe immunizations (or other medications such as antibiotics).

Currently, healthcare providers are required by federal mandate to provide CDC-developed Vaccine Information Statements (VISs) to individuals or in the case of a minor, their parent/legal guardian prior to vaccination. VISs provide individuals

with current, relevant information regarding vaccinations in an accessible format, and include information regarding possible side effects of vaccination and how parents and providers may report adverse effects to VAERS, should they occur.

The wording of each VIS is carefully written to ensure that it adheres to the health literacy criteria set forth in the health literacy standards, which includes:

- Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury; and
- Three members who are attorneys, including at least one who represents individuals who have been vaccine-injured.
- The VIS have been translated into over 40 languages, ensuring important information related to vaccination is available to and accessible by most persons.
- Requesting healthcare providers to obtain informed consent prior to vaccination is unnecessary and discourages vaccination, placing individuals and communities at-risk for outbreaks of vaccine-preventable diseases.

I urge you to stop these unnecessary and harmful resolutions from passing, so that we can use our resources to focus on keeping our families healthy in Hawai‘i.

Many thanks for your consideration,

Forrest Batz, PharmD
Keaau, HI

HCR-157
Submitted on: 3/20/2018 12:35:38 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
SueAnn Yasuoka	Individual	Oppose	No

Comments:

March 20, 2018

Representative John Mizuno, Chairman, Representative Bertrand Kobayashi, Vice Chair, and other members of the Committee of Health and Human Services

I am STRONGLY OPPOSED TO HCR157 / HR107. As a pharmacist who administers vaccines, the information about vaccines is readlily available. All a patient needs to do is ask. Consent to administer is provided prior to administration. Any adverse effects to a vaccine is reported to the Vaccine Adverse Event Reporting System (VAERS), which collects the data and reports back to the manufacturer. Vaccines are studied and undergo testing before they are approved. By asking the Dept of Health and the CDC to conduct a study is redundant and a waste of resources. Please DO NOT SUPPORT this measure.

Sincerely,

Sue-Ann Yasuoka, Pharmacist

HCR-157
Submitted on: 3/20/2018 1:49:27 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Gwen Navarrete Klapperich	Individual	Oppose	No

Comments:

Chair, Vice Chair, and committee members, thank you for this opportunity to provide testimony on HCR157 and HR107.

As a concerned resident of Hawaii and parent, I oppose these resolutions as unnecessary, costly, and dangerous. These resolutions would required the use of limited state time and resources to investigate vaccine adverse events, even though the evidence clearly demonstrates vaccine effectiveness, safety, and importance for health. Please consider the following points:

- An "adverse event" is any health problem that happens after vaccination. It may or may not have been caused by the vaccine.
- The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) closely monitor vaccine safety using a collection of passive and active surveillance systems:
    - Vaccine Adverse Event Reporting System (VAERS)
    - Vaccine Safety Datalink (VSD)
    - Post-Licensure Rapid Immunization Safety Monitoring (PRISM)
    - Clinical Immunization Safety Assessment Project (CISA)
- These systems have the funding, resources, and expertise to monitor vaccines currently in use. Requesting the Department of Health and CDC to conduct additional studies is duplicative and unnecessary.
- The National Childhood Vaccine Injury Act (NCVIA) requires providers to report adverse events to VAERS. In addition, recommendations for healthcare professionals to report to VAERS are a part of the Standards for Pediatric Immunization Practices, which are endorsed by multiple professional organizations, including the American Academy of Pediatrics.
- "Informed consent" is a legal term under the purview of the Hawaii Medical Board (HRS §671-3) and applies to a "proposed medical or surgical treatment or a diagnostic or therapeutic procedure" – none of which accurately describe immunizations (or other medications such as antibiotics).
- Currently, healthcare providers are required by federal mandate to provide CDC-developed Vaccine Information Statements (VISs) to individuals or in the case of a

minor, their parent/legal guardian prior to vaccination. VISs provide individuals with current, relevant information regarding vaccinations in an accessible format, and include information regarding possible side effects of vaccination and how parents and providers may report adverse effects to VAERS, should they occur.

- The wording of each VIS is carefully written to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of The Patient Protection and Affordable Care Act of 2010.
- The VIS are then reviewed and approved by the Advisory Committee on Childhood Vaccines (ACCV) which includes:
- Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury; and
- Three members who are attorneys, including at least one who represents individuals who have been vaccine-injured.
- The VIS have been translated into over 40 languages, ensuring important information related to vaccination is available to and accessible by most persons.
- Requesting healthcare providers to obtain informed consent prior to vaccination is unnecessary and discourages vaccination, placing individuals and communities at-risk for outbreaks of vaccine-preventable diseases.

I urge you to stop these unnecessary and harmful resolutions from passing, so that we can focus on keeping our families healthy in Hawaii.

Mahalo for your consideration.

HCR-157
Submitted on: 3/20/2018 1:56:51 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Ron Klapperich	Individual	Oppose	No

Comments:

As a concerned resident of Hawaii and parent, I oppose these resolutions as unnecessary, costly, and dangerous. These resolutions would required the use of limited state time and resources to investigate vaccine adverse events, even though the evidence clearly demonstrates vaccine effectiveness, safety, and importance for health.

HCR-157
Submitted on: 3/20/2018 2:11:04 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Richard Weinstein	Individual	Oppose	No

Comments:

HCR-157
Submitted on: 3/20/2018 2:51:16 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Lee Buenconsejo-Lum	Individual	Oppose	No

Comments:

Chair, Vice Chair, and committee members, thank you for this opportunity to provide testimony on HCR157 and HR107.

As a concerned resident of Hawaii and as a physician and parent, I oppose these resolutions as unnecessary, costly, and dangerous. These resolutions would required the use of limited state time and resources to investigate vaccine adverse events, even though the evidence clearly demonstrates vaccine effectiveness, safety, and importance for health. Please consider the following points:

- An "adverse event" is any health problem that happens after vaccination. It may or may not have been caused by the vaccine.
- The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) closely monitor vaccine safety using a collection of passive and active surveillance systems:
  - Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine Safety Datalink (VSD)
  - Post-Licensure Rapid Immunization Safety Monitoring (PRISM)
  - Clinical Immunization Safety Assessment Project (CISA)
- These systems have the funding, resources, and expertise to monitor vaccines currently in use. Requesting the Department of Health and CDC to conduct additional studies is duplicative and unnecessary.
- The National Childhood Vaccine Injury Act (NCVIA) requires providers to report adverse events to VAERS. In addition, recommendations for healthcare professionals to report to VAERS are a part of the Standards for Pediatric Immunization Practices, which are endorsed by multiple professional organizations, including the American Academy of Pediatrics.
- "Informed consent" is a legal term under the purview of the Hawaii Medical Board (HRS §671-3) and applies to a "proposed medical or surgical treatment or a diagnostic or therapeutic procedure" – none of which accurately describe immunizations (or other medications such as antibiotics).
- Currently, healthcare providers are required by federal mandate to provide CDC-developed Vaccine Information Statements (VISs) to individuals or in the case of a minor, their parent/legal guardian prior to vaccination. VISs provide individuals with current, relevant information regarding vaccinations in an accessible format,

and include information regarding possible side effects of vaccination and how parents and providers may report adverse effects to VAERS, should they occur.

- The wording of each VIS is carefully written to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of The Patient Protection and Affordable Care Act of 2010.
- The VIS are then reviewed and approved by the Advisory Committee on Childhood Vaccines (ACCV) which includes:
- Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury; and
- Three members who are attorneys, including at least one who represents individuals who have been vaccine-injured.
- The VIS have been translated into over 40 languages, ensuring important information related to vaccination is available to and accessible by most persons.
- Requesting healthcare providers to obtain informed consent prior to vaccination is unnecessary and discourages vaccination, placing individuals and communities at-risk for outbreaks of vaccine-preventable diseases.

I urge you to stop these unnecessary and harmful resolutions from passing, so that we can focus on keeping our families healthy in Hawaii.

Mahalo for your consideration.

HCR-157
Submitted on: 3/20/2018 2:57:52 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Michele Nakata	Individual	Oppose	No

Comments:

This work is already done on a national level by the Vaccine Adverse Event Reporting System (VAERS). Commissioning such a study would be a waste of state governmental resources.

HCR-157
Submitted on: 3/20/2018 4:12:18 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Lorene Ng	Individual	Oppose	No

Comments:

As a concerned resident of Hawaii and parent, I oppose these resolutions as unnecessary, costly, and dangerous. These resolutions would required the use of limited state time and resources to investigate vaccine adverse events, even though the evidence clearly demonstrates vaccine effectiveness, safety, and importance for health. Please consider the following points:

- An “adverse event” is any health problem that happens after vaccination. It may or may not have been caused by the vaccine.
- The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) closely monitor vaccine safety using a collection of passive and active surveillance systems:
  - Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine Safety Datalink (VSD)
  - Post-Licensure Rapid Immunization Safety Monitoring (PRISM)
  - Clinical Immunization Safety Assessment Project (CISA)
- These systems have the funding, resources, and expertise to monitor vaccines currently in use. Requesting the Department of Health and CDC to conduct additional studies is duplicative and unnecessary.
- The National Childhood Vaccine Injury Act (NCVIA) requires providers to report adverse events to VAERS. In addition, recommendations for healthcare professionals to report to VAERS are a part of the Standards for Pediatric Immunization Practices, which are endorsed by multiple professional organizations, including the American Academy of Pediatrics.
- “Informed consent” is a legal term under the purview of the Hawaii Medical Board (HRS §671-3) and applies to a “proposed medical or surgical treatment or a diagnostic or therapeutic procedure” – none of which accurately describe immunizations (or other medications such as antibiotics).
- Currently, healthcare providers are required by federal mandate to provide CDC-developedVaccine Information Statements (VISs) to individuals or in the case of a minor, their parent/legal guardian prior to vaccination. VISs provide individuals with current, relevant information regarding vaccinations in an accessible format, and include information regarding possible side effects of vaccination and how parents and providers may report adverse effects to VAERS, should they occur.

- The wording of each VIS is carefully written to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of The Patient Protection and Affordable Care Act of 2010.
- The VIS are then reviewed and approved by the Advisory Committee on Childhood Vaccines (ACCV) which includes:
- Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury; and
- Three members who are attorneys, including at least one who represents individuals who have been vaccine-injured.
- The VIS have been translated into over 40 languages, ensuring important information related to vaccination is available to and accessible by most persons.
- Requesting healthcare providers to obtain informed consent prior to vaccination is unnecessary and discourages vaccination, placing individuals and communities at-risk for outbreaks of vaccine-preventable diseases.

I urge you to stop these unnecessary and harmful resolutions from passing, so that we can focus on keeping our families healthy in Hawaii.

Mahalo for your consideration.

HCR-157
Submitted on: 3/20/2018 4:17:24 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Kristyn Nishimoto	Individual	Oppose	No

Comments:

To Chair, Vice Chair, and committee members,

As a concerned resident of Hawaii, parent, and pediatrician, I **strongly oppose** HCR 157 and HR 107. These resolutions are unnecessary, costly, and dangerous. They would require the use of limited state time and resources to investigate vaccine adverse events, even though the evidence clearly demonstrates vaccine effectiveness, safety, and importance for health.

An “adverse event” is any healthy problem that happens after vaccination, regardless of if it was caused by the vaccine or not. The Federal Drug Administration and the Centers for Disease Control closely monitor vaccine safety using a collection of passive and active surveillance systems, such as the Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink (VSD), Post-Licensure Rapid Immunization Safety Monitoring (PRISM), and the Clinical Immunization Safety Assessment Project (CISA). These systems have the funding, resources, and expertise to monitor vaccines currently in use and covers a much larger segment of the population. Requesting the Hawaii Department of Health and CDC to conduct additional studies is duplicative and unnecessary.

The National Childhood Vaccine Injury Act (NCVIA) requires providers to report adverse events to VAERS. In addition, recommendations for healthcare professionals to report to VAERS are a part of the Standards for Pediatric Immunization Practices, which are endorsed by multiple professional organizations, including the American Academy of Pediatrics.

Currently, health care providers are required by federal mandate to provide CDC-developed Vaccine Information Statements (VISs) to individuals or in the case of a minor, their parent/legal guardian prior to vaccination. VISs provide individuals with current, relevant information regarding vaccinations in an accessible format and include information regarding possible side effects of vaccination and how parents and

providers may report adverse effects to VAERS, should they occur. The wording of each VIS is carefully written to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of The Patient Protection and Affordable Care Act of 2010.

Requesting health care providers to obtain informed consent prior to vaccination is unnecessary and discourages vaccination, placing individuals and communities at risk for outbreaks of vaccine-preventable diseases. This includes our most vulnerable populations, such as infants, those with chronic medical conditions that prevent vaccination, and the elderly.

I urge you to prevent these unnecessary and harmful resolutions from passing, so that we can focus on keeping our families healthy in Hawaii.

Thank you for your consideration.

Kristyn Nishimoto, MD

HCR-157
Submitted on: 3/20/2018 4:36:28 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Shilpa Patel	Individual	Oppose	No

Comments:

Chair, Vice Chair, and committee members, thank you for this opportunity to provide testimony on HCR157 and HR107.

As a concerned resident of Hawaii and parent, I oppose these resolutions as unnecessary, costly, and dangerous. These resolutions would required the use of limited state time and resources to investigate vaccine adverse events, even though the evidence clearly demonstrates vaccine effectiveness, safety, and importance for health. Please consider the following points:

- An “adverse event” is any health problem that happens after vaccination. It may or may not have been caused by the vaccine.
- The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) closely monitor vaccine safety using a collection of passive and active surveillance systems:
    - Vaccine Adverse Event Reporting System (VAERS)
    - Vaccine Safety Datalink (VSD)
    - Post-Licensure Rapid Immunization Safety Monitoring (PRISM)
    - Clinical Immunization Safety Assessment Project (CISA)
- These systems have the funding, resources, and expertise to monitor vaccines currently in use. Requesting the Department of Health and CDC to conduct additional studies is duplicative and unnecessary.
- The National Childhood Vaccine Injury Act (NCVIA) requires providers to report adverse events to VAERS. In addition, recommendations for healthcare professionals to report to VAERS are a part of theStandards for Pediatric Immunization Practices, which are endorsed by multiple professional organizations, including the American Academy of Pediatrics.
- “Informed consent” is a legal term under the purview of the Hawaii Medical Board (HRS §671-3) and applies to a “proposed medical or surgical treatment or a diagnostic or therapeutic procedure” – none of which accurately describe immunizations (or other medications such as antibiotics).
- Currently, healthcare providers are required by federal mandate to provide CDC-developed Vaccine Information Statements (VISs) to individuals or in the case of a minor, their parent/legal guardian prior to vaccination. VISs provide individuals with current, relevant information regarding vaccinations in an accessible format,

and include information regarding possible side effects of vaccination and how parents and providers may report adverse effects to VAERS, should they occur.

- The wording of each VIS is carefully written to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of The Patient Protection and Affordable Care Act of 2010.
- The VIS are then reviewed and approved by the Advisory Committee on Childhood Vaccines (ACCV) which includes:
- Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury; and
- Three members who are attorneys, including at least one who represents individuals who have been vaccine-injured.
- The VIS have been translated into over 40 languages, ensuring important information related to vaccination is available to and accessible by most persons.
- Requesting healthcare providers to obtain informed consent prior to vaccination is unnecessary and discourages vaccination, placing individuals and communities at-risk for outbreaks of vaccine-preventable diseases.

I urge you to stop these unnecessary and harmful resolutions from passing, so that we can focus on keeping our families healthy in Hawaii.

Mahalo for your consideration.

Shilpa Patel, MD

HCR-157
Submitted on: 3/20/2018 4:41:55 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Elisa Chong	Individual	Oppose	No

Comments:

Chair, Vice Chair, and committee members, thank you for this opportunity to provide testimony on HCR157 and HR107.

I am concerned resident of Hawaii, parent, Medical Povider (Physician Assistant) working in Travel medicine, Immunizations at Straub and Emergency Medicine at Tripler. I OPPOSE these resolutions as unnecessary, costly, and dangerous. In the ER we have had to do more lab work on unimmunized infants and children as we don't know if their fevers are from one of the diseases that could have been prevented from immunizations or a bacterial disease.These resolutions would required the use of limited state time and resources to investigate vaccine adverse events, even though the evidence clearly demonstrates vaccine effectiveness, safety, and importance for health. Please consider the following points:

- An “adverse event” is any health problem that happens after vaccination. It may or may not have been caused by the vaccine.
- The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) closely monitor vaccine safety using a collection of passive and active surveillance systems:
    - Vaccine Adverse Event Reporting System (VAERS)
    - Vaccine Safety Datalink (VSD)
    - Post-Licensure Rapid Immunization Safety Monitoring (PRISM)
    - Clinical Immunization Safety Assessment Project (CISA)
- These systems have the funding, resources, and expertise to monitor vaccines currently in use. Requesting the Department of Health and CDC to conduct additional studies is duplicative and unnecessary.
- The National Childhood Vaccine Injury Act (NCVIA) requires providers to report adverse events to VAERS. In addition, recommendations for healthcare professionals to report to VAERS are a part of the Standards for Pediatric Immunization Practices, which are endorsed by multiple professional organizations, including the American Academy of Pediatrics.
- “Informed consent” is a legal term under the purview of the Hawaii Medical Board (HRS §671-3) and applies to a “proposed medical or surgical treatment or a diagnostic or therapeutic procedure” – none of which accurately describe immunizations (or other medications such as antibiotics).

- Currently, healthcare providers are required by federal mandate to provide CDC-developed Vaccine Information Statements (VISs) to individuals or in the case of a minor, their parent/legal guardian prior to vaccination. VISs provide individuals with current, relevant information regarding vaccinations in an accessible format, and include information regarding possible side effects of vaccination and how parents and providers may report adverse effects to VAERS, should they occur.
- The wording of each VIS is carefully written to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of The Patient Protection and Affordable Care Act of 2010.
- The VIS are then reviewed and approved by the Advisory Committee on Childhood Vaccines (ACCV) which includes:
- Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury; and
- Three members who are attorneys, including at least one who represents individuals who have been vaccine-injured.
- The VIS have been translated into over 40 languages, ensuring important information related to vaccination is available to and accessible by most persons.
- Requesting healthcare providers to obtain informed consent prior to vaccination is unnecessary and discourages vaccination, placing individuals and communities at-risk for outbreaks of vaccine-preventable diseases.

I urge you to stop these unnecessary and harmful resolutions from passing, so that we can focus on keeping our families healthy in Hawaii.

Our resources would be better spent keeping our Residents vaccinated to prevent these unnecessary outbreaks of Measles and Mumps caused by Unimmunized people and no Herd protection.

Mahalo for your consideration.

Elisa Chong

VINCE YAMASHIROYA, M.D., FAAP
GENERAL PEDIATRICS

March 20, 2018

RE: House Concurrent Resolution 157 (HCR 157) and House Resolution (HR 107)

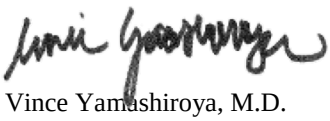
Dear Rep. Mizuno and members of the Health and Human Services Committee:

Thank you for the opportunity to provide testimony on HCR 175 and HR 107. I am in strong OPPOSITION to these resolutions.

Let me be blunt. These are **anti-vaccine** resolutions. It has nothing to do with vaccine safety. If you have done your research, there are hundreds if not thousands of vaccine safety studies globally and the verdict is that vaccines are safe and is one of the greatest achievements of public health since the twentieth century. EVERY medical professional organization promotes vaccines as being safe and necessary to ensure that diseases that cause CANCER AND DEATH are eradicated. We have already eliminated smallpox in the world and are trying to do the same with polio. We know the benefits of vaccines. However, if you, as a committee, agree to what is in these resolutions and order our Department of Health to provide yet ANOTHER safety study, you are wasting their valuable time and resources that should be better spent on our current mumps outbreak, and other future outbreaks, whether it be influenza, measles, or rat lungworm disease. And their efforts will be for naught because besides the ad nauseum amount of safety data out there, these antivaccine folks who asked Representative Tupola to introduce the previous house bill 2622, will NEVER consider vaccines safe since they have already ignored the many safety studies done already. In fact, after many physicians and medical professionals testified against this bill, HB2622 was considered DEAD.

I ask that this committee find the courage to side with science rather than politics. I am a busy, full-time pediatrician in private practice. I know it is unfortunate that there are very few to no pediatricians or practicing physicians who can testify in person against these resolutions, but it is because we are busy in our offices, providing the best care possible to our patients, and vaccinating all of them against these life-threatening diseases. If you've ever been to a pediatrician's office, you know how busy we are. To ask us to emphasize the serious rare side effects from vaccines that is already in the Vaccine Information Statement and to obtain informed consent from each vaccine is a disservice to every child that should be protected. Let us, as your pediatricians, take charge in ensuring the best health possible of your child. Do not allow anti-vaxxers and politics get in the way of what we do.

Sincerely yours,



Vince Yamashiroya, M.D.

1010 S. KING STREET, SUITE 105 ● HONOLULU, HAWAII 96814
TELEPHONE (808) 596-2030 ● PHYSICIANS EXCHANGE (808) 524-2575

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Hawaii Chapter

March 20, 2018

AAP - Hawaii Chapter
P.O. Box 25817
Honolulu, HI 96825
Website: hawaiiaap.org

Hawaii Chapter Board

President
Mae S. I. Kyono, MD, FAAP
1319 Punahou Street, 7th Floor
Honolulu, HI 96826
Phone: 808/780-5286
Email: mkyono@hawaii.edu

Vice-President
Michael Ching, MD, MPH, FAAP
2828 Paa Street
Honolulu, HI 96819
Phone: 808/432-5656
Email: michael.s.ching@kp.org

Secretary
Josephine Quensell, MD, FAAP
1319 Punahou Street, Suite 1050
Honolulu, HI 96826
Phone: 808/942-8144
Email: quensell@hawaii.edu

Treasurer
Vince Yamashiroya, MD, FAAP
1010 S. King Street, Suite 105
Honolulu, HI 96814
Phone : 808/596-2030
Email : vinceyamashiroya@gmail.com

Immediate Past President
R. Michael Hamilton, MD,MS,FAAP
1010 Pensacola Street
Honolulu, HI 96814
Phone : 808/375-3961
Email : michael.r.hamilton@kp.org

Chapter Executive Director
Sharon Hicks
P.O. Box 25817
Honolulu, HI 96825
Phone: 808/282-4944
Email: haapsharon@gmail.com

AAP Headquarters
141 Northwest Point Blvd
Elk Grove Village, IL 60007-1098
Phone: 847/434-4000
E-mail: kidsdocs@aap.org
www.aap.org

Dear Rep. Mizuno and Members of the Health and Human Services Committee,

The American Academy of Pediatrics—Hawaii Chapter (HAAP) is in strong opposition to the House Concurrent Resolution 157 (HCR 157) requesting the Dept. of Health and the Centers for Disease Control and Prevention to conduct a study on the incidences of adverse effects to vaccines in Hawaii.

There are so many misleading claims in the "whereas" statements that it will be a disservice to the community to hear this resolution in open session.

First, the Food and Drug Administration (FDA) and the Center for Disease Control and Prevention (CDC) closely monitor vaccine safety using a collection of passive and active surveillance systems. These systems include; the Vaccine Adverse Event Reporting Systems (VAERS), the Vaccine Safety Datalink (VSD), Post-Licensure Rapid Immunization Safety Monitoring (PRISM) and the Clinical Immunization Safety Assessment Project (CISA). These systems already have funding and resources as well as the expertise to monitor vaccines currently in use. To require the Hawaii Dept. of Health to Conduct a study would be redundant and would spend unnecessary tax dollars.

Secondly, Physicians and Nurses who take care of children are trained in evaluating "adverse" reactions in children who have been vaccinated. Indeed, we do know how to "recognize signs of adverse reactions" and this is something that we talk about with each of our patients and parents each day in the clinic setting for each child who is being protected by an immunization. The term "adverse reaction" as used in the context of this resolution is misleading. By definition, an adverse event is any health problem that has been reported to happen after the vaccine has been administered. It may or may not have been caused by the vaccine. By far and away, the number of "reactions" that occur are mild soreness at the injection site and low-grade fever that last for less than 24 hours. The "whereas" statement quoting the number of "incidences" is potentially misleading and at best incomplete. There have been many studies done both nationally and internationally that show the effectiveness and safety of vaccines. To have the Hawaii Dept. of Health conduct their own safety study is a waste of valuable resources that would be better spent on current outbreaks such as the flu or mumps!

Currently, healthcare providers are required by federal mandate to provide CDC-developed Vaccine Information Statements (VIS) to parents of children being vaccinated. These VIS's provide individuals with current and relevant information regarding vaccines in an easy-to-understand and accessible format. Vaccine Information Sheets include information regarding possible side effects of administered vaccines and tell parents and providers how they may report adverse effects to VAERS, if any adverse events do occur. The wording of each VIS is carefully written to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of the Patient Protection and Affordable Care Act of 2010. The VIS has been translated into over 40 languages, ensuring important information related to vaccination is available to and accessible by most persons.

The “whereas” statement regarding the “additional ingredients” is also misleading and incomplete. Additives in vaccine products are miniscule and necessary. Additives such as aluminum, for example, have been studied extensively regarding how they are processed in the body as well as what levels are toxic. Aluminum is present in certain vaccines to improve the immune response. Aluminum is the most common metal found in nature. During the first 6 months of life, infants could receive about 4 milligrams of aluminum from vaccines. During this same period babies will also receive about 10milligrams of aluminum in breast milk and about 40 milligrams of aluminum in infant formula or about 120 milligrams from a soy-based formula. (see vaccine.chop.edu)

The mission of the Hawaii Chapter of the American Academy of Pediatrics is to attain optimal physical, mental, and social health and well-being for infants, children, adolescents and young adults. The HAAP is dedicated to helping and protecting our keiki. One of the best and safest ways to protect our keiki is to have them fully vaccinated against many vaccine-preventable diseases. These diseases can lead to series complications or even death. Please do not allow this legislation to move forward.

R. Michael Hamilton, MD, MS, FAAP
Past President, Legislative Chair
American Academy of Pediatrics
Hawaii Chapter

HCR-157
Submitted on: 3/20/2018 5:08:58 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Cristeta Ancog	Individual	Oppose	No

Comments:
Dear Rep. Mizuno and Members of the Health and Human Services Committee,

I am a mother, and a board certified pediatrician who has been practicing in Hawaii for over 25 years. I STRONGLY OPPOSE HCR 157, which requests the Department of Health and the CDC to conduct a study on the adverse effects of vaccines in Hawaii.

Vaccines, and the additives in vaccines, have been proven over and over to be safe and effective. Childhood immunizations prevent serious, and sometimes fatal, diseases in our keiki. There are many systems in place already to monitor adverse reactions after receiving an immunization. Health care providers are well trained to recognize and discuss adverse reactions with parents. This bill duplicates federal programs, and requires the use of limited state time and resources that could be spent on other issues.

Most importantly, passage of this resolution gives parents the impression that vaccines are dangerous, and may decrease the chance of a child getting fully immunized.

Let's keep our keiki safe and healthy and not allow this legislation to proceed.

Sincerely,

Cristeta Ancog MD

Certified, American Board of Pediatrics

HCR-157
Submitted on: 3/20/2018 5:11:15 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
JohnNagamine	Individual	Oppose	No

Comments:

I worry that Physicians are chained to others with no understanding of medicine. We are being forced down a treacherous path of untruths and fear which will cause harm to children. Sadly, political leaders push ahead without proper knowledge. Leading only with emotion can be dangerous.

I oppose these resolutions which are CLEARLY unnecessary, costly, and dangerous. These resolutions are a WASTE of state time and resources.

HCR-157
Submitted on: 3/20/2018 5:53:00 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Brijit Reis	Reis Pediatrics	Oppose	No

Comments:

As a pediatrician I strongly oppose this bill. Vaccines are one of the most well studied medical interventions and have been shown to save lives.

As vaccine-preventable diseases have become less common, the vaccines that prevent them have come under scrutiny. While life expectancy has increased and countries like the United States have stopped hearing about deaths caused by diseases like measles and rubella, other parts of the world still struggle to control them. Indeed, in parts of Africa, some families wait to name their children until the threat of measles has passed.

Unfortunately, rather than celebrating the successes of vaccines, some have started to wonder whether vaccines could be causing other conditions, such as asthma, autism, arthritis, diabetes and multiple sclerosis. In addition, conditions such as shaken baby syndrome, mad-cow disease and SIDS have also been blamed on vaccines. However, every time questions have been asked, studies have been completed and have not found vaccines to be causally associated with these conditions.

HCR-157
Submitted on: 3/20/2018 7:17:52 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Carolyn Ma	Individual	Oppose	No

Comments:

As Dean of the Daniel K. Inouye College of Pharmacy, I am very familiar with adverse drug reaction reporting. Inherent to any adverse drug reaction reporting system, reporting relies on health care professionals to report events. All health care organizations including hospitals, clinics, pharmacies, long term care facilities, nursing homes, face challenges in reporting even in the best interest of safety and improving quality of patient care. If such a study were to be conducted, I believe the data reported would be inadequate thus producing inaccurate results.

HCR-157
Submitted on: 3/20/2018 9:10:46 PM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Lance Taniguchi	Individual	Oppose	No

Comments:

Chair, Vice Chair, and committee members, thank you for this opportunity to provide testimony on HCR157 and HR107.
As a concerned resident of Hawaii and parent, I oppose these resolutions as unnecessary, costly, and dangerous. These resolutions would required the use of limited state time and resources to investigate vaccine adverse events, even though the evidence clearly demonstrates vaccine effectiveness, safety, and importance for health. Please consider the following points:

- An "adverse event" is any health problem that happens after vaccination. It may or may not have been caused by the vaccine.
- The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) closely monitor vaccine safety using a collection of passive and active surveillance systems:
  - Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine Safety Datalink (VSD)
  - Post-Licensure Rapid Immunization Safety Monitoring (PRISM)
  - Clinical Immunization Safety Assessment Project (CISA)
- These systems have the funding, resources, and expertise to monitor vaccines currently in use. Requesting the Department of Health and CDC to conduct additional studies is duplicative and unnecessary.
- The National Childhood Vaccine Injury Act (NCVIA) requires providers to report adverse events to VAERS. In addition, recommendations for healthcare professionals to report to VAERS are a part of the Standards for Pediatric Immunization Practices, which are endorsed by multiple professional organizations, including the American Academy of Pediatrics.
- "Informed consent" is a legal term under the purview of the Hawaii Medical Board (HRS §671-3) and applies to a "proposed medical or surgical treatment or a diagnostic or therapeutic procedure" – none of which accurately describe immunizations (or other medications such as antibiotics).
- Currently, healthcare providers are required by federal mandate to provide CDC-developed Vaccine Information Statements (VISs) to individuals or in the case of a minor, their parent/legal guardian prior to vaccination. VISs provide individuals with current, relevant information regarding vaccinations in an accessible format, and include information regarding possible side effects of vaccination and how parents and providers may report adverse effects to VAERS, should they occur.
- The wording of each VIS is carefully written to ensure that it adheres to the health

literacy criteria set forth in the health literacy standards of The Patient Protection and Affordable Care Act of 2010.

- The VIS are then reviewed and approved by the Advisory Committee on Childhood Vaccines (ACCV) which includes:
- Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury; and
- Three members who are attorneys, including at least one who represents individuals who have been vaccine-injured.
- The VIS have been translated into over 40 languages, ensuring important information related to vaccination is available to and accessible by most persons.
- Requesting healthcare providers to obtain informed consent prior to vaccination is unnecessary and discourages vaccination, placing individuals and communities at-risk for outbreaks of vaccine-preventable diseases.

I urge you to stop these unnecessary and harmful resolutions from passing, so that we can focus on keeping our families healthy in Hawaii.

Mahalo for your consideration.

HCR-157
Submitted on: 3/21/2018 2:16:53 AM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Derek Ching	Individual	Oppose	No

Comments:

Hi my name is Derek Ching and I am a pediatrician here on Oahu. I like many of my collegues are concerned about this bill and that it will take a lot of energy and effort from more important things that the DOH should be focusing on. There are already many check points and studies that have been done proving the efficacy and importance of our current recommended vaccines. Please consider the following points.

- An “adverse event” is any health problem that happens after vaccination. It may or may not have been caused by the vaccine.

• The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) closely monitor vaccine safety using a collection of passive and active surveillance systems:
o Vaccine Adverse Event Reporting System (VAERS)
o Vaccine Safety Datalink (VSD)
o Post-Licensure Rapid Immunization Safety Monitoring (PRISM)
o Clinical Immunization Safety Assessment Project (CISA)
• These systems have the funding, resources, and expertise to monitor vaccines currently in use. Requesting the Department of Health and CDC to conduct additional studies is duplicative and unnecessary.
• The National Childhood Vaccine Injury Act (NCVIA) requires providers to report adverse events to VAERS. In addition, recommendations for healthcare professionals to report to VAERS are a part of the Standards for Pediatric Immunization Practices, which are endorsed by multiple professional organizations, including the American Academy of Pediatrics.
• “Informed consent” is a legal term under the purview of the Hawaii Medical Board (HRS §671-3) and applies to a “proposed medical or surgical treatment or a diagnostic or therapeutic procedure” – none of which accurately describe immunizations (or other medications such as antibiotics).
• Currently, healthcare providers are required by federal mandate to provide CDC-developed Vaccine Information Statements (VISs) to individuals or in the case of a minor, their parent/legal guardian prior to vaccination. VISs provide individuals with current, relevant information regarding vaccinations in an accessible format, and include information regarding possible side effects of vaccination and how parents and

providers may report adverse effects to VAERS, should they occur.

- The wording of each VIS is carefully written to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of The Patient Protection and Affordable Care Act of 2010.
- The VIS are then reviewed and approved by the Advisory Committee on Childhood Vaccines (ACCV) which includes:
- Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury; and
- Three members who are attorneys, including at least one who represents individuals who have been vaccine-injured.
- The VIS have been translated into over 40 languages, ensuring important information related to vaccination is available to and accessible by most persons.
- Requesting healthcare providers to obtain informed consent prior to vaccination is unnecessary and discourages vaccination, placing individuals and communities at-risk for outbreaks of vaccine-preventable diseases.

I urge you to stop these unnecessary and harmful resolutions from passing, so that we can focus on keeping our families healthy in Hawaii.

Thanks you for your attention in this matter.

APIC HAWAII
Chapter 39

March 22, 2018 at 9:00 AM
Conference Room 329

House Committee on Health and Human Services

To: Chair John M. Mizuno
Vice Chair Bertrand Kobayashi

From: Stella Laroza
President-Elect
Association for Professionals in Infection Control, Hawaii Chapter 39

Re: Testimony in Opposition
HCR 157 and HR 107, Requesting the Department of Health and the Centers for Disease Control and Prevention to Conduct a Study on the Incidents of Adverse Effects to Vaccines in Hawaii

The Association for Professionals in Infection Control and Epidemiology (APIC), Hawaii Chapter 039 serves as the leading body in promoting safer care in preventing healthcare-associated events or infections. Each member is employed in their respective entities who work diligently with multidisciplinary teams in adhering to best practices. Members are staffed in major acute care hospitals, skilled nursing facilities, home health agencies, assisted living facilities, self-employed as consultants along with associate members who are partners in new product innovations. Our members contribute significantly to Hawaii's healthcare system in making our patient populations a safer place while receiving their care.

Thank you for the opportunity to provide testimony **opposing** HCR 157 and HR 107. Patients should be informed decision-makers when it comes to their healthcare choices—however, the report requested by this resolution would not achieve that aim. We have three main concerns. First, we believe that following "adverse events" can be confusing for consumers since it would include any incident post-vaccination. For example, a broken arm could be listed as an adverse event even if that injury was sustained riding a bike, rather than from the vaccination.

Second, we would note that there are currently a number of surveillance systems in place to help monitor the safety of vaccines, including the Vaccine Adverse Event Reporting System. We believe those systems provide accurate statistics on this matter. Lastly, we would oppose the use of informed consent for vaccines. Under federal law, all providers are required to give patients a Vaccine Information Statement (VIS). The VIS is produced by the Centers for Disease

Control and Prevention (CDC) and serves to inform all recipients of vaccines about the benefits and risks of a vaccine they will receive. The VIS must be given prior to the vaccination, and prior to each dose of a multi-series dose. According to the CDC, because VIS forms "cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed." This practice meets the spirit of the proposed resolution on making information available prior to making a decision on a vaccination.

Thank you for the opportunity to testify on this matter.

HCR-157
Submitted on: 3/21/2018 6:43:03 AM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Linda Weiner	Hawaii AAP	Oppose	No

Comments:

The issue of vaccine safety has been exhaustively studied with an enormous amount of expensive research by many accredited medical institutions and organizations. Vaccine safety is a medically established fact. It is also a fact that dedicated nonvaccinators continue to believe, without any scientific evidence, that there is some harm from vaccines. They are primarily responsible for the recent mumps and pertussis epidemics on Kauai, resulting in significant school absences among exposed and ill children, not to mention the many medical consequences. There is absolutely no reason for the State of Hawaii legislature to revisit this extensively researched issue to satisfy a small group of committed nonvaccinators. It would be a criminal waste of time and valuable resources. One needs only to do a little online research to realize the exhaustive research that has already been dedicated to this issue, which was initially required beacuse of a discredited English physician, Andrew Wakefield, with a financial interest in hypothesizing a link between MMR and autism. I would appreciate the legislators doing their own research into this subject before voting on such an important public health issue.

HCR-157
Submitted on: 3/21/2018 8:30:16 AM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Joni Kamiya	Individual	Oppose	No

Comments:

At a time when diseases were thought to be eradicated, why are taxpayers needing to foot this kind of measure? I'd like to see a refocus of DOH's work on stopping measles, mumps, diphtheria, and whooping cough.

The premise of this resolution is faulty and based on a bad study by an unscrupulous medical doctor. Hawaii does not need more anti-vaccine rhetoric.

HCR-157
Submitted on: 3/21/2018 8:57:14 AM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Sandra P Chang	Individual	Oppose	No

Comments:

As a concerned resident of Hawaii, parent and grandparent, I oppose these resolutions as unnecessary, costly, and dangerous. These resolutions would require the use of limited state time and resources to investigate vaccine adverse events, even though the evidence clearly demonstrates vaccine effectiveness, safety, and importance for health. In addition, a federal program already exists to monitor vaccine adverse events (Vaccine Adverse Event Reporting System, VAERS). Requesting healthcare providers to obtain informed consent prior to vaccination is unnecessary and discourages vaccination, placing individuals and communities at-risk for outbreaks of vaccine-preventable diseases.

I urge you to stop these unnecessary and harmful resolutions from passing, so that we can focus on keeping our families healthy in Hawaii.

Mahalo for your consideration.

HCR-157
Submitted on: 3/21/2018 9:07:57 AM
Testimony for HHS on 3/22/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Ailene Barranco	Individual	Oppose	No

Comments: