



STATE OF HAWAII  
DEPARTMENT OF HEALTH  
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**Testimony in OPPOSITION to H.B. 2622**  
**RELATING TO INFORMED CONSENT FOR VACCINATIONS**

REPRESENTATIVE JOHN M. MIZUNO, CHAIR  
HOUSE COMMITTEE ON HEALTH AND HUMAN SERVICES

Hearing Date: 02/06/2018

Room Number: 329

1 **Fiscal Implications:** None for the Department.

2 **Department Testimony:** The department opposes this measure as its requirements are  
3 duplicative of current Federally-mandated vaccine risk/benefit communication requirements, are  
4 excessively burdensome, and would serve as a barrier to immunization.

5 Currently, health care providers in the United States who administer routinely  
6 recommended vaccines are required under the National Childhood Vaccine Injury Act ([42](#)  
7 [U.S.C. §300aa-26](#), specified in the measure), to provide Centers for Disease Control and  
8 Prevention (CDC)-developed [Vaccine Information Statements \(VIS\)](#) to individuals or, in the case  
9 of a minor, their parent or legal guardian. VIS documents provide information on the benefit of  
10 vaccination, recommendations regarding who should be vaccinated and when, contraindications,  
11 risk (i.e., adverse events) information, advice in the event of an adverse reaction, information  
12 regarding the [Vaccine Adverse Event Reporting System \(VAERS\)](#) and the [National Vaccine](#)  
13 [Injury Compensation Program](#), as well as who to contact if individuals are interested in obtaining  
14 additional information about the vaccine. Although VIS's are not "informed consent"  
15 documents, the VIS process provides individuals with current, relevant information regarding  
16 vaccinations in a brief, accessible format.

17 In clinical settings, the measure's requirement for review of a "complete individual and  
18 family health history" would reduce the efficiency of vaccine administration, invariably  
19 impacting the limited time available for patient care. In non-clinical settings such as pharmacies,

1 complete individual and family health histories may not be available, therefore limiting  
2 community access to immunizations.

3         The measure's requirement for the provision of the vaccine manufacturer's product insert  
4 is deeply concerning as these documents contain medical and legal terminology not written for  
5 public understanding. Product inserts are lengthy legal documents regulated by the U.S. Food  
6 and Drug Administration and are intended to provide information to prescribing medical  
7 practitioners. For example, vaccine manufacturers are required by law to report via the product  
8 insert any adverse event that occurred after their product was administered during clinical trials  
9 as well as post-market experience, *whether causally related to the vaccination or not*. Provision  
10 of the product insert could result in public misunderstanding regarding post-vaccination adverse  
11 events, potentially causing unwarranted and excessive alarm and potential refusal of  
12 vaccinations.

13         The maintenance of high immunization rates is of critical importance because vaccines  
14 provide both individual and community protection, especially during outbreaks such as our  
15 ongoing mumps epidemic or past ones caused by hepatitis A and measles or even the 2009 flu  
16 pandemic. On an individual level, parental decisions regarding vaccination can have both  
17 immediate and lifelong ramifications, affecting children in infancy as well as years later, should  
18 exposure to disease occur. On the community level, most vaccine-preventable diseases are  
19 transmitted from person-to-person. When a sufficiently large proportion of individuals in a  
20 community are immunized, those persons serve as a protective barrier against the likelihood of  
21 transmission of the disease in the community and protect those who are not immunized or who  
22 received the vaccine but have not responded and therefore have no antibodies or protection  
23 (vaccine failures). This phenomenon is referred to as "herd immunity." With the threat of  
24 vaccine-preventable infectious diseases ever-present, including a severe nationwide influenza  
25 season in addition to our mumps outbreak, this measure jeopardizes the health of our community.

26         Thank you for the opportunity to testify.



February 5, 2018

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

Re: **Strong Opposition for HB2622**

Hrg: February 6, 2018 at 8:30am at Capitol Room 329

The Hawaii Public Health Association is a group of over 600 community members, public health professionals and organizations statewide dedicated to improving public health. HPHA also serves as a voice for public health professionals and as a repository for information about public health in the Pacific.

HPHA strongly opposes HB2622 which will add costly, burdensome, and unnecessary hurdles against making certain that all persons are vaccinated against dangerous vaccine-preventable diseases. Vaccines are life-saving measures and any formidable steps that add burden to the family or individual will reduce immunization coverage levels and put everyone at risk for these diseases. With recent outbreaks in hepatitis A, mumps, and flu in Hawaii, many of us have witnessed firsthand the harmful effects on the health and economy of Hawaii when the community is not appropriately vaccinated.

Furthermore, this bill also does not take into consideration the important points below:

- The federal Vaccine Information Statement (VIS) requirement already ensures relevant information regarding vaccinations is provided to individuals and parents/guardians prior to vaccination. Providing a VIS for each vaccine administered is standard and accepted procedure in all vaccine-administration settings.
- Package inserts are not written in a manner that can be easily understood by a layperson. It is grossly impractical in a medical office or pharmacy setting to provide package inserts to patients. Many inserts can be between 25 and 36 pages of technical language. They are meant to be read by medical professionals.
- This would add an additional burden in terms of time, costs, and capacity for our healthcare providers, especially pediatricians.
- "Informed consent" is under the scope of the Hawaii Medical Board per [HRS 671-3](#) and applies to a "proposed medical or surgical treatment or a diagnostic or therapeutic procedure" – none of which accurately describe immunizations.

For these reasons, we ask that **you oppose this bill**. It is a detriment and danger to the health and well-being of our families and communities in Hawaii.

Thank you for the opportunity to provide testimony on important health issues affecting people in Hawai'i.

Respectfully submitted,

A handwritten signature in black ink that reads "Holly Kessler".

Holly Kessler, Executive Director  
Hawaii Public Health Association

RE: HB 2622

RELATING TO INFORMED CONSENT FOR VACCINATIONS

From: John M. Nagamine, M.D. / Pediatrician

02-06-18 8:30AM in House conference room 329

[Current Referral](#): HHS, CPC, FIN

I am a pediatrician with a well-established practice serving upwards of 2000 children. I service more than 450 children all less than 2 years of age.

Let me be brief and clear regarding your consideration of adding additional barriers against excellence in health care.

If this measure is passed, **YOU WILL BE KILLING CHILDREN.**

The introducers of this bill are clearly uneducated regarding the challenges already faced by primary care physicians and nurses. They hide their “anti-vaccine” agenda behind a facade of “informed consent.”

We are amid a Mumps epidemic. We are trying to recover from a Measles epidemic. We have had multiple Hepatitis A outbreaks and new cases are on the way from San Diego.

We have H3N2 influenza coming our way and already have a Tami-Flu shortage. Emergency Rooms are already backed up and we have not yet started the peak of influenza in Hawaii.

Pediatricians and Family Practice Physicians are already overwhelmed by paper work. Primary care providers are already in short supply.

**IT IS CLEAR:**

**If this measure is passed, YOU WILL BE KILLING CHILDREN.**

Sadly, their lack of education and understanding directly threatens other children and infants. This measure is an embarrassment and a direct threat to children of Hawaii.

Please open you eyes to the needs of Hawaii and DENY passage of HB 2622. Follow FACTS! Be educated. (Don't Google it.)

John M. Nagamine, MD.



**HB-2622**

Submitted on: 2/2/2018 1:12:24 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Michael Hamilton	Hawaii Chapter, American Academy of Pediatrics	Oppose	No

Comments:

I would like to share with you some concerns I have with HB 2622 and SB 3061 relating to informed consent for vaccinations. Any measure that impedes the process of getting our keiki vaccinated concerns me. I am concerned that these bills will do this. The Vaccine Information Statement (VIS) forms already provide details on the risks and benefits of vaccines and provides info on how to access the National Vaccine Injury Compensation Program (there is a 1-800 # as well as website address) should the parent feel the need to contact them. So, this seems redundant. Further, a requirement to provide the vaccine package insert will be a real burden and potentially delay individuals from getting vaccinated. The package inserts are very detailed and not written in simple language as is the VIS. Thus, parents may become more confused and this may cause them to want to wait on getting their child immunized in a timely fashion. This could potentially lead to a devastating outcome.

Thank you,

R. Michael Hamilton, MD, MS, FAAP

# FAX

**Fax:** +1 808-5866311

**To:** Hawaii House HHS Committee

**From:** Laurie Sommers West, RN

**Phone:** 8083430120

**E-Mail:** lwest402@hotmail.com

**Date:** Feb 5, 2018

**Subject:** HB2622 Testimony Resend

**Pages:** 5

Urgent     Please Reply     For Review     Please Recycle     Please Comment

Comments:

Aloha, I was told by Chairman Mizuno's staff to make this third attempt to submit my written testimony for tomorrow's HB2622 hearing. I plan to give oral testimony, as well. Thank you!

**ifax**  
ifaxapp.com

Aloha Chairman Mizuno, Vice-Chairman Kobayashi and to the rest of the Committee,

My name is Laurie West. I'm an Oahu resident and I'm a formerly practicing RN, now a stay-at-home mother. I strongly **SUPPORT HB2622** and I urge you to support it, as well.

To make the best healthcare decisions, both healthcare professionals and laypeople need to become more aware of the peer-reviewed science and literature highlighting the risks of vaccination. The current CDC's Vaccine Information Statements [VISs], which are given to patients usually just prior to vaccination—without time to research risks and benefits effectively—are inadequate to inform people of some of the scientifically documented side effects people have incurred post-vaccination. Side effects and ingredients are better documented on vaccine manufacturers' package inserts than on the VISs, and are easily accessible to anyone online, if they are apprised of their existence and where to find them; they convey critical information for patients to give their informed consent. Since some side effects of vaccination can be serious and life-long, or even deadly, legislation requiring access to more complete, readily-available information by both patients and healthcare workers will help people make better risk-versus-benefits assessments regarding vaccination.

I would like to share with you a list of just some of the *hundreds* of summaries, verbatim, of peer-reviewed scientific papers from Neil Z. Miller's book entitled, *Miller's Review of Critical Vaccine Studies: 400 Important Scientific Papers Summarized for Parents and Researchers*. These papers document scientific evidence countering the mantra of vaccine safety and efficacy by CDC, media and other entities who promote vaccine mandates:

- Developed nations that require the most vaccines tend to have the worst infant mortality rates.
- Fully vaccinated children are significantly more likely to require emergency care than under-vaccinated children
- Developmental delays are three times more common in children who received vaccines with mercury
- A CDC-sponsored database shows significant links between thimerosal in vaccines and neurodevelopmental disabilities, including autism and ADD
- 180 studies provide evidence that thimerosal is dangerous; thimerosal-containing vaccines are unsafe for humans
- Six CDC studies showing that mercury in vaccines is safe are unreliable and provide evidence of scientific malfeasance
- Aluminum in vaccines can provoke permanent malfunctions of the brain and immune system
- Aluminum adjuvant vaccines can damage the nervous system and cause autoimmune disorders
- CDC policy to vaccinate pregnant women with thimerosal-containing influenza vaccines is not supported by science
- Annual vaccination against common strains of influenza reduces protective immunity against more dangerous strains of the disease
- Prior vaccination against seasonal influenza may increase the risk of contracting a severe case of pandemic influenza.
- Influenza vaccines are not effective in young children; safety data can't be trusted



- Healthcare policies that mandate influenza vaccination for healthcare workers to protect their patients are not supported by science
- The CDC collaborates with vaccine manufacturers to increase uptake by intentionally using scare tactics and inflated influenza death figures
- Pertussis vaccine failures are due to genetic changes in pertussis strains and poor efficacy, not because too many people are unvaccinated
- People who are vaccinated against pertussis can still spread the disease, making herd immunity and eradication unattainable
- The HPV vaccine may cause chronic pain, fatigue and nervous system damage
- The HPV vaccine may cause autoimmunity and ovarian failure
- Measles and mumps infections in childhood protect against deadly heart attacks and strokes during adulthood
- Measles can be spread from fully vaccinated people to other fully vaccinated people
- The MMR vaccine may be associated with brain autoimmunity and autism
- Scientists knew that vaccinating children against chickenpox would cause an epidemic of shingles in adults
- It's not ethical to increase cases of shingles in adults and the elderly by reducing cases of chickenpox in children
- The hepatitis B vaccine significantly increases the risk of multiple sclerosis and other serious autoimmune diseases
- Guillain-Barré syndrome (a neuromuscular disorder that can paralyze and kill) occurs after hepatitis B or influenza vaccination
- Childhood vaccines significantly increase the risk of seizures
- The mumps vaccine may increase the risk of developing type 1 diabetes
- Hexavalent vaccines significantly increase the risk of sudden infant death
- A mumps infection—but not mumps vaccination—protects women against ovarian cancer
- Childhood diseases experienced early in life protect against many different types of cancer later in life
- Wild chickenpox infections protect against brain tumors
- Vitamin A supplementation is highly protective against complications and death from measles
- Eleven randomized studies show that vitamin D significantly reduces the risk of influenza, pneumonia and other respiratory infections
- Influenza epidemics are due to weaker winter sunlight, inducing vitamin D deficiency
- Seasonal influenza occurs in the winter when solar radiation is weak and vitamin D levels are low
- Severe lower respiratory infections are significantly more likely to occur in children with a vitamin D deficiency
- Medical doctors recommend vitamin D supplementation for healthcare workers as an alternative to influenza vaccination
- Pediatricians reject vaccines for their own children
- Pediatricians do not vaccinate their own children against chickenpox; doctors refuse vaccines for influenza, pertussis, and hepatitis B
- Many European doctors think that measles is a harmless disease and do not recommend mandatory MMR vaccines

- Doctors and nurses in many different countries resist influenza vaccines
- Mothers who don't vaccinate their children are highly educated, value scientific knowledge and are sophisticated at researching vaccine
- Top scientists in the United States regularly engage in scientific misconduct that threatens the integrity of science
- Conflicts of interest are pervasive within the vaccine industry and compromise the objectivity of vaccine safety research
- The CDC receives money from the pharmaceutical industry that influences decisions it makes about the public welfare
- Anyone who is critical of vaccines may be unfairly suppressed, exposed by threats, censorship, and loss of their livelihood
- Authorities are tracking anti-vaccine information on the internet

Those are merely the summaries of a fraction of the scientific papers Miller so diligently researched and provided further details on in his book. As my gift to this Committee, I donate to you for your referral my personal copies of this invaluable reference book, so that you can follow the citations and see more details and direct quotes from those studies. Compare that peer-reviewed research to any VIS or media sound bite promoting the safety and efficacy of vaccines and ask yourself if the VIS adequately informs about known potential side effects leading to the best healthcare decisions.

Miller's other indispensable book, *Vaccine Safety Manual For Concerned Families and Health Practitioners*, which I am also giving to the Committee, has hundreds of notes and citations in almost every chapter. For the sake of all Hawaii residents across the age spectrum, I hope you weigh this wealth of information and support HB2622 in the effort to bring patients and healthcare workers more balanced, scientific, peer-reviewed information on vaccine ingredients and documented side effects.

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I would like to share an anecdote of a Guillain-Barré Syndrome patient in a hospital, as was recounted by a nurse case manager. Guillain-Barré Syndrome affects the nervous system through destruction of the "myelin sheath," surrounding nerve cells. Patients with the disease suffer from paralysis which may be temporary or permanent, and may require victims to be put on a ventilator to survive. Some people with GBS die from associated complications.

A Guillain-Barré victim who was paralyzed was admitted to the case manager's hospital; the first thing the patient's nurses and doctors asked him was, "Did you recently have a flu shot?" The patient later expressed his FURY to the nurse case manager over being left out of this "dirty little secret" among his care providers—what was it that healthcare professionals seemed to know about paralysis after flu vaccine that was not shared with this patient PRIOR to his consenting to the flu shot? Why did no one apprise him of this apparently known risk among his caregivers when he actually had an opportunity to do a PROPER risk and benefits assessment beforehand, taking potential paralysis into consideration? He felt robbed of this critical knowledge to decide whether to take or reject the flu shot.

The fact that the national Vaccine Injury Compensation Program has already paid out approximately \$3.8 BILLION in acknowledged vaccine injury claims to the small fraction of claims made for injuries which were accepted for adjudication is a testament to the fact that vaccine injuries do occur and are not safe and effective for everyone. Vaccine manufacturers and all people and entities involved in

administering vaccines to patients are completely shielded from liability, leaving injured people to fend for themselves—often destroying their lives and their families’ dreams. Where there is risk, there must be the right to refuse—especially when injured persons assume all liability. Many people are concerned about the overly-simplistic information contained in the CDC’s Vaccine Information Statements. This can be remedied to some extent by increasing awareness of the information contained in vaccine manufacturers’ package inserts. Healthcare workers who do not currently refer to manufacturer package inserts will have a legal imperative to do so if HB2622 becomes law, thereby helping to safeguard and fulfill their solemn mandate to educate patients for their informed consent deliberations.

I urge Hawaii legislators to support measures such as HB2622 seeking to enhance individuals’ right to informed consent.

Thank you.

Sincerely,

Laurie Sommers West, RN

Citations:

Miller, Neil Z. *Miller's Review of Critical Vaccine Studies: 400 Important Scientific Papers Summarized for Parents and Researchers*. Santa Fe, NM: New Atlantean, 2016. Print.

Miller, Neil Z. *Vaccine Safety Manual for Concerned Families and Health Practitioners*. Santa Fe, NM: New Atlantean, 2015. Print.

## **kobayashi2 - Kevin**

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**From:** Olivia Rose <breathingbirth@gmail.com>  
**Sent:** Friday, February 2, 2018 4:08 PM  
**To:** hhstestimony  
**Subject:** I support HB 2184!

HB2184 Relating to the Licensure of Midwives

Health and Human Services Committee

2/6/2018

Ashley Olivia Rose  
71 Hooahale Street  
Kihei, HI 96753

### **I am testifying in support of HB2184.**

Licensing professional midwives creates more access to quality women's healthcare, prenatal care, safe birthing options, postpartum care, breastfeeding support and reproductive care.

By legalizing professional midwives, the public has reassurance that midwives are educated according to national requirements, are held accountable to maintain national standards and complete continuing education.

Two sunrise audits completed in 1999 and 2017 concluded that Hawaii should regulate the profession of midwifery.

I urge you to support this bill.

Thank you.

Olivia Rose



**February 6, 2018 at 8:30 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**  
**HB 2622, Relating to Informed Consent for Vaccinations**

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** HB 2622. Patients should be informed decision-makers when it comes to their healthcare choices. However, this measure would not provide meaningful additional information to consumers while creating duplicative processes that would burden healthcare providers and make the administration of vaccines to vulnerable populations difficult and cumbersome. This is especially concerning as Hawaii prepares for the full arrival of the flu season, which has been particularly virulent and deadly on the U.S. mainland.

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."

Current practices meet the spirit of the proposed legislation, which is to ensure that patients are able to gain access to important information prior to making a decision on a vaccination. This measure would instead create undue burdens on patients seeking vaccinations, and we would request that your committee defer this measure. Thank you for your consideration of this matter.

Tuesday, February 6, 2018; 8:30 a.m.  
Conference Room 329

**House Committee on Health & Human Services**

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

From: Michael Robinson  
Vice President – Government Relations & Community Affairs

**Re: HB 2622 – Testimony in Opposition**

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My name is Michael Robinson, and I am the Vice President of Government Relations and Community Affairs at Hawai'i Pacific Health (HPH). Hawai'i Pacific Health is a not-for-profit health care system with over 70 locations statewide including medical centers, clinics, physicians and other caregivers serving Hawai'i and the Pacific Region with high quality, compassionate care. Its four medical centers – Kapi'olani, Pali Momi, Straub and Wilcox – specialize in innovative programs in women's health, pediatric care, cardiovascular services, cancer care, bone and joint services and more. Hawai'i Pacific Health is recognized nationally for its excellence in patient care and the use of electronic health records to improve quality and patient safety.

I am writing in opposition to HB 2622 which would require health care providers to obtain written informed consent before administering vaccinations. This bill adds costly, burdensome, and unnecessary hurdles against making certain that all persons are vaccinated against dangerous vaccine-preventable diseases.

Vaccines are life-saving measures and any formidable steps that create burdens to the family or individual will reduce immunization coverage levels and put everyone at risk for these diseases. With recent outbreaks in hepatitis A, mumps, and flu in Hawaii, many of us in the health care field have witnessed firsthand the harmful effects on the health and economy of Hawaii when our residents are not appropriately vaccinated.

Furthermore, these bill does not take into consideration the important points below:

- The federal Vaccine Information Statement (VIS) requirement already ensures relevant information regarding vaccinations is provided to individuals and parents/guardians prior to vaccination. Providing a VIS for each vaccine administered is standard and accepted procedure in all vaccine-administration settings. All VIS are published by the CDC.
- Package inserts are not written in a manner that can be easily understood by a layperson. It is grossly impractical in a medical office or pharmacy setting to provide

package inserts to patients. Many inserts can be between 25 and 36 pages of technical language. They are meant to be read by medical professionals.

- This would add an additional burden in terms of time, costs, and capacity for our healthcare providers, especially pediatricians.
- “Informed consent” is under the scope of the Hawaii Medical Board per HRS 671-3 and applies to a “proposed medical or surgical treatment or a diagnostic or therapeutic procedure” – none of which accurately describe immunizations.

Thank you for this opportunity to testify.

**HB-2622**

Submitted on: 2/1/2018 11:32:18 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Dawn Poiani		Support	Yes

Comments:

The informed consent principle, which was defined as a human right at the Doctors Trial at Nuremberg in 1947. Informed consent means you have the right to be fully informed about the benefits and risks of a medical intervention and the freedom to make a voluntary decision about whether or not to accept those risks without being coerced or punished for the decision you make. Informed consent applies not just to risks taken by participants in scientific experiments, but also to risks taken by patients under the care of physicians.

## **Informed Consent Principle Applies to All Medical Risk-Taking**

Today, when a person publicly advocates for informed consent protections in vaccine laws, an “anti-vaccine” label is usually immediately applied to shut down any further conversation. Perhaps because a conversation about ethics opens up a wider conversation about **freedom**.

The right and responsibility for making a decision about risk taking rightly belongs to the person taking the risk. When you become informed and think rationally about a risk that you or your minor child may take - and then follow your conscience - you own that decision. And when you own it, you can defend it. And once you can defend it, you will be ready to do whatever it takes to fight for your freedom to make it, no matter who tries to prevent you from doing that.

## **Never Do Anything Against Conscience**

Albert Einstein, who risked arrest in Germany in the 1930’s when he spoke out against censorship and persecution of minorities, said, “Never do anything against conscience even if the State demands it.”

There is no liberty more fundamentally a natural, inalienable right than the freedom to think independently and follow our conscience when choosing what we are willing to risk our life or our child’s life for.



Because the journey we take on this earth is defined by the choices we make. If we are not free to make choices, the journey is not our own. The choices we make that involve risk of harm to our physical body, which houses our mind and spirit, those are among the most profound choices we make in this life.

## **Vaccine Risks Not Being Borne Equally By Everyone in Society**

So, vaccination must remain a choice because it is a medical intervention performed on the body of a healthy person that carries a risk of injury or death. And while we are all born equal, with equal rights under the law, we are not born all the same. Each one of us is born with different genes and a unique microbiome influenced by epigenetics that affects how we respond to the environments we live in.

We do not all respond the same way to pharmaceutical products like vaccines, so vaccine risks are not being borne equally by everyone in society.

Why should the lives of those vulnerable to vaccine complications be valued any less than those vulnerable to complications of infections? And why should people not be free to choose to stay healthy in ways that pose far fewer risks?

## **Vaccines Carry Risks and Do Not Guarantee Protection**

The act of vaccination involves the deliberate introduction of killed live attenuated or genetically engineered microbes into the body of a healthy person, along with varying amounts of chemicals, metals, human and animal RNA and DNA and other ingredients that atypically manipulate the immune system to mount an inflammatory response that stimulates artificial immunity.

But there is no guarantee that vaccination will not compromise biological integrity or cause the death of a healthy or vaccine vulnerable person either immediately or in the future. There is also no guarantee that vaccination will protect a person from getting an infection with or without symptoms and transmitting it to others.

## **Vaccine Science Gaps, Doctors Cannot Predict Who Will React**

Reports published by physician committees at the Institute of Medicine confirm that vaccines, like infections, can injure and kill people but that:

- very little is known about how vaccines or microbes act at the cellular and molecular level in the human body; and

- the Institute of Medicine confirms that an unknown number of us have certain genetic, biological and environmental susceptibilities that make us more vulnerable to being harmed by vaccines, but doctors cannot accurately predict who we are; and
- that clinical trials of experimental vaccines are too small to detect serious reactions before they are licensed; and
- that the U.S. recommended child vaccine schedule through age six has not been adequately studied to rule out an association with allergies, autoimmunity, learning and behavior disorders, seizures, autism and other brain and immune dysfunction.

Yet, with these large gaps in scientific knowledge, government health officials direct physicians to vaccinate 99.99 percent of children regardless of known or unknown risks.

## **Government Licensed Vaccines “Unavoidably Unsafe”**

Therefore, vaccination is a medical procedure that can be termed experimental each time it is performed on a person. By extension, “no exceptions” mandatory vaccination laws create a de facto uncontrolled, population based scientific experiment that enrolls every child at birth and never ends, sacrificing an unknown number of vaccine vulnerable children.

Further, the US Congress and Supreme Court have declared federally licensed vaccines to be “unavoidably unsafe,” removing civil liability from doctors who give vaccines and drug companies that sell vaccines in what has become a very lucrative multi-billion dollar business in the U.S. At the same time, the federal vaccine injury compensation program created by Congress in 1986 that was supposed to be a no-fault alternative to a lawsuit – not instead of a lawsuit – has been gutted by federal agencies so that, today, almost no child receives compensation when they are hurt by vaccines.

Now, a global vaccine injury compensation program is being created to shield multinational corporations from liability for injuries caused by the hundreds of new genetically engineered vaccines governments will mandate in the future.

All this, while medical trade groups affiliated with industry and government join forces to lobby for removal of flexible medical, conscientious and religious belief exemptions from state health laws, as was done in California in 2015, so that those who refuse government endorsed vaccines for themselves or their minor children can be denied an education, employment, health care and other civil rights.

## **Utilitarianism Should Not Be Foundation of Public Health Law**

The Holocaust Museum in Washington, D.C., a conference on the role of physicians and scientists implementing public health policy during the Third Reich, there is an inscription that says “the first to perish were the children...from these a new dawn might have risen.”

-Thank you **Barbara Loe Fisher** for your clear conversation on this complex subject in content above.

Anytime there is risk there must be the option to make an informed decision and to deny treatment if after being properly informed the conclusion that the treatment is not right for that individual. The actual number of injuries or impact to health on an individual is only know after a vaccination. Additionally the US government has done a dismal job tracking the actual numbers. The fact is people are injured from vaccines and they do carry a risk. Where there is risk there must be choice.

Thank you,

Dawn Poiani

**HB-2622**

Submitted on: 2/2/2018 8:54:07 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
zeshan chisty		Oppose	No

Comments:

I oppose this bill, it will make it more difficult and time consuming for people to get their vaccinations.

**HB-2622**

Submitted on: 2/2/2018 11:19:30 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Mitsuko Hayakawa		Support	No

Comments:

Aloha Chair and Members of the Health and Human Services Committee,

I am in strong support of HB2622 relating to informed consent for vaccinations. People should be made aware of the known risks and benefits of any medical procedure.

Thank you for your consideration to this matter.

Mitsuko Hayakawa

**HB-2622**

Submitted on: 2/2/2018 12:37:10 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Thaddeus Pham		Oppose	No

Comments:

Chair Mizuno, Vice Chair Kobayashi, and House Committee members, thank you for this opportunity to provide testimony on HB2622.

As a public health professional and concerned resident of Hawaii, I **strongly oppose this bill**. This bill adds costly, burdensome, and unnecessary hurdles against making certain that all persons are vaccinated against dangerous vaccine-preventable diseases.

Vaccines are life-saving measures and any formidable steps that add burden to the family or individual will reduce immunization coverage levels and put everyone at risk for these diseases. With recent outbreaks in hepatitis A, mumps, and flu in Hawaii, many of us have witnessed firsthand the harmful effects on the health and economy of Hawaii when the community is not appropriately vaccinated.

Furthermore, these bills also do not take into consideration the important points below:

- The federal Vaccine Information Statement (VIS) requirement already ensures relevant information regarding vaccinations is provided to individuals and parents/guardians prior to vaccination. Providing a VIS for each vaccine administered is standard and accepted procedure in all vaccine-administration settings. All VIS are published by the CDC, and more information can be found [here](#).
- Package inserts are not written in a manner that can be easily understood by a layperson. It is grossly impractical in a medical office or pharmacy setting to provide package inserts to patients. Many inserts can be between 25 and 36 pages of technical language. They are meant to be read by medical professionals.
- This would add an additional burden in terms of time, costs, and capacity for our healthcare providers, especially pediatricians.
- “Informed consent” is under the scope of the Hawaii Medical Board per [HRS 671-3](#) and applies to a “proposed medical or surgical treatment or a diagnostic or therapeutic procedure” – none of which accurately describe immunizations.

For these reasons, I ask that **you oppose this bill**. It is a detriment and danger to the health and well-being of our families and communities in Hawaii.

Thank you for your consideration.

**HB-2622**

Submitted on: 2/2/2018 1:36:15 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Joseph Gary Dela Cruz		Oppose	No

Comments:

I am a pediatrician in the State of Hawaii. I oppose this bill for the following reasons:

1. We already provide information with the Federal Vaccine Information Statements, which is already a requirement in all vaccine-administration settings.
2. The package inserts for vaccinations will be difficult to understand for non-medical professionals. The federal vaccine information statements already have the required information.



**HB-2622**

Submitted on: 2/2/2018 2:46:03 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Derek Ching	Children's Doctors LLC	Oppose	No

Comments:

This will severely slow down the work flow of the office making it more difficult to care for our keiki.

It is another unnecessary step we have to do and another barrier we will have to climb to get our keiki vaccinated.

**HB-2622**

Submitted on: 2/2/2018 1:52:48 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Vince Yamashiroya, MD	Vince Yamashiroya, MD, Inc.	Oppose	No

Comments:

Chair Mizuno, Vice Chair Kobayashi, and House Committee members, thank you for this opportunity to provide testimony on HB2622 Relating to Informed Consent for Vaccinations.

**I am in STRONG opposition to this bill.** I am a pediatrician in private practice and have been immunizing my patients since birth according to the Centers for Disease Control Recommended Vaccine Schedule. These recommended vaccines have been studied by many experts, including the Advisory Committee on Immunization Practices (ACIP). Many professional organizations work with ACIP in developing this vaccine schedule such as the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians. These vaccines go through many rigorous clinical trials to ensure safety and careful reviews before it is recommended to the public. There is ongoing surveillance of safety after these vaccines are released some of which were taken out of the market such as RotaShield or not recommended any more such as the oral polio vaccine which are determined by these experts. In my opinion, forcing our families to decide if a vaccine is safe or unsafe by studying the package insert is silly and a waste of time and resources. These package inserts are over 20 pages long and includes information on studies on clinical trials which can be daunting to many parents without a medical background or who have limited reading skills. Unlike the Vaccine Information Statement that is provided by the CDC, these package inserts are not in different languages making informed consent impossible to many immigrant families in Hawaii.

This bill will be a major barrier in immunizing our children and adults by needlessly lengthening the time taken in administering the vaccines and has the potential of scaring parents and patients in receiving them. In our current situation of a major influenza outbreak in the United State with 53 children dead from this disease, an outbreak of mumps in Hawaii with 842 confirmed cases and 24 reports of complications of orchitis (inflammation of the testicles which can lead to sterility) and hearing loss as of this writing, and our recent outbreaks of measles and hepatitis A in the islands, we cannot afford any barriers to vaccination, which is one of the 10 greatest public health achievements of the 20th century.

Please oppose this dangerous bill.

**HB-2622**

Submitted on: 2/2/2018 5:56:00 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Kat Culina		Support	No

Comments:

**HB-2622**

Submitted on: 2/2/2018 11:48:27 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Brian Lehmann		Comments	No

Comments:

My unqualified support would be contingent on inclusion of a philosophical exemption to immunization requirements for school attendance in Hawaii. .

**HB-2622**

Submitted on: 2/3/2018 8:53:08 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Carmen Golay		Support	No

Comments:

Dear Committee Members,

Thank you for hearing this bill. When I was a teenager I witnessed my infant brother have a severe reaction right after a routine doctor visit that included vaccinations. He broke out in a horrible rash, became almost unresponsive and ran a fever for several days. My mother took him back to the ER where she was told it was normal and we were sent home. When I became a parent, I asked my clinic at our well-baby checks for information on the vaccinations. They told me that wasn't possible because there was only one vaccine insert per box of vaccinations and they had to retain that information at the clinic. Also, they told me that it wasn't guaranteed that I'd get the same brand of vaccine each time "due to cost variations." So through post partum issues, exhaustion, breastfeeding struggles I had to do my own research and find the inserts for the vaccines that my child would be injected with. This was particularly difficult because I didn't know which brand of vaccine would be used. This bill would greatly assist parents and all patients receiving vaccinations to know exactly what they are getting, what to look for should they have a reaction and what to do. It seems like common sense since all other medications administered are discussed in this way, either by your doctor, nurse practitioner or pharmacist. Vaccinations should be the same.

I support full informed consent of all medical procedures, including vaccinations. Thank you for hearing this bill.

**HB-2622**

Submitted on: 2/3/2018 9:01:49 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Galen Chock	American Academy of Pediatrics, Hawaii Chapter	Oppose	No

## Comments:

We pediatricians focus on the health care needs of our younger patients. To do so, we must invest in nurturing and building a trusting, professional relationship with our patients and their families. This bill would only serve to intrude into this relationship building. It would create barriers towards better, informed health care for our children, therefore I am opposed to it.



## Hawaii Chapter

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February 2, 2018

Thank you for this opportunity to testify on *HB2622*, Relating to Informed Consent for Vaccinations. Hawaii American Academy of Pediatrics (HAAP) is in STRONG opposition to this bill.

HAAP is a voluntary organization of over 200 pediatricians in Hawaii. Our mission is to attain optimal physical, mental and social health and well being for infants, children, adolescents and young adults in Hawaii.

We believe in immunizations to prevent major outbreaks of preventable diseases. We immunize our patients according to the Centers for Disease Control Recommended Vaccine Schedule. These recommended vaccines have been studied by many experts, including the Advisory Committee on Immunization Practices (ACIP). Many professional organizations work with ACIP in developing this vaccine schedule such as the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians. These vaccines go through many rigorous clinical trials to ensure safety and careful reviews before it is recommended to the public. There is ongoing surveillance of safety after these vaccines are released. Pediatricians use the VIS (vaccine information statements) which are vaccine information sheets that are produced by the Centers for Disease Control. VIS explains the risks and benefits for the vaccine. It is written in language easy to understand and is available in many different languages.

*We oppose the bill, HB2622, it will be a major barrier in immunizing our children and adults by needlessly lengthening the time taken in administering the vaccines and has the potential of scaring parents and patients in receiving them.*

Thank you for this opportunity to provide this testimony. Please feel free to contact us if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Mae S. I. Kyono".

Mae Kyono, MD  
President, American Academy of Pediatrics – Hawaii Chapter





Testimony of  
Hawaii Immunization Coalition (HIC)

Before:  
Committee on Health  
Representative John Mizuno, Chair  
Representative Bertrand Kobayashi, Chair

Tuesday, February 6, 2018  
8:30 AM  
State Capitol, 415 South Beretania Street, Conference Room 329

**Re: HB2622 Relating to Vaccines.**

Chair, Vice Chair, and Committee members,

Thank you for this opportunity to provide testimony on HB2622.

The Hawaii Immunization Coalition (HIC) **strongly opposes HB2622/SB3061**. This bill adds costly, burdensome, and unnecessary barriers to appropriate and recommended vaccinations to protect people in Hawaii from dangerous vaccine-preventable diseases.

Vaccines are demonstrably life-saving health interventions, and any formidable steps that add burden to the family or individual will reduce immunization coverage levels and put everyone at risk for these diseases. With recent outbreaks in hepatitis A and mumps in Hawaii, many of us have witnessed firsthand the harmful effects on the health and economy of Hawaii when the community is not appropriately vaccinated.

Furthermore, these bills also do not take into consideration the important points below:

- The federal Vaccine Information Statement (VIS) requirement already ensures relevant information regarding vaccinations is provided to individuals and parents/guardians prior to vaccination. Providing a VIS for each vaccine administered is standard and accepted procedure in all vaccine-administration settings. For example, a VIS for a specific vaccine administered can be read at this link: [DTaP VIS](#).
- Package inserts are not written in a manner that can be easily understood by a layperson. It is grossly impractical in a medical office or pharmacy setting to provide package inserts to patients. Many inserts can be between 25 and 36 pages of technical language. They are meant to be read by medical professionals.
- The bill would add an additional burden in terms of time, costs, and capacity for our healthcare providers, especially pediatricians.
- “Informed consent” is under the scope of the Hawaii Medical Board per [HRS 671-3](#) and applies to a “proposed medical or surgical treatment or a diagnostic or therapeutic procedure” – none of which accurately describe immunizations.

The Hawaii Immunization Coalition (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 of Hawaii's families are appropriately vaccinated against vaccine-preventable diseases

[www.immunizehawaii.org](http://www.immunizehawaii.org) Tax ID #20-2164266

Hawaii's families are appropriately vaccinated against vaccine-preventable diseases. Focus: Immunizations across the lifespan. The coalition has been active in Hawaii since 1979 and has more than four hundred immunization supporters.

**For these reasons, we respectfully request that you do not support or pass HB2622. It is a detriment and danger to the health and well-being of our families and communities in Hawaii.**

Thank you for your consideration.

**HB-2622**

Submitted on: 2/3/2018 9:40:45 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Debra Koonohiokala Norenberg		Support	No

Comments:

**HB-2622**

Submitted on: 2/3/2018 10:18:21 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Elisa Chong	Straub & Tripler	Oppose	No

Comments:

I am a Concerned Resident of Hawaii and I **STRONGLY OPPOSE THIS BILL**. I work at Tripler ED and Straub and have seen the COSTLY, PAINFUL (Blood work, catheterizations, Blood Cultures, Etc) evaluations we have had to do on UNIMMUNIZED Children. We have a Mumps epidemic here in Hawaii, Measles epidemic nationwide, and now we are in the midst of an Influenza Epidemic and the legislature wants to add more work which will cause delays in vaccinations. We already have difficulty getting people vaccinated and now legislature wants to add a further burden to all Health Care Providers.

This bill adds costly, burdensome, and unnecessary hurdles against making certain that all persons are vaccinated against dangerous vaccine-preventable diseases.

Vaccines are life-saving measures and any formidable steps that add burden to the family or individual will reduce immunization coverage levels and put everyone at risk for these diseases. With recent outbreaks in hepatitis A, mumps, and flu in Hawaii, many of us have witnessed firsthand the harmful effects on the health and economy of Hawaii when the community is not appropriately vaccinated.

Furthermore, these bills also do not take into consideration the important points below:

- The federal Vaccine Information Statement (VIS) requirement already ensures relevant information regarding vaccinations is provided to individuals and parents/guardians prior to vaccination. Providing a VIS for each vaccine administered is standard and accepted procedure in all vaccine-administration settings. All VIS are published by the CDC, and more information can be found [here](#).
- Package inserts are not written in a manner that can be easily understood by a layperson. It is grossly impractical in a medical office or pharmacy setting to provide package inserts to patients. Many inserts can be between 25 and 36 pages of technical language. They are meant to be read by medical professionals.
- This would add an additional burden in terms of time, costs, and capacity for our healthcare providers, especially pediatricians.

- “Informed consent” is under the scope of the Hawaii Medical Board per [HRS 671-3](#) and applies to a “proposed medical or surgical treatment or a diagnostic or therapeutic procedure” – none of which accurately describe immunizations.

For these reasons, I ask that **you oppose this bill**. It is a detriment and danger to the health and well-being of our families and communities in Hawaii.

Thank you for your consideration.

**HB-2622**

Submitted on: 2/3/2018 10:08:05 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Mary Smart		Support	No

Comments:

This bill makes sense. There is no rational reason to oppose it. It is essential that there is full disclosure of all chemicals/biological materials that are proposed for injection/ingestion into one's body. Individual and parental consent in the case of minors is a must for any vaccine. Everyone has the right to protect their body from foreign substances being introduced to their systems.

February 3, 2018

**Committee on Health and Human Services**

Rep. John Mizuno, Chair

Rep. Bertrand Kobayashi, Vice Chair

**Committee Members:**

Re. Della Au Belatte

Rep. Lei R. Learnmont

Rep. Andria Tupola

Regarding: HB 2622 Relating to Informed Consent for Vaccinations

Please note that I do support this bill.

There is much concern as to some the ingredients contained in many of the vaccines and potential side effects.

There are many people who are not aware that some vaccines contain ingredients like Aluminum, Formaldehyde, Mercury, Human and Animal Cells, Monosodium Glutamate, just to name a few.

These are then injected into ourselves and our children, without knowledge of the possible side effects.

This bill requiring health care providers to obtain written informed consent prior to administering the vaccination is a positive move.

Again, I support the passing of this bill.

Respectfully,  
Rita Kama-Kimura  
Mililani, HI

**HB-2622**

Submitted on: 2/3/2018 8:16:42 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

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

Comments:

As a concerned pediatrician and parent of young children, I **strongly oppose this bill**. This bill adds costly, burdensome, and unnecessary hurdles against making certain that all persons are vaccinated against dangerous vaccine-preventable diseases.

With recent outbreaks of vaccine-preventable diseases of Hepatitis A, mumps, and influenza in Hawaii, we have witnessed firsthand the harmful effects on the health and economy of Hawaii when the community is not appropriately vaccinated. Many of my patients are also too young to be immunized against many of these vaccine-preventable illnesses, and rely on immunity from the community. In addition, as a tourist destination, with visitors traveling from destinations where these vaccine-preventable diseases are still commonplace, it also behooves use to improve our community immunization rates to prevent these vaccine-preventable diseases from establishing here as well.

As a pediatrician, caring for young children, this bill could create barriers toward building better, informed health care for our children. It would introduce more confusion about vaccines that have been approved and endorsed by multiple medical experts in organizations such as the AAP and ACIP. At a time when physicians are already burdened with paperwork and we have attrition of primary care providers, it would also add additional burdens in terms of time, costs, and capacity.

As a parent, I try to foster healthy habits in my children, one of which is receiving immunizations against vaccine-preventable illnesses. I do this not only to protect them but also for others in their schools and community who may not be able to receive the vaccines for life-threatening medical conditions or age.

For these reasons, I ask that you **oppose this bill**. It is a detriment and a danger to the health and well-being of our families and communities in Hawaii.

Thank you.



**HB-2622**

Submitted on: 2/3/2018 10:25:02 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
susan higa		Support	No

Comments:

I STRONGLY support HB 2622.

Vaccines mediate an inflammatory response because it is introducing foreign substances into the body and causing it to react.

Vaccines trials are only done on healthy individuals. For those with underlying but undetected health issues, vaccine effects become questionable in the least and lethal at the most. Vaccines also contain a long list of substances that are toxic to the body but an infant's detoxification pathways are still developing, therefore unable to properly flush them out.

Unknowing to me or my doctor, my infant son had inherited my systemic yeast infection. The vaccines added much to the already burdened immune system, increasing inflammation and resulting in encephalitis (inflammation of brain). Had I been informed about ingredients in vaccines, the opportunity to understand potential damage, I might have reconsidered getting those vaccines, or in the least, refused some of them. And from that slight turn of events, my son might have become an active and productive member of society today. But that is not so. Today he is a twenty year old with a mind of a five year old. The most concerning thought going forth is how to continue ensuring his safety when I become too old to take care of him.

Every parent must be made aware of the cocktail of ingredients in vaccines and its potential for adverse effects. They must be given the knowledge and time to consider the potential consequences vaccines can bring.

Both my children were C-section deliveries. With the second child, I made sure to breastfeed. Because of the tremendous hardship experienced by my first son, I avoided vaccines. Instead he went through the childhood diseases. Today, his health is more robust, rarely gets sick and when he does, recovers quickly.

It has been my experience working with my first son that overall health including cognitive functions is inextricably tied with the health of the gut, and what we eat and drink. Our current model of agriculture however, utilizing petrochemical fertilizers, pesticides and even pre harvest desiccants is both creating nutritional deprivation and damaging soil and waterways. Glyphosate, the key ingredient of Roundup (most

commonly used pesticide), has been categorized as a carcinogen, cancer causing, by the World Health Organization, but little is done to bring much needed awareness. It is an ingredient found in vaccines. If the status quo is allowed to continue, steep decline in health is only to be expected. The World Health Organization has already stated that this generation of children will not outlive their parents.

I urge you to please support HB2622. Informed consent should be the norm rather than the exception.

I am in **STRONG SUPPORT** of HB2622.

Thank you for your attention.

Susan Higa

Kapolei

Re: HB2622 Relating to Informed Consent for Vaccinations

From: Lorene Ng, MD  
Pediatrician

Date of Hearing: 2/06/18 8:30am in House Conference room 329

As a mother and as a pediatrician caring for Hawaii's keiki, I strongly oppose bill HB2622 (Relating to Informed Consent for Vaccinations). This bill will create more barriers to providing life-saving vaccines to children. It will continue to place the most vulnerable members of our community at risk and it will increase the number of outbreaks of preventable diseases in our State.

Many pediatricians in Hawaii, including myself, provide informed consent to families with each opportunity to vaccinate our patients at every office visit. In addition, parents and guardians are given a Federal Vaccine Information Statement (VIS) which is produced by the Centers for Disease Control and Prevention (CDC). VISs explain both the benefits and risks of a vaccine to a recipient, and in the case of children, to their parents or legal representatives. VISs are also available in more than 30 languages and are updated when new information becomes available.

Vaccine package inserts are NOT written in a manner that is easily understood by all. Many inserts can be between 25 to 36 pages of technical language that may be misunderstood. They are not available in multiple languages and they are impractical in a medical office or pharmacy setting. Requiring medical providers to provide and review information from vaccine package inserts would add additional burdens of time, cost, and capacity. It creates another obstacle to keeping the children of Hawaii healthy and safe from preventable illnesses.

For these reasons, I ask that you oppose bill HB2622. It is detrimental to the well-being of our local communities. I ask that you protect the health of our keiki and their families.

Lorene Ng, MD

**HB-2622**

Submitted on: 2/3/2018 10:31:53 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
natasha sky		Support	No

Comments:

Dear Health committee members,

I am writing to ask you to **support** this bill. As a concerned resident of Hawaii I believe all vaccine consumers deserve accurate safety information from actual vaccine inserts, so that they may make informed choices for themselves and their children, and so that they also know what side effect symptoms to be aware of. This way proper medical care for any side effects/injuries can be given, and it will also improve the vaccine injury reporting system VAERS.

Thankyou for upholding the Nuremburg Code of voluntary informed consent.

Sincerely, Natasha Sky

**HB-2622**

Submitted on: 2/3/2018 10:55:15 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
martina dodson		Support	No

Comments:

Informed consent is a basic human right. 1986 the same year Congress gave vaccine manufacturers immunity so parents can not sue, the vaccine schedule tripped. Coincidence? I grew up with 4 doses vaccine. Now it is 74 doses before the age of 18. Where is the justification for that?

I almost died from a vaccine. My mom was not told the dangers. My parents watched me struggle to survive. Also my friends perfectly healthy 4 year old twin boys were permanently brain damaged by 11 doses of vaccines, she was never told that could happen. There has never been one study on the cumulative effects on the children's vaccine schedule nor on multidose vaccine appointments. Not one!

Where is the Informed consent to that fact?

Are parents told that gardasil has never once been proven to prevent cervical cancer in one person? Are parents told that there are criminal charges in Colombia, Japan, Spain and Ireland against the maker for injuring and killing children all over the world. Are parents told that in the U.S alone Gardasil has been reported to VAERS with over 300 deaths and over 50.000 adverse events, and VAERS is very under reported.

Would you allow lead to be injected into your child?

Of course not, you know that would cause brain damage, not to mention other problems. However, millions of mothers across America are allowing doctors to inject mercury and aluminum into their children, both of which are severely neurotoxic (mercury many more times so than lead...and yes, mercury is still in vaccines given to infants and children, in addition to those given to pregnant women). To make matters worse, mercury and aluminum are synergistically neurotoxic, meaning that when they are given together, as is often done during vaccination, their individual toxicity is made far worse by the presence of the other, many times worse. Interestingly, we are seeing record numbers of children in our country with brain damage, which manifests as: speech and language disorders, including complete lack of speech; attention, learning, and behavior disorders; social skills deficits; seizure disorders; OCD; extreme anxiety disorders; sensory processing disorders; tics; and of course, Autism. Coincidence?

Would you allow something that could cause cancer, say asbestos, to be injected into your child? Of course not, you know that cancer is often akin to a death sentence, if not the first go-round, then the times that often follow. However, millions of mothers across

America are allowing doctors to inject formaldehyde, phenol, and MSG into their children, all of which are known carcinogens. To boot, recent tests have revealed the presence of glyphosate, one of the active and toxic ingredients in Round Up and other herbicides, in a number of vaccines, including very high levels of glyphosate in the MMR vaccine. Glyphosate is a highly-suspected carcinogen, shown to cause massive tumors in rats fed food laced with it. It is synergistically toxic when paired with aluminum, an ingredient found in the majority of today's vaccines. It's no wonder pharmaceutical companies don't test to see whether or not their vaccine products cause cancer, they already know the answer. Instead, they simply write "not tested for carcinogenicity" on their package inserts, and our unethical government regulators let them get away with that. Interestingly, we are seeing record numbers of children in our country with leukemia, lymphoma, and other cancers. Coincidence?

Would you allow something that could cause life-threatening auto-immune diseases, something like aluminum, to be injected into your child? Of course not. You know that auto-immune diseases are progressive and lead to premature death. However, millions of mothers across America are allowing doctors to inject not only aluminum, but also mercury, polysorbate 80, retroviruses from pigs, mice, monkeys, and other animals, DNA fragments from other humans, specifically from aborted fetuses, and from various animals, and laboratory-created live and killed viruses and retroviruses from both humans and animals, all of which are known to cause auto-immune diseases.

Interestingly, we are seeing record numbers of children in our country with Type 1 diabetes, asthma, Crohn's disease, juvenile rheumatoid arthritis, demyelination, ulcerative colitis, and many more auto-immune diseases. Coincidence?

Would you allow something that could cause life-altering and life-threatening asthma and allergies to be injected into your child? Of course not. You know that both asthma and allergies severely restrict a child's life in many ways and that both can result in death. However, millions of mothers across America are allowing doctors to inject food proteins (which the blood is incapable of breaking down into amino acids, resulting in inflammation), antibiotics such as neomycin, polymyxin B, gentamicin, and streptomycin, and toxic chemicals at the same time as adjuvants (e.g. aluminum), which are designed to artificially overstimulate the immune system, resulting in the chronic and sometimes fatal conditions of asthma and allergies. Additionally, new studies regarding what is called "molecular mimicry" continue to emerge, demonstrating that when protein fragments in vaccine antigens match protein fragments of proteins in the body, it sets the stage for allergies and other autoimmune problems. Interestingly, we are seeing record numbers of children in our country with asthma, life-threatening peanut allergies, numerous types of food allergies and food intolerances, and numerous types of environmental allergies. Coincidence?

Would you allow something that could cause infertility, such as nonstick chemicals and solvents, to be injected into your child? Of course not. You know that you would never want to destroy your child's future reproductive capabilities. However, millions of mothers across America are allowing doctors to inject their children with polysorbate 80, known to adversely affect fertility. And who knows what propylene glycol (antifreeze), Triton X100 (detergent), aluminum, mercury, foreign DNA fragments, and the myriad other vaccine ingredients do to one's future reproductive ability, especially when injected in conjunction with polysorbate 80. We know that the HPV vaccine has caused

Primary Ovarian Failure (which is premature menopause) and amenorrhea (the prolonged cessation of a female's menstrual cycle) in girls and young women, rendering them infertile, and possibly sterile for life. We know that tetanus vaccines given to girls and women in Kenya were laced with Human Chorionic Gonadotropin (HCG), rendering them sterile. How? Administering HCG via vaccination stimulates the production of antibodies to HCG, and these antibodies then cause the woman's body to reject embryos, effectively sterilizing her. Such an HCG-laced tetanus vaccine is in actuality a contraception vaccine. Do you think any of these Kenyan women was told that prior to vaccination? To add to the evilness and deception, the Kenyan women were given a 5-dose tetanus program spread over a number of years, versus the 2-3 dose norm. Clearly, those vaccines were being used for induced sterility and birth control without the girls' and women's knowledge or consent. Does any parent or vaccine recipient really know what is in the vaccines being injected into their child or themselves? It's no wonder pharmaceutical companies don't test to see whether or not their vaccine products cause infertility, they already know the answer. Instead, they simply write "not tested for impairment of fertility" on their package inserts, and our unethical government regulators let them get away with that. Interestingly, we are seeing record numbers of couples struggling with infertility issues. Coincidence?

Would you allow something that could kill your baby to be injected into your otherwise healthy child? Of course not! Mothers would lay down their lives for their children, they don't purposefully put them in harm's way. However, millions of mothers across America are allowing doctors to inject their children with more and more vaccines, not knowing that each and every one carries the risk of death, even more so when combined, as they most often are. Interestingly, we are seeing record numbers of babies who are dying before their 1st birthday in the U.S., including many of "SIDS" and "SBS" (the labels that unethical doctors and unethical medical examiners use for vaccine-induced deaths instead of calling them what they are...i.e. vaccine-induced deaths). Coincidence?

Here is a link to a letter written to the HHS with proof that vaccines are dangerous and should at least be given informed consent if not recalled. 5 million people represent the letter that includes doctors, scientists, nurses and parents of injured and dead children from vaccines.

<http://icandecide.com/white-papers/ICAN-HHS-Notice.pdf>

Here is a web site with thousands of medical studies peer review of dangers of vaccines

[www.medscienceresearch.com](http://www.medscienceresearch.com)

This bill will not only help patients to do a informed decision, it will also help medical staff to be more informed of the dangers and adverse reactions to look for from vaccines.

Sincerely,

Martina D.



Date: February 3, 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 HB 2622 relating to Informed Consent for Vaccinations

Scheduled Hearing: Tuesday, February 6, 2018 at 8:30 a.m., Hawaii State Capitol Room 329

My name is Cheryl Toyofuku and I am a mother, grandmother, registered nurse and health advocate. **Please SUPPORT HB 2622** that would *“require health care providers to obtain written informed consent before administering a vaccination and to increase awareness about the possible adverse effects of vaccinations”*.

Parents and many others depend on their health care providers to provide them with the information about the benefits and risks of vaccines due to their busy schedules of caring for children and employment responsibilities. An increasing amount of people have questions about the vaccine ingredients, the safety and effectiveness of each vaccine and the possibilities of vaccine injury, but they have not had the time to research and educate themselves.

The one or two Vaccine Information Statement sheets usually given to parents appear insufficient to make a well-informed decision about an invasive medical intervention. Vaccine ingredients listed on the vaccine product insert should be discussed and if combination vaccines are prescribed, the product inserts for each vaccine should be provided and discussed. Since the vaccination schedule has increased to approximately 72 doses or more by age 18, the purposes for this increase as well as concerns for combination vaccines or boosters can be discussed in order to provide more information for health care decisions. Having read the product inserts, I have been able to make a wiser health decision for myself and family in regards to vaccinations. Below are just 3 examples of vaccines that I have researched: 1) Influenza vaccine, 2) MMR (Mumps, Measles and Rubella) vaccine and 3) Hepatitis A vaccine. Also, below is the CDC's Vaccine Expedient and Media Summary that lists all components, other than antigens, shown in the manufacturers' package insert (PI) for each vaccine.

As our lawmakers, please do some diligent research before promoting, recommending and/or mandating vaccines as a solution for Hawaii's health care. Options to vaccines would include building up our natural immunity and encouraging healthy lifestyles to assist in preventing diseases more than injecting toxic substances into our bodies. **Increased awareness, education and informed consents should be foundational and paramount in health care decisions.** Please review the 3 vaccine information and helpful links below.

\* \* \* \* \*

### **INFLUENZA VACCINE aka FLU SHOT**

There many pharmacy signs, media, health care promotion to get the flu shot for the current flu “outbreak”. My ohana, many friends and I have done our research and it appears that the science is settled: the flu shot is not effective and can actually increase health problems.

On this website are **many links to well-documented studies** on the flu shot / influenza vaccine: <https://www.learntherisk.org/flu-shot/>

Scroll down further on this website to see news reports *“Is the Flu Vaccine Safe?”*, *“Deceptive Marketing of the Flu Shot”*, *“Thousands of Nurses Rise Up in Defiance of Big Pharma’s Flu Shot Threat”*, *“The Ineffectiveness of the Flu Shot”*, *“The Flu Shot Exposed”*, etc.....

Here is one interesting cohort study of 263 children who were evaluated at the Mayo Clinic:  
**Children Who Get Flu Vaccine Have Three Times Risk Of Hospitalization For Flu, Study Suggests**

Article: <https://www.sciencedaily.com/releases/2009/05/090519172045.htm>

Study: **Increased Risk of Non-influenza Respiratory Virus Infections Associated with Receipt of Inactivated Influenza Vaccine:**

<https://academic.oup.com/cid/article/54/12/1778/455098>

**Influenza Vaccine Effectiveness a Dismal 10 Percent:**

<https://www.thevaccinereaction.org/2018/01/influenza-vaccine-effectiveness-a-dismal-10-percent/>

From the **Product Insert for the Influenza vaccine:**

<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM220624.pdf>

page 3 – **Warning and precautions:** Guillain Barre Syndrome, syncope (fainting), allergic reactions  
pages 11-12 – Post Marketing experience , **Adverse reactions** (too many to list here), click on link to read.

page 13 – **Risk Summary:** *“There are **insufficient data** on FLUARIX QUADRIVALENT in pregnant women to inform vaccine-associated risks”.*

page 14 – Description of **ingredients:** influenza viruses propagated in embryonated chicken eggs, formaldehyde, octoxynol-10 (TRITON X-100), α- tocopheryl hydrogen succinate, polysorbate 80, hydrocortisone, gentamicin sulfate, ovalbumin

\*\*\*\*\*

## **MMR (MUMPS, MEASLES & RUBELLA) VACCINE**

There appears to be many questions over the Mumps and the **MMR (Mumps, Measles & Rubella) vaccine** due to the “outbreak” in our islands. Lots of links below to begin research.

**Mumps** was a common childhood illness in the older generation, many infected by age 15. The virus is spread by direct contact with respiratory droplets, and symptoms include headache, muscle aches, tiredness, loss of appetite, with salivary gland swelling, usually the parotid, as the most common physical manifestation. Males, past puberty, can experience swelling of the testes, and rarely sterility. There is no specific treatment for mumps except alleviation of symptoms with rest, hydration, pain relievers if necessary and cool compresses. An infection of this innocuous viral disease confers lifetime immunity.

More information on Mumps and the MMR vaccine can be found at the National Vaccine Information Center website:

<http://www.nvic.org/vaccines-and-diseases/Mumps.aspx>

From the **Product Insert for the MMR vaccine:**

[https://www.merck.com/product/usa/pi\\_circulars/m/mmr\\_ii/mmr\\_ii\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf)

page 1 - lists the **description of the MMR vaccine with the ingredients:** propagated in chick embryo cell culture, Wistar RA 27/3 strain of live attenuated rubella virus propagated in **WI-38** human diploid lung fibroblasts, growth medium for measles and mumps is Medium 199 (a buffered salt solution containing vitamins and amino acids and supplemented with fetal bovine serum) containing SPGA (sucrose, phosphate, glutamate, and recombinant human albumin) as stabilizer and

neomycin. (WI-38 is a cell line produced from the lung tissue of a 3 months gestation female baby, electively aborted in Sweden.)

pages 6 to 8 – lists the many **adverse reactions** to the vaccines including disorders of the cardiovascular, digestive, respiratory, immune, endocrine, musculo-skeletal, uro-genital and nervous systems.

**There are questions about the safety and effectiveness of the MMR vaccine, yet many children have received 2 doses of the MMR vaccine and now a 3rd dose of the MMR vaccine is being considered. ????????** Please consider the articles below and continue your research before deciding on the vaccine.

***Mumps Being Spread By and Among Vaccinated People*** (May 10, 2016):  
<https://articles.mercola.com/sites/articles/archive/2016/05/10/mumps-vaccine.aspx>

***Vaccine Failure is Well Established: Malignant Mumps in MMR Vaccinated Children***  
<https://www.sott.net/article/289614-Vaccine-failure-is-well-established-Malignant-mumps-in-MMR-vaccinated-children>

***Mumps Vaccine Proves Ineffective*** (June 20, 2014):  
<https://www.sott.net/article/280301-Mumps-vaccine-proves-ineffective>

***Arkansas Hit by Mumps Outbreak Only Among the Vaccinated*** (Sept 13, 2016):  
<https://www.sott.net/article/328246-Arkansas-hit-by-mumps-outbreak-only-among-the-vaccinated>

***Former Merck Scientists Sue Merck Alleging MMR Vaccine Efficacy Fraud:***  
<http://ahrp.org/former-merck-scientists-sue-merck-alleging-mmr-vaccine-efficacy-fraud/>

The documentary “**VAXXED: from Cover-Up to Catastrophe**” shared about the investigation into how the CDC (Centers for Disease Control and Prevention), destroyed data on their 2004 study that showed a link between the MMR vaccine and autism. It explores an alarming deception that may have contributed to the skyrocketing increase of autism, potentially the most catastrophic epidemic of our lifetime: <https://www.youtube.com/watch?v=6y09WNx4njY&feature=youtu.be&ct=t%28%29>

***Vaxxed Movie, MMR Vaccine Autism Risk and Vaccination Danger Awareness:***  
(There is also a link to watch the movie VAXXED on this page)  
<https://www.youtube.com/watch?v=m2V6p6riQ8o>

***The Brady Bunch Tackles Measles*** (My Incredible Opinion):  
[https://www.youtube.com/watch?v=47RUI5xqs\\_s](https://www.youtube.com/watch?v=47RUI5xqs_s)

\*\*\*\*\*

## HEPATITIS A VACCINE

Here’s some information on **Hepatitis A and the Hepatitis A Vaccine**, since there appears to be concern over the recent “outbreak” in Hawaii. Over the years, concerned parent/grandparents have followed the “epidemics” or “outbreaks” that were declared internationally, nationally or locally, such as the swine flu, bird flu, ebola, dengue, zika, etc. Vaccines are quickly recommended as the solution to prevent getting these diseases. Many disagree.

Instead of vaccinations, well-informed individuals focus on building and maintaining strong immune systems with good nutrition and supplementation, instead of injecting more toxins into their bodies. Possible viral infection may still occur, but most of the research says that there is no treatment for the Hepatitis A virus and 99 percent of persons who get infected recover without treatment. Therapy, if any, focuses on rehydration, immune boosting nutrients and supplements to replace what is lost from vomiting and diarrhea and to aid in recovery.

More info about the virus and the vaccine can be found at the National Vaccine Information Center:

### **Hepatitis A and Hepatitis A Vaccine:**

<http://www.nvic.org/vaccines-and-diseases/Hepatitis-A.aspx>

On the above link, read the entire prescribing information (product insert) for the 3 different vaccines that are available for Hepatitis A:

**HAVRIX** (Glaxo Smith Kline), **TWINRIX** (Glaxo Smith Kline – Hep A & Hep B combined) and **VAQTA** (Merck & Co.)

From the **Product Insert for HAVRIX vaccine:**

page 7 - lists some of the **adverse events to the vaccine**, including disorders of the blood & lymphatic system, nervous system, respiratory system, hepatobiliary system, including hepatitis and jaundice.

page 9 – lists the **ingredients in the vaccine**, including the HM175 virus, **MRC-5 (residual fetal human cellular diploid proteins taken from the lung tissue of an aborted fetus)**, formalin, sodium borate, amino acid supplement, polysorbate 20, neomycin sulfate.

page 13 – states “The **duration of immunity** following a complete schedule of immunization with HAVRIX **has not been established.**”

So, the inactivated hepatitis virus (strain HM175) is propagated in the MRC-5 human diploid cells. More are deciding to prevent hepatitis infection by building natural immunity instead of being injected with this vaccine..

**“Where there is risk, there must be a choice”.** Increased awareness and informed consent must be required for vaccinations.

### **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?**

[https://www.learntherisk.org/wp-content/uploads/2016/02/LTR\\_VaccineIngredients\\_White1.pdf](https://www.learntherisk.org/wp-content/uploads/2016/02/LTR_VaccineIngredients_White1.pdf)

### **Vaccine Doses for U.S. Children**

[https://www.learntherisk.org/wp-content/uploads/2016/03/Doses\\_v2.pdf](https://www.learntherisk.org/wp-content/uploads/2016/03/Doses_v2.pdf)

**HB-2622**

Submitted on: 2/3/2018 11:57:15 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Sarah Silva		Support	No

Comments:

Please support this. I believe that all parents and caregivers should be fully informed whenever anything is injected into someones body.

Date: February 4, 2018

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

Re: **OPPOSITION for HB2622**, relating to informed consent for vaccinations  
Hrg: February 6, 2018 at 8:30am at Conference Room 329

Aloha House Committee on Health and Human Resources,

As a concerned resident of Hawai'i, I **strongly oppose HB2622**. This bill adds costly, burdensome, and unnecessary hurdles to making certain that all persons are vaccinated against dangerous vaccine-preventable diseases.

Vaccines save lives. Adding barriers will reduce immunization coverage levels putting everyone at risk, especially the most vulnerable, our young keiki and kupuna. With recent outbreaks of hepatitis A, mumps, and flu in Hawai'i, many of us have witnessed firsthand the harmful effects on the health and economy of our state when the community is not appropriately vaccinated.

Federal law requires that a Vaccine Information Statement (VIS) be provided to all individuals and parents/guardians before each vaccine is administered. They inform recipients (and their parents/guardians) of the benefits and risks of the vaccine they are about to receive. VISs are written for the general public, regularly updated and published by the Centers for Disease Control and Prevention (CDC). More information on VISs can be found [here](#).

On the other hand, vaccine package inserts are a poor source of information for the lay public. They are written in technical language for medical professionals and often are more than 20 pages long.

Without adding any individual or community benefits, HB2622 would add additional burdens in terms of time, costs, and capacity for our healthcare providers, especially pediatricians.

"Informed consent" is defined under the scope of the Hawai'i Medical Board per [HRS 671-3](#) and applies to a "proposed medical or surgical treatment or a diagnostic or therapeutic procedure" – none of which accurately describe immunizations.

For all of these reasons, I respectfully ask that **you oppose HB2622**. It is a detriment and danger to the health and well-being of our families and communities in Hawai'i.

Mahalo nui for your consideration,

Forrest Batz, PharmD  
Keaau, HI

**HB-2622**

Submitted on: 2/4/2018 8:33:54 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
gretchen		Support	No

Comments:

Please pass this bill. Vaccinations are unavoidably unsafe and people should have easy access to opt out of them. Members of my family have been harmed by them. Please support medical freedoms.

Thank you.



**HB-2622**

Submitted on: 2/4/2018 10:24:11 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Elyse Warren		Support	No

Comments:

Vaccines should be treated like every other medication and as such we should receive the same information prior to being vaccinated. You cannot make an informed decision without all the risk and benefits. Please vote to pass this bill.

**HB-2622**

Submitted on: 2/4/2018 1:51:16 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Lauren Adler		Support	No

Comments:

I write this testimony as a concerned registered nurse who is pursuing education and licensure as a nurse practitioner. I have been an RN since 2010, and over the past few years through my own diligent research, have noticed a tremendous lack of informed consent in the ever controversial world of immunization. I testify that both in my undergraduate and now in my graduate training, RNs and APRNs are educated very little on vaccination. We are merely informed of the schedule of when to give vaccines and how to administer them, with very little mention of very serious risks. In my schooling and professional training, no information has ever been provided about the neurotoxic ingredients in vaccinations, or any ingredients in vaccines for that matter. My advanced pharmaceutical textbook this past year blatantly stated that it is safe to give six vaccinations at once (it failed to mention which six), without citing any study. I have yet to find a study that supports this erroneous claim. In my clinical experience as a maternity nurse, our responsibility is to give parents of newborn babies a very heavily diluted vaccine information sheet (VIS) from the CDC, which downplays the risk for the hepatitis B vaccine. This document does not at all reflect the actual risks posed on the vaccine insert from the manufacturer. In this world of such heated debate, I have heard the argument that parents/patients should not be given the vaccine package insert because it is "too medical". This argument, that vaccine inserts can not be interpreted by lay people, is highly insulting to the intelligence of the general public. In fact, I would argue that the most optimal time to give parents/patients this information is the health care setting by a trained professional so they can voice their questions or concerns. It is the right of the public to have this information shared with them. It is only with this information that the patient is being given true informed consent. Withholding this information and leaving the responsibility in the hands the of health care professionals is essentially cherry picking. I can attest that in my experience, the vast majority of health care providers relaying this cherry picked information are not well versed nor educated on the actual risks from vaccinations (many of my colleagues don't even know the vaccine insert exists). This is a travesty and an infringement on the rights of the public. It is the right of our people to have access to true informed consent, and I urge you to please support HB2622. I encourage each of you, as I encourage each of patients in my care, to be open minded and to question the "facts". The truth is hidden in plain sight. If you don't believe me, try and get your hands on a vaccine package insert. I kindly thank you for your time and review of my testimony.



**HB-2622**

Submitted on: 2/4/2018 4:04:05 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
samantha pang		Support	Yes

Comments:

I am in support of this bill. I feel it is imperative that informed consent and everything outlined in this bill is given to parents so that they may make an educated and informed decision on whether or not to vaccinate their kids.

**HB-2622**

Submitted on: 2/4/2018 7:25:37 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Jamie Shimabukuro		Support	No

Comments:

I strongly support this bill regarding your former consent

**HB-2622**

Submitted on: 2/4/2018 7:31:29 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Lorraine Winfield		Oppose	No

Comments:

No to this bill!

**HB-2622**

Submitted on: 2/4/2018 7:34:18 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Kristen Coles		Support	No

Comments:

I support HB2622 to help prevent vaccine injury for children in the state of Hawaii

**HB-2622**

Submitted on: 2/4/2018 8:30:35 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Jessica McCormick		Support	No

Comments:

Dear Representatives,

Please SUPPORT HB2622 that provides TRUE INFORMED CONSENT for vaccines which are the only drugs that do not provide patients with all the information they need to make an informed decision about their health.



**HB-2622**

Submitted on: 2/4/2018 8:56:09 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Stacey Jimenez		Support	No

Comments:

Please pass this common sense legislation. People need to be informed about all possible risks and benefits before making any healthcare decision for themselves or their family. Requirements should be created to provide a consistency of care for all the people of Hawaii.

**HB-2622**

Submitted on: 2/4/2018 9:32:11 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
LISA WILFORD		Support	No

Comments:

I write in favor of Passing HB 2622, thank you!

**HB-2622**

Submitted on: 2/4/2018 9:43:53 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Candice Roberts		Support	No

Comments:

**HB-2622**

Submitted on: 2/4/2018 9:45:01 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Jennifer Noelani Ahia		Support	No

Comments:

Aloha,

My name is Jennifer Noelani Ahia and I support HB2622. For far to long the pharmaceutical corporations have gotten away with convincing people that vaccines are always safe. While the safety varies from person to person and product to product, the public has a RIGHT to know what their risks are and to make an informed decision about whether to receive each vaccination.

Please support HB2622

Mahalo,

Jennifer Noelani Ahia

Wailuku, Maui

**HB-2622**

Submitted on: 2/4/2018 9:51:25 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Darrell Gella		Support	No

Comments:

Please support this bill. It is important that every individual considering a vaccination first be adequately screened and informed. This is not happening currently.

**HB-2622**

Submitted on: 2/4/2018 10:03:12 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Aubrey Aea		Support	No

Comments:

Aloha,

I am in support of this bill. Informed consent for vaccinations should be freely given to all patients so that they may be able to make the best decision for themselves and their families. Patients should not be subjected to undue pressure or influence by medical staff. As it stands now, our pediatrician hands out a simple copy for each vaccination that is in no way completely informative. It does not include adverse effects or ingredients. Every patient should be shown a vaccine insert and have a chance to read and inform themselves before making a decision. A basic handout is not enough information and patients blindly trust their physicians. Let the patients be fully informed.

Thank you,

Aubrey Aea

**HB-2622**

Submitted on: 2/4/2018 10:14:36 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Lori Glorioso		Support	No

Comments:

Please support HB2622 relating to informed consent for vaccinations. I am a registered nurse, a parent, and a caregiver of a loved one permanently disabled from vaccines.

A patient/parent should be made aware of all potential risks associated with vaccinations. Only then can one make a truly informed choice. Parkinson's Disease is an incurable, progressive, debilitating disease that attacks the brain. Understanding that some vaccines attack the central nervous system would be a significant factor when considering vaccination.

Never take for granted such pleasures as walking, talking, smiling, writing, holding an eating utensil, or playing with your young children.

**HB-2622**

Submitted on: 2/4/2018 11:28:58 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Erin Kumai		Support	No

Comments:

I am in support of this bill because I think it is important that parents/guardians are properly informed and educated prior to deciding to vaccinate their child



**HB-2622**

Submitted on: 2/4/2018 11:40:54 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Alexandra Kisitu		Support	No

Comments:



Student Immunization Initiative  
Registered Independent Organization  
siihi@hawaii.edu  
www.siihawaii.org

February 4, 2018

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

Re: HB2622 – Relating to Informed Consent for Vaccinations

Dear Chair Mizuno, Vice Chair Kobayashi, and Committee Members:

The Student Immunization Initiative (SII) is an organization led by graduate students at the University of Hawai'i at Mānoa, who have experience in fields like virology, bacteriology, and immunology. Our mission is to use science-based knowledge to promote educational outreach programs and events where we explain difficult health topics to the community in ways they can understand, always stressing the importance of disease prevention. We believe that everyone should have access to information, and we understand that the purpose of this bill is to obtain written consent for vaccinations and to increase awareness about the possible adverse effects. However, we ask the Committee to consider the following:

- All vaccine providers are already required by law to give the appropriate Vaccine Information Statement (VIS) to the patient, parent, or legal representative prior to every dose of specific vaccines. Every VIS includes the benefits and risks of a particular vaccine, as well as information about what to do in case of adverse effects. In fact, every VIS contains information about the Vaccine Adverse Event Reporting System and the National Vaccine Injury Compensation Program. Vaccine Information Statements are written in a way that the majority of the population can comprehend, and in addition to English, most VIS are available in more than 40 languages. Therefore, patients, parents or legal representatives are already receiving the necessary information.
- Vaccines have saved millions of lives, and have eliminated many diseases from certain regions of the world, but unfortunately, we live in times where false or distorted information about vaccines can be easily disseminated, especially through social media, where anyone can write a misleading statement that sounds like real information, which gets propagated by thousands of people who, out of fear, keep on spreading that message, thinking that they are helping others. This particular bill concerns us because we believe that by adding this extra barrier for access to vaccines, the state will be adding to the unfounded fear that the rare risk of severe adverse reactions to vaccines outweighs the benefits.

For these reasons, the Student Immunization Initiative **opposes** this bill.

Thank you so much for your time and consideration,

SII Officers

**HB-2622**

Submitted on: 2/5/2018 1:08:38 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
carla favata		Support	Yes

Comments:

As a concerned Certified Pediatric nurse of Hawaii, I **strongly support HB2622.**

Implementation of this bill would not be costly or burdensome, but is necessary in making certain that all persons are truly informed of the many potential adverse reactions that vaccinations can cause.

Completing a thorough individual and family health history then evaluating the risk versus benefit analysis for each person are life-saving measures that need to be in place.

Informing families of the ingredients and potential adverse reactions could absolutely save a person from a lifelong debilitating condition, or worse, death.

As a nurse on a busy pediatric medical surgical unit, I cared for many children that suffered adverse vaccine reactions. Most of the children were transferred to me from the emergency room, where they were brought in for seizures following vaccines. I consoled every parent as they cried. They blamed themselves as they helplessly watched their child either lying lifeless or convulsing.

I also cared for many children that were newly diagnosed with type 1 diabetes: an autoimmune disorder in which the body cannot produce insulin. Every single family goes through a grieving process when their child receives that diagnosis. Their while way of life is completely changed and that change is permanent. They will rely on insulin shots for the rest of their lives. I vividly remember consoling a mother of a young child that had just been diagnosed. She asked me if it could have been from the vaccines that her child recently received, but I was quick to defend there was no correlation. I was wrong. On select vaccine package inserts included from the manufacturer, DIABETES MELLITIS is listed as a potential adverse reaction. Additionally, reports were never filed with VAERS, contributing to the grossly under reporting of vaccine injuries.

The goal of the bill is to help:

1. Prevent vaccine injury
2. Create more awareness around the extent and severity of vaccine injury.

3. Increase better reporting of vaccine injury to VAERS due to better awareness on WHAT constitutes a vaccine injury.

Pro life persons would think twice about vaccines if they knew some of them contained aborted fetal cells. Vegans deserve to know that animal DNA is an ingredient in some vaccines. People with a family history of Alzheimer's would weigh the risk vs benefits of vaccines including aluminum. At this time, these truths are being withheld from consumers as they are not included on the VIS. Parents should have the right to know and understand what is being injected into their child. Some could have religious objections to certain vaccine materials but do not know to object to them since they aren't given the opportunity to know the ingredients. Parents are also not given pros and cons of vaccines and vaccine side effects and this needs to change!

There have been outbreaks in hepatitis A, mumps, and flu in Hawaii, and those opposing this bill say there will be harmful effects on the health and economy of Hawaii if the community is not appropriately vaccinated.

What you won't hear are these truths:

- The mumps portion of the MMR vaccine is woefully ineffective. In recent years, we have seen mumps outbreaks in 100% vaccinated populations like the University of Richmond, Loyola University, and Fordham University.
- In 2014 a Pennsylvania federal judge ruled in favor of whistleblowing scientists who accused Merck of lying about the efficacy of its mumps vaccine (which is currently only available in combo with MMR). Merck is the only manufacturer licensed by the FDA to sell the mumps vaccine in United States, and if it could not show that the vaccine was 95 percent effective, it risked losing its lucrative monopoly
- The MMR and the flu mist vaccine are live virus vaccines, and the virus can infect other people who come into contact with the person that was vaccinated. Shedding has been proven to occur up to 37 days after someone is vaccinated.

I'd like to take in consideration the important points below:

- The federal Vaccine Information Statement (VIS) that is published by the CDC and provided to individuals and parents/guardians prior to vaccination is lacking very important information, such as vaccine ingredients (some of which include chicken, monkey, cocker spaniel DNA and abort fetal cells).
- Package inserts contain important information that can absolutely be comprehended by a layperson. It is grossly negligent for medical offices or pharmacies to refuse package inserts to patients. The fact that inserts can be between 25 and 36 pages is exactly why people should be receiving true

informed consent before agreeing to a vaccine that could do more harm than good.

For these reasons, I ask that **you support this bill**. It is imperative to the health and well-being of our families and communities in Hawaii.

**HB-2622**

Submitted on: 2/5/2018 1:14:47 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Janet Edghill		Support	No

## Comments:

Vaccinations are not safe for many people and the true risks and contents of vaccines are not disclosed and are made to sound extremely rare ("1 in a million"--does that sound like an actual statistic?). The vaccine inserts list many serious effects which are not simply glossed over. Vaccination is a medical procedure and the risks and benefits must be clearly understood.

**HB-2622**

Submitted on: 2/5/2018 3:54:54 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
renee kawelo	none	Support	Yes

Comments:

It is unfortunate that we have to create laws to FORCE our medical professionals to advise us of the truth. We seek their expertise because we are suppose to trust in what they say as a matter of fact and that they are working for us to insure medically we are getting the correct treatment as a person not as a mass of people. But everything I have experienced has shown me that this isn't true and that it is just a front to sound good. Many Dr.'s have not studied vaccines but are so willingly to pressure us to the point of duress into vaccinating our children and our selves.

As a young mom at 17 I have always just done what I was told. I was pro vaccine until I noticed things that confused me and I had more questions then answers. We are deceived when a Dr. hands us the short form of reactions. I was never told of the severe reactions nor did I see what was in the vaccines. I understand that there is a chart and a numeric status of our population. LET ME TELL YOU MY CHILD IS NOT A NUMBER. Every child matters to their parent and to clump us all up and run a risk analysis on our kids is not ethical as one size fits all. Per Hawaii State Epidemiologist **Dr. Sarah Park** stated when talking on PBS about vaccines back in 2015 "I don't disagree with you that one size doesn't fit all." This tells me that we need to chose whats best for each individual. We treat vaccines as if it isn't potentially deadly when in fact people DO DIE of vaccines. They repeat it over and over again that it is safe. When in fact science is ALWAYS changing and we are always learning. Whats safe today might be deemed dangerous tomorrow.

I am tired of being treated as if I am stupid and have no say in what goes into my body or into my children's body. I should be aware OF ALL THE RISKS, provided with a manufacturers insert and have time to communicate all my concerns I have with my Dr without feeling as if I have no say over my families health .

When I take medicines there is a detailed instruction sheet with whats in the medicine I will be taking along with risks. Why cant I have that when going in for vaccines?

This should be a common sense law! If passed this isn't taking anything away from us but instead giving us the opportunity to be open with our Dr. And take accountability over our own health. We have the right to an informed decision. It is very important for us to be aware of reactions that could happen so we know when to seek medical care and also to report the reactions. This will help create an acceptance and understanding that there is risk when taking a vaccine just like there is risk with other medicines and or procedures. Personally if vaccines were not so hard to talk about and reactions weren't denied as hard as they are within the pro vaccine community then I would be more open to looking at the research they have. But majority of what I have witnessed in person and online is that the consensus is its ok if your kid has a severe reaction including death as long as they were vaccinated.

People that are having reactions HAVE NO IDEA that they are having one because the Dr.'s Only warn them about redness, fevers and bruising. Those that have some of the more severe reactions are ostracized and are treated as if its just in their mind and that they are crazy. They do not have the support of the general pro vaccine medical/science community. I can only imagine how it would be when people are confirmed to have {GBS} Guillain-Barré Syndrome or other serious conditions they were not aware that could have been caused by a vaccine. If your Dr. is pro vaccine vs non biased they do miss the reactions them selves because they are in denial that a vaccine could cause harm. This is based off of many peers that went from pro vaccine to now being an ex vaxxer because this is their story.

I am Renee Kawelo and I appreciate more common sense laws that is why I support HB2622.



February 4th, 2018

Hearing: Feb 6th, 2018 House Health Committee room 329

Re: Strong support for HB2622 the Informed Consent to Vaccination Act

Dear Chair Mizuno and Honorable House Health Committee Representatives,

Thank you for hearing this very important bill. The public's health and safety are probably the most important issues facing all lawmakers; for if the community at large is sick, no other legislation truly matters.

As a mother and stepmother of 5 children, the Informed Consent to Vaccination Act is important to my family, and the future viability of our state. This vital piece of legislation will help bring more credibility to the vaccine program in Hawaii, and more awareness to both patient and vaccine providers, helping to prevent possible vaccine injury.

Vaccination is a medical intervention, like all prescription drugs, that carries a risk of serious injury, death, and failure to prevent infection in some people. Unfortunately under current vaccine procedures and guidelines, doctors still cannot predict conclusively who will be harmed. There are genetic, biological, and environmental risk factors that make some individuals more susceptible to vaccine reactions than others. Having information such as vaccine ingredients, and the more comprehensive list of post-marketing adverse reactions in hand to discuss with one's doctor, would help initiate the coveted "precautionary principle" of medicine, and could prevent serious, lifelong injury.

Vaccine injuries are real and are becoming more prevalent every day. Our own Department of Health and Human Services estimates that only 1-10% of vaccine injuries are ever reported, still the Federal Vaccine Injury Compensation Program has paid out close to 4 billion dollars in death and disability claims, with 2 out of 3 claims denied.

Children born in the 90's are the sickest generation in America's history. According to our own CDC and HHS statistics:

- 54% of kids have some type of chronic illness (cancer, autoimmune disease, allergies asthma)
- 1 in 6 have a neurodevelopmental disability (ADD ADHD learning or behavioral disorders)
- we have an EPIDEMIC of AUTISM at 1 in 36
- the U.S. has the highest infant mortality rate out of 30 developed nations, and yet we give 2-3x more vaccines in childhood

We need to consider what has grown co-terminously with this explosion of illness and disability is the Childhood Vaccination Schedule. Since the 1986 National Childhood Vaccine Injury Act sheltered the vaccine manufacturers from all product liability, the schedule exploded from:

- 24 doses of 7 vaccines (from 2 months to 18 years) to a current
- 69 doses of 16 vaccines ( from the HepB at birth to 18) with
- 2 vaccines, influenza and Tdap routinely recommended in pregnancy

Pregnant women have the right to know that within the influenza and Tdap Package inserts it states that neither safety nor effectiveness have been established in pregnant women.

All patients have the right to know that within every vaccine package insert it states that said vaccine has “not been evaluated for carcinogenic or mutagenic potentials, or impairment of fertility”.

The right to Voluntary Informed Consent to Medical Risk Taking is central to our own American Medical Association’s Code of Ethics, and has been a core ethical principle in modern medicine since the Nuremberg Code was issued by the Nuremberg Tribunal after World War II. Informed Consent is a basic human right.

The first line in the AMA’s Code of Ethics page, Section 8.08

- Informed Consent reads: “The patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice.”

There cannot be an accurate risk/benefit analysis and true informed consent to vaccination without complete transparency regarding vaccine ingredients, actual risks, efficacy, and disease prevalence.

The current Vaccine Information Statement (VIS) given to patients, is lacking in this vital information that exists within the manufacturers package

insert. We can no longer continue accepting with blind faith that vaccines are “safe and effective” for everyone. The “1 in a million” VIS statistic for vaccine injuries is simply false. True an accurate Informed Consent to Vaccination is our first step to recovering the health of our keiki.

Sincerely,  
Kim Haine

**HB-2622**

Submitted on: 2/5/2018 6:29:28 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Maly Nakoa		Support	Yes

Comments:

As a mother and a nurse of 21 years I write this testimony in support of HB2622. In nursing school we had to take a pharmacology class and learned about medication side effects, drug interactions, allergies, and contraindications amongst other things. When I looked back at what I was taught about vaccines I could not remember much aside from how it saved humanity from such diseases as small pox and polio and how everyone needed to be vaccinated. They taught us about the vaccine schedule and that vaccines were safe and effective. I do not recall being taught that there was any downside or risk to vaccines. I believed what I was taught and fully vaccinated my daughter without question. About 3 years ago I began to actually do my own research. I began reading vaccine package inserts and could not believe how little I knew about vaccine ingredients, side effects, and ultimately vaccine injury. As a parent I felt negligent that I had not done my due diligence and as a nurse I felt short changed by my education. I even went back to my textbooks to see what I was taught and it reinforced what I recalled, I learned very little about vaccinations. It is because of this that I feel so strongly about this bill being passed.

When patients leave the doctors office or the hospital on medication they go to the pharmacy. The pharmacist asks several questions; do they have allergies, have they taken the medication before, do they have any questions, etc. They are handed pages of information from the pharmacist about their medications which include both benefits and potential risks. Whether they read it is their prerogative but they are given the information. This is what this bill is asking for, that we treat vaccines the way we would treat any other medication. When a consumer of our health care system goes to get a vaccine they should be able to trust that the health care professional who is caring for them is properly educated on each vaccine. This bill will help to ensure this is happening because currently it is not. Most physicians ordering vaccinations and those administering [the vaccines](#) have not read the inserts, do not know the ingredients, do not know what a vaccine reaction looks like, so how can they give informed consent?

We live in a different time. Up to 10 percent of people report being allergic to penicillin. We can no longer send our kids to school with a peanut butter and jelly sandwich because it may cause a life threatening reaction for another student. If we can understand this very simple truth why is it that we will not accept that some have had an adverse reaction to a vaccine? This too is truth and our government has paid out over \$3.7 Billion to validate this truth. By taking the extra steps to gather individual and family

medical history injury can be prevented.

There is great trust placed in health care professionals, a blind faith that first and foremost they would "do no harm". It is time that we stop making excuses for not doing the right thing and actually do the right thing. Please support HB 2622.

**HB-2622**

Submitted on: 2/5/2018 7:52:53 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
jenny hudson		Support	No

Comments:

**HB-2622**

Submitted on: 2/5/2018 8:26:01 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Erica DeWald	Every Child By Two	Oppose	No

Comments:

Thank you for considering the important issue of informed consent regarding vaccines. We are pleased to report that the current Vaccine Information Statements (VIS) include many of the elements of “informed consent” proposed in this bill. A vaccine’s VIS includes both the benefits and risks of the vaccine and clearly outlines the process for reporting to the Vaccine Adverse Event Reporting System (VAERS) as well as filing a claim with the National Vaccine Injury Compensation Program (VICP). Federal law already requires that a VIS statement be provided to parents before each and every vaccine is administered.

Each VIS is written by the Centers for Disease Control and Prevention (CDC) and informed by a group of experts and parents including Every Child By Two and the National Vaccine Information Center – two organizations with divergent views of vaccinations. 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.

Sometimes, a VIS does not exactly match a manufacturer’s product insert. That’s because VIS follow the Advisory Committee for Immunization Practices’ (ACIP’s) recommendations. ACIP carefully considers whether adverse events reported during clinical trials could be causally linked to the vaccination. Manufacturers, however, are required by FDA to report all events during a clinical trial. For example, if a child is involved in a car accident during the clinical trial and reports to the hospital with a broken arm, the manufacturer must report a broken arm as an adverse event. ACIP has the ability to weed out non-related injuries for the sake of clarity on a VIS. It is important to note, however, that the final section of each VIS, titled “How can I learn more?”, states parents and patients can ask their health care providers for the package insert.

It is also important to remember that VAERS is not the only reporting system in the U.S. While VAERS is a passive reporting system, the Vaccine Safety Datalink (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.

In addition to the VSD, the Clinical Immunization Safety Assessment (CISA) project is an active surveillance system in which the CDC partners with medical centers to study vaccines in particular groups of people. This system allows the CDC to study rare potential side effects in vulnerable populations. The FDA also has its own active surveillance system called the Post-licensure Rapid Immunization Safety Monitoring System (PRISM).

It is important that parents have access to critical information about vaccines before choosing to vaccinate their children. Luckily, the VIS statements and current, robust monitoring infrastructure means that is already happening. HB2622 would add unnecessary layers of bureaucracy that would not better inform parents, but that would unduly burden overworked health care providers' offices with duplicative paperwork.



**HB-2622**

Submitted on: 2/5/2018 8:34:56 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Caitlin Cook		Oppose	No

Comments:

Chair Mizuno, Vice Chair Kobayashi, and House Committee members, thank you for this opportunity to provide testimony on HB2622.

As a concerned resident of Hawaii, I **strongly oppose this bill**. This bill adds costly, burdensome, and unnecessary hurdles against making certain that all persons are vaccinated against dangerous vaccine-preventable diseases.

Vaccines are life-saving measures and any formidable steps that add burden to the family or individual will reduce immunization coverage levels and put everyone at risk for these diseases. With recent outbreaks in hepatitis A, mumps, and flu in Hawaii, many of us have witnessed firsthand the harmful effects on the health and economy of Hawaii when the community is not appropriately vaccinated.

Furthermore, these bills also do not take into consideration the important points below:

- The federal Vaccine Information Statement (VIS) requirement already ensures relevant information regarding vaccinations is provided to individuals and parents/guardians prior to vaccination. Providing a VIS for each vaccine administered is standard and accepted procedure in all vaccine-administration settings. All VIS are published by the CDC, and more information can be found [here](#).
- Package inserts are not written in a manner that can be easily understood by a layperson. It is grossly impractical in a medical office or pharmacy setting to provide package inserts to patients. Many inserts can be between 25 and 36 pages of technical language. They are meant to be read by medical professionals.
- This would add an additional burden in terms of time, costs, and capacity for our healthcare providers, especially pediatricians.
- “Informed consent” is under the scope of the Hawaii Medical Board per [HRS 671-3](#) and applies to a “proposed medical or surgical treatment or a diagnostic or therapeutic procedure” – none of which accurately describe immunizations.

For these reasons, I ask that **you oppose this bill**. It is a detriment and danger to the health and well-being of our families and communities in Hawaii.

Thank you for your consideration.

**HB-2622**

Submitted on: 2/5/2018 8:36:43 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Benjamin Kilinski		Oppose	No

Comments:

**HB-2622**

Submitted on: 2/5/2018 8:49:43 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Lee Yen Anderson		Support	No

Comments:

I fully support all patients being informed of the accurate safety information from actual vaccine inserts, so that they may make informed choices for themselves and their children, and so that they also know what side effect symptoms to be aware of. This way proper medical care for any side effects/injuries can be given, and it will also improve the vaccine injury reporting system VAERS.

With gratitude

Lee Yen

**HB-2622**

Submitted on: 2/5/2018 9:36:35 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Lea Minton		Support	No

Comments:

**HB-2622**

Submitted on: 2/5/2018 9:58:04 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

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

Comments:

Chair Mizuno, Vice Chair Kobayashi, and House Committee members, thank you for this opportunity to provide testimony on HB2622.

As a concerned resident of Hawaii, a parent and a health provider, I **strongly oppose this bill**. This bill adds costly, burdensome, and unnecessary hurdles against making certain that all persons are vaccinated against dangerous vaccine-preventable diseases.

Vaccines are life-saving measures and any formidable steps that add burden to the family or individual will reduce immunization coverage levels and put everyone at risk for these diseases. With recent outbreaks mumps and measles -- that largely occurred in communities with low vaccination rates for these childhood illnesses -- communities and families were burdened with illness, days of work / school lost.

Furthermore, these bills also do not take into consideration the important points below:

- The federal Vaccine Information Statement (VIS) requirement already ensures relevant information regarding vaccinations is provided to individuals and parents/guardians prior to vaccination. Providing a VIS for each vaccine administered is standard and accepted procedure in all vaccine-administration settings. All VIS are published by the CDC, and more information can be found [here](#).
- Package inserts are not written in a manner that can be easily understood by a layperson. It is grossly impractical in a medical office or pharmacy setting to provide package inserts to patients. Many inserts can be between 25 and 36 pages of technical language. They are meant to be read by medical professionals.
- This would add an additional burden in terms of time, costs, and capacity for our healthcare providers, especially pediatricians and family physicians.
- “Informed consent” is under the scope of the Hawaii Medical Board per [HRS 671-3](#) and applies to a “proposed medical or surgical treatment or a diagnostic or therapeutic procedure” – none of which accurately describe immunizations.

For these reasons, I ask that **you oppose this bill**. It is a detriment and danger to the health and well-being of our families and communities in Hawaii.

**HB-2622**

Submitted on: 2/5/2018 11:46:10 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Malia Rasa		Oppose	No

Comments:

I am a pediatrician, and I OPPOSE this bill. This bill will put into place procedures that will only serve as a barrier to patients to receive life-saving vaccines. The vaccine manufacturer's product insert sheet is not written to be easily understood by patients or their families, and will lead to more confusion over vaccine safety. This will not only affect the patients who choose not to receive the vaccines, but it will also affect our patients who are most vulnerable: newborns, and immunocompromised patients who rely on herd immunity to protect them from vaccine preventable diseases. We are already currently in a mumps outbreak, had a recent outbreak of hepatitis A, and have seen in recent years both measles and pertussis outbreaks, all of which are vaccine preventable diseases. Anything that creates a barrier to vaccination will only ensure that more children die from diseases that we can prevent. Please OPPOSE this bill as it threatens the health and lives of our children and families.

Thank you for your consideration.

Malia Rasa, M.D.



**HB-2622**

Submitted on: 2/5/2018 12:06:44 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

**LATE**

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Tawni Gesteuyala	Children's Doctors LLC	Oppose	No

Comments:

As a community pediatrician, I strongly OPPOSE this bill. Our training as pediatricians focuses on preventative care, trying to KEEP our keiki healthy, and much of this revolves around preventing the spread of deadly diseases with vaccinations. We have already seen the aftermath of vaccine refusal in the recent outbreaks of Mumps, Hepatitis A, Measles, and Pertussis. As a young pediatrician, these are diseases the horrors of which I had hoped would become medical history rather than a medical reality. This bill creates yet another barrier to our efforts in protecting our patients that need it the most -- the young, premature, immunocompromised, and medically fragile. Please OPPOSE this bill. Thank you.

**HB-2622**

Submitted on: 2/5/2018 2:32:23 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Lori Auldridge		Support	No

Comments:

As a Maui resident, I support Hawaii residents' right to informed consent. I support medical freedom and the right to choose what is best for individuals on a case by case basis. Mahalo.

**LATE**

**HB-2622**

Submitted on: 2/5/2018 2:45:32 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Catalina Cross	Times Pharmacy	Oppose	No

**Comments:**

Chair Mizuno, Vice Chair Kobayashi, and House Committee members, thank you for this opportunity to provide testimony on HB2622.

As a concerned resident of Hawaii, I **strongly oppose this bill**. This bill adds costly, burdensome, and unnecessary hurdles against making certain that all persons are vaccinated against dangerous vaccine-preventable diseases.

Vaccines are life-saving measures and any formidable steps that add burden to the family or individual will reduce immunization coverage levels and put everyone at risk for these diseases. With recent outbreaks in hepatitis A, mumps, and flu in Hawaii, many of us have witnessed firsthand the harmful effects on the health and economy of Hawaii when the community is not appropriately vaccinated.

Furthermore, these bills also do not take into consideration the important points below:

- The federal Vaccine Information Statement (VIS) requirement already ensures relevant information regarding vaccinations is provided to individuals and parents/guardians prior to vaccination. Providing a VIS for each vaccine administered is standard and accepted procedure in all vaccine-administration settings. All VIS are published by the CDC, and more information can be found [here](#).
- Package inserts are not written in a manner that can be easily understood by a layperson. It is grossly impractical in a medical office or pharmacy setting to provide package inserts to patients. Many inserts can be between 25 and 36 pages of technical language. They are meant to be read by medical professionals.
- This would add an additional burden in terms of time, costs, and capacity for our healthcare providers, especially pediatricians.
- “Informed consent” is under the scope of the Hawaii Medical Board per HRS 671-3 and applies to a “proposed medical or surgical treatment or a diagnostic or therapeutic procedure” – none of which accurately describe immunizations.

For these reasons, I ask that **you oppose this bill**. It is a detriment and danger to the health and well-being of our families and communities in Hawaii.

Thank you for your consideration.

**LATE**

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

Tuesday, February 6, 2018 at 8:30am

## **Testimony IN SUPPORT of House Bill No. 2622, Relating to Informed Consent for Vaccinations**

*"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

In general, the purpose of Informed Consent is to allow a healthy individual to make an informed decision prior to receiving a VOLUNTARY medical procedure such as a vaccination that carries inherent risks. Vaccines have been documented to cause an array of medical conditions, including paralysis, chronic autoimmune conditions, neurological conditions and death. In seeking informed consent, healthcare providers who believe the benefits of a vaccine are greater than the risk should be willing to provide additional information such as commonly reported adverse events and a package insert. Providers should welcome this open dialogue.

The purpose of HB 2622 is not to discourage individuals from vaccinating as most organizations fear, but to preserve individual autonomy by allowing individuals to take an active role in controlling their own health and wellness based on informed decisions for their own individual circumstances. We do not and will not, fit into the same cookie cutter.

As an experienced pharmacist, I can state without hesitation, that 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.

Vaccines contain specific antigens as well as vaccine excipients<sup>1</sup> 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.

#### **A. Background on Informed Consent:**

Historically, Informed Consent in the United States arose in the legal system in the early 1900's but it was not until *Salgo v. Leland Stanford Jr. University Board of Trustees* (1957), where Informed Consent was attached with a legal duty for physicians to disclose facts to his patient to allow for an intelligent consent to the proposed treatment.<sup>2</sup> Consider the following to illustrate the need for informed consent.

##### **a. Willowbrook State School:**

Willowbrook State School in Staten Island, N.Y. was a school that housed and cared for mentally disabled children. Since 1955, Dr. Saul Krugman from New York University School of Medicine and his co-workers conducted hepatitis experiments on mentally ill children at this facility. Willowbrook had a capacity of 4000 children but at its peak, housed more than 6000 children where over 700 children were used in Dr. Krugman's Hepatitis experiments spanning 15 years.<sup>3</sup> The reason why Hepatitis was rampant at Willowbrook was that the majority of children were often left to sit in their own feces, in an overcrowded facility, for extended amounts of time, creating an ideal environment for the rampant transmission of Hepatitis A.<sup>4</sup>

Dr. Krugman's findings on Hepatitis may have been for the greater good but they were at the expense of disabled individuals. **No matter how small healthcare providers deem the risks of any procedure to be, it is the individual who assumes the risk of injury or death, not the provider. It should not be too much to allow the individual to have the appropriate and necessary information to a make an informed decision as proposed in HB2622.**

One of the most troubling aspects of Dr. Krugman's experiments was how he acquired consent from parents. He enticed parents' **approval by overstating the benefits and minimizing the risks.** This deception led parents to naïvely consent to these human experiments which in the end led to unnecessary suffering of their already disabled children. This purposeful disinformation was not true Informed Consent.

Thankfully, Dr. Krugman's methods would be illegal today but if you, the legislators, have the ability to offer a small remedy towards improving the quality of information used for informed consent, you should act according to your responsibility to the public. Over stressing benefits and minimizing risks of vaccines is exactly what HB2622 is intended to reduce. Informed consent, with the necessary information available to the parent or patient, presented in a fair and unbiased way, is an appropriate method to further the education of healthcare providers' knowledge about the adverse effects of vaccines, to better recognize vaccine injuries, and to educate their patients. It is a win-win solution for everyone involved.

##### **b. Tuskegee Syphilis Study**

One of the most egregious experiments of consent violations was the Tuskegee Syphilis Study conducted by the United States Public Health Service (PHS). The PHS studied the effects of untreated syphilis on 600 black men in Alabama<sup>5</sup> in "hopes of justifying treatment programs for blacks."<sup>6</sup> This federal agency collected data on these men, conducted painful spinal taps, drew their blood regularly, and enticed

them with “special free treatments” like hot meals and free medical exams.<sup>7</sup> Although syphilis was treatable with penicillin in 1947, these men did not receive any treatment from 1932 to 1972. Instead, these black, mostly illiterate men, their families, wives, girlfriends and children were never informed that they were collectively participating in an experiment. Instead many were forced to suffer a frequently chronic, painful disease, often leading to multiple organ failure, blindness, insanity and eventually death.<sup>8</sup>

This lack of informed consent in the Tuskegee Experiment led to the three basic requirements of true Informed Consent summarized in the Belmont Report. The three principles are 1) respect for persons, 2) beneficence, and 3) justice. The Belmont Report eventually led to the creation and adoption of federal policy regarding Informed Consent in the Protection of Human Subjects, codified in separate regulations by 15 federal departments and agencies, known as the Common Rule, 45 CFR part 46.<sup>9</sup>

#### **B. Humans in the Marketplace are Guinea Pigs for Newly approved FDA vaccines and the Importance of the Package Insert:**

One may argue that Informed Consent does not apply to the Willowbrook and the Tuskegee experiments. However, the use of vaccines is equivalent to a large Phase 4 clinical Trial. Vaccines undergo fewer clinical trial testing 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.<sup>10</sup> 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”<sup>11</sup> meaning that the public may be unwilling participants in a grand experiment for identifying the adverse effects of a particular vaccine. **The FDA admits that “until a vaccine is given to the general population, all potential adverse events cannot be anticipated.”<sup>12</sup>**

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. However, there are many drawbacks from using the VIS. According to the FDA:<sup>13</sup>

- 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 and thus the VIS alone does not provide the additional and potential adverse events seen on a package insert. The VIS alone is not necessarily representative of offering Informed Consent.
- 3) Not all combination vaccines administered have an associated VIS thus pediatricians who use various vaccine combinations all of the time, may not be providing Informed Consent as

required by Hawaii's HRS 671-3(b) or by the National Childhood Vaccine Injury Act (NCVIA) of 1986 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.

These problems associated with the use of a VIS is one of the main reasons why HB2622 is so important to an individual receiving a vaccine. The package insert includes all adverse effects based on findings from the clinical trials in contrast to the selective information recommended by the ACIP printed on the VIS. The package insert is more representative of the adverse events caused by a vaccine and thus is more informative for the individual. **Whether or not this information is relevant to the individual, the healthcare provider should not make the decision for the individual but together with the individual after appropriate disclosure and discussion. Otherwise, the individual cannot provide Informed Consent.**

### C. Definition of Informed Consent:

Bioethical and medical definitions of Informed Consent have evolved. For example, in "Goldman's Cecil Medicine," 24<sup>th</sup> Edition, Informed Consent is defined as "a person's autonomous authorization of a physician to undertake diagnostic or therapeutic interventions for himself or herself where the four requirements of informed consent are present: mental capacity, disclosure, understanding, and voluntariness. Provided that mental capacity is not an issue, it is the physician's responsibility to disclose crucial information relevant to the person making a decision, the patient should understand the information and its implications and the patient must make a voluntary decision, without coercion or manipulation by the physician."<sup>14</sup> The act of signing a form without discussion does not constitute as Informed Consent despite what many healthcare providers believe.

The "Essential Clinical Procedures," adds that "A patient, through the exercise of personal autonomy, may either agree to or refuse a proposed procedure or treatment, but it is the responsibility of the practitioner to disclose ALL (my emphasis) relevant and pertinent information regarding the risks and benefits of the procedure to the patient to allow for an informed decision."<sup>15</sup>

Furthermore, Hawaii's Revised Statutes 671-3(b) requires Hawaii's medical board to establish the following standards of Informed Consent from a healthcare provider to a patient, patient's guardian, or legal surrogate to ensure that the patient's consent is an Informed Consent:

**(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.

These bioethical and medical definitions clearly describe how Informed Consent can be achieved. The appropriate disclosure of information from the healthcare provider to a patient, leading to the patient's understanding of the risks and benefits of the proposed intervention, among other things, is necessary before the patient can make an informed decision.

If HRS 671-3(b) is not applicable to vaccines, then supporting HB2622 must be seriously considered since a great number of physicians as well as other recognized healthcare providers regularly recommend vaccinations as a medical intervention for health purposes. The public should be able to make informed decisions regarding this medical intervention, just like any other medical intervention where informed consent is required.

#### **D. Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Injury Compensation Program (VICP)**

As discussed earlier, vaccines do not typically undergo Phase 4 clinical trials. Rather, data is passively collected in the Vaccine Adverse Event Reporting System (VAERS) on adverse events related to a vaccine in the marketplace. 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.<sup>16</sup> Although reporting to VAERS is mandated by federal law, the majority of healthcare providers do not report adverse reactions since most providers do not believe vaccines have any risks, are unaware of the VAERS system, do not have the time, and do not observe the federal mandate for submitting a VAERS report, and do not suffer consequences for non-reporting.<sup>17</sup>

The CDC and FDA co-administer this passive reporting surveillance system. Whether the information gathered 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.<sup>18</sup> Many times information is inaccurate, incomplete or delayed.<sup>19</sup> Since 1990, VAERS has logged over 607,202 documented adverse event reports observed in the marketplace<sup>20</sup> with an average of 40,588 VAERS reports filed every year.<sup>21</sup> However, due to under-reporting, 40,588 may actually represent less than one percent of vaccine adverse events reported to the FDA.<sup>22</sup>

The Vaccine Injury Compensation Program (VICP) also created through NCVIA collects \$0.75 per vaccine, and is designated to compensate vaccine-injured individuals.<sup>23</sup> For FY 2016, approximately \$271 million dollars in vaccine excise taxes were collected and approximately \$3.8 billion dollars have been paid since 1987 to compensate vaccine-injured individuals, including deaths.<sup>24</sup> **Despite what most healthcare providers believe, vaccine injuries DO occur and they are not as rare as healthcare providers represent them to be. If the majority of healthcare providers fail to report vaccine injuries to VAERS, then all vaccines are more than likely to carry a higher risk of adverse events than reported in either the VIS or the package insert.**

## E. 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 a package insert as directed in HB2622 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 satisfy the medical definitions of Informed Consent, including the guidelines outlined by HRS 671-3(b) so that the patient is more involved in their own health care while maintaining autonomy and making decisions to benefit their own well-being.

HB2622 is needed to allow individuals to make informed decisions about provider recommended vaccines. **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.

Please vote **IN SUPPORT of HB2622**. This would allow healthcare providers to learn more about the vaccines they recommend to their patients and most likely reduce the number of unreported adverse events occurring in the marketplace while improving the physician-patient relationship leading to better health outcomes.

Sincerely,

T. Ocampo

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- <sup>1</sup><https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf>. (See Appendix I).
- <sup>2</sup><http://nrs.harvard.edu/urn-3:HUL.InstRepos:885219>, 7.
- <sup>3</sup> <https://timeline.com/willowbrook-the-institution-that-shocked-a-nation-into-changing-its-laws-c847acb44e0d>
- <sup>4</sup> <http://www.thereviewatnyu.com/all/2016/2/20/the-duality-of-medicine-the-willowbrook-state-school-experiments>
- <sup>5</sup> <http://nrs.harvard.edu/urn-3:HUL.InstRepos:885219>, 23.
- <sup>6</sup> <https://www.cdc.gov/tuskegee/timeline.htm>.
- <sup>7</sup> <https://www.cdc.gov/tuskegee/timeline.htm>.
- <sup>8</sup> <https://www.sciencedirect.com/topics/medicine-and-dentistry/tuskegee-syphilis-experiment>.
- <sup>9</sup> <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>.
- <sup>10</sup> <https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm>.
- <sup>11</sup><https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm>.
- <sup>12</sup><https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm>.
- <sup>13</sup> <https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html>.
- <sup>14</sup> Ezekiel J. Emanuel, "Bioethics in the Practice of Medicine," Goldman's Cecil Medicine, 24<sup>th</sup> Ed., 2012.
- <sup>15</sup> Ted J. Ruback, "Informed Consent," Essential Clinical Procedures," 3<sup>rd</sup> Ed., 2013.
- <sup>16</sup> [42 USCS § 300aa-25](#) (b) (2017).
- <sup>17</sup> 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.
- <sup>18</sup>"Surveillance Manual | Vaccine Adverse Event Reporting System | VPDS | CDC." Cdc.Gov, <https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html>.
- <sup>19</sup> 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>.
- <sup>20</sup> 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).
- <sup>21</sup>"Surveillance Manual | Vaccine Adverse Event Reporting System | VPDS | CDC." Cdc.Gov, <https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html>.
- <sup>22</sup> 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).
- <sup>23</sup> "About the National Vaccine Injury Compensation Program | Official Web Site of the U.S. Health Resources & Services Administration." Hrsa.Gov, <https://www.hrsa.gov/vaccine-compensation/about/index.html>.
- <sup>24</sup> <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/monthly-website-stats-2-01-18.pdf>.

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APPENDIX I

Vaccine Excipient & Media Summary  
Excipients Included in U.S. Vaccines, by Vaccine

In addition to weakened or killed disease antigens (viruses or bacteria), vaccines contain very small amounts of other ingredients – excipients or media.

Some excipients are added to a vaccine for a specific purpose. These include:

Preservatives, to prevent contamination. For example, thimerosal.

Adjuvants, to help stimulate a stronger immune response. For example, aluminum salts.

Stabilizers, to keep the vaccine potent during transportation and storage. For example, sugars or gelatin.

Others are residual trace amounts of materials that were used during the manufacturing process and removed.

These include:

Cell culture materials, used to grow the vaccine antigens. For example, egg protein, various culture media.

Inactivating ingredients, used to kill viruses or inactivate toxins. For example, formaldehyde.

Antibiotics, used to prevent contamination by bacteria. For example, neomycin.

The following table lists all components, other than antigens, shown in the manufacturers' package insert (PI) for each vaccine. Each of these PIs, which can be found on the FDA's website (see below) contains a description of that vaccine's manufacturing process, including the amount and purpose of each substance. In most PIs, this information is found in Section 11: "Description."

All information was extracted from manufacturers' package inserts, current as of January 6, 2017.

If in doubt about whether a PI has been updated

since then, check the FDA's website at:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm> Vaccine

Vaccine:

Ingredients:

**Adenovirus**

**human-diploid fibroblast cell cultures (strain WI-38), Dulbecco's Modified Eagle's Medium, fetal bovine serum, sodium bicarbonate, monosodium glutamate, sucrose, D-mannose, D-fructose, dextrose, human serum albumin, potassium phosphate, plasdane C, anhydrous lactose, microcrystalline cellulose, polacrillin potassium, magnesium stearate, microcrystalline cellulose, magnesium stearate, cellulose acetate phthalate, alcohol, acetone, castor oil, FD&C Yellow #6 aluminum lake dye**

**Anthrax (Biothrax)**

**amino acids, vitamins, inorganic salts, sugars, aluminum hydroxide, sodium chloride, benzethonium chloride, formaldehyde**

**BCG (Tice)**

**glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, iron ammonium citrate, lactose**

**Cholera (Vaxchora)**

**casamino acids, yeast extract, mineral salts, anti-foaming agent, ascorbic acid, hydrolyzed casein, sodium chloride, sucrose, dried lactose, sodium bicarbonate, sodium carbonate**

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<b>DT (Sanofi)</b>	aluminum phosphate, isotonic sodium chloride, formaldehyde, casein, cystine, maltose, uracil, inorganic salts, vitamins, dextrose
<b>DTaP (Daptacel)</b>	aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, 2-phenoxyethanol
<b>DTaP (Infanrix)</b>	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80)
<b>DTaP-IPV (Kinrix)</b>	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, VERO cells, a continuous line of monkey kidney cells, Calf serum, lactalbumin hydrolysate, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B
<b>DTaP-IPV (Quadracel)</b>	modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, formaldehyde, ammonium sulfate aluminum phosphate, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, MRC-5 cells, normal human diploid cells, CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, 2-phenoxyethanol, polysorbate 80, glutaraldehyde, neomycin, polymyxin B sulfate
<b>DTaP-HepB-IPV (Pediatrix)</b>	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, VERO cells, a continuous line of monkey kidney cells, calf serum and lactalbumin hydrolysate, aluminum hydroxide, aluminum phosphate, aluminum salts, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B, yeast protein.
<b>DTaP-IPV/Hib (Pentacel)</b>	aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate, modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin. glutaraldehyde, MRC-5 cells (a line of normal human diploid cells), CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, modified Mueller and Miller medium
<b>Hib (ActHIB)</b>	sodium chloride, modified Mueller and Miller medium (the culture medium contains milk-derived raw materials [casein derivatives]), formaldehyde, sucrose

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<b>Hib (Hiberix)</b>	saline, synthetic medium, formaldehyde, sodium chloride, lactose
<b>Hib (PedvaxHIB)</b>	complex fermentation media, amorphous aluminum hydroxyphosphate sulfate, sodium chloride
<b>Hib/Mening. CY (MenHibrix)</b>	saline, semi-synthetic media, formaldehyde, sucrose, tris (trometamol)-HCl
<b>Hep A (Havrix)</b>	MRC-5 human diploid cells, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic
<b>Hep A (Vaqta)</b>	MRC-5 diploid fibroblasts, amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride
<b>Hep B (Engerix-B)</b>	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate
<b>Hep B (Recombivax)</b>	soy peptone, dextrose, amino acids, mineral salts, phosphate buffer, formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein
<b>Hep A/Hep B (Twinrix)</b>	MRC-5 human diploid cells, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein
<b>Human Papillomavirus (HPV) (Gardasil)</b>	vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein
<b>Human Papillomavirus (HPV) (Gardasil 9)</b>	vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein
<b>Influenza (Afluria) Trivalent &amp; Quadrivalent</b>	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multi-dose vials)
<b>Influenza (Fluad)</b>	squalene, polysorbate 80, sorbitan trioleate, sodium citrate dehydrate, citric acid monohydrate, neomycin, kanamycin, barium, egg proteins, CTAB (cetyltrimethylammonium bromide), formaldehyde
<b>Influenza (Fluarix) Trivalent &amp; Quadrivalent</b>	octoxynol-10 (TRITON X-100), $\alpha$ -tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride

Influenza (Flublok) Trivalent & Quadrivalent	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and Spodoptera frugiperda cell proteins, baculovirus and cellular DNA, Triton X-100, lipids, vitamins, amino acids, mineral salts
Influenza (Flucelvax) Trivalent & Quadrivalent	Madin Darby Canine Kidney (MDCK) cell protein, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethylammonium bromide, and $\beta$ -propiolactone
Influenza (Flulaval) Trivalent & Quadrivalent	ovalbumin, formaldehyde, sodium deoxycholate, $\alpha$ -tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials)
Influenza (Fluvirin)	ovalbumin, polymyxin, neomycin, betapropiolactone, nonylphenol ethoxylate, thimerosal
Influenza (Fluzone) Quadrivalent	formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials), sucrose
Influenza (Fluzone) High Dose	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde, sucrose
Influenza (Fluzone) Intradermal	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, sucrose
Influenza (FluMist) Quadrivalent	monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA)
Japanese Encephalitis (Ixiaro)	aluminum hydroxide, protamine sulfate, formaldehyde, bovine serum albumin, host cell DNA, sodium metabisulphite, host cell protein
Meningococcal (MenACWY-Menactra)	Watson Scherp media containing casamino acid, modified culture medium containing hydrolyzed casein, ammonium sulfate, sodium phosphate, formaldehyde, sodium chloride
Meningococcal (MenACWY-Menveo)	formaldehyde, amino acids, yeast extract, Franz complete medium, CY medium
Meningococcal (MPSV4-Menomune)	Mueller Hinton casein agar, Watson Scherp casamino acid media, thimerosal (multi-dose vials), lactose
Meningococcal (MenB – Bexsero)	aluminum hydroxide, E. coli, histidine, sucrose, deoxycholate, kanamycin
Meningococcal (MenB – Trumenba)	defined fermentation growth media, polysorbate 80, histidine, buffered saline.
MMR (MMR-II)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, vitamins, amino acids, fetal bovine serum, sucrose, glutamate, recombinant human albumin, neomycin, sorbitol, hydrolyzed gelatin, sodium phosphate, sodium chloride

MMRV (ProQuad) (Frozen)	chick embryo cell culture, WI-38 human diploid lung fibroblasts MRC-5 cells, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride; potassium phosphate dibasic, neomycin, bovine calf serum
MMRV (ProQuad) (Refrigerator Stable)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells, sucrose, hydrolyzed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate potassium chloride, neomycin, bovine serum albumin
Pneumococcal (PCV13 – Prevnar 13)	soy peptone broth, casamino acids and yeast extract-based medium, CRM197 carrier protein, polysorbate 80, succinate buffer, aluminum phosphate
Pneumococcal (PPSV-23 – Pneumovax)	phenol
Polio (IPV – Ipol)	Eagle MEM modified medium, calf bovine serum, M-199 without calf bovine serum, vero cells (a continuous line of monkey kidney cells), phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B
Rabies (Imovax)	human albumin, neomycin sulfate, phenol red indicator, MRC-5 human diploid cells, beta-propiolactone
Rabies (RabAvert)	chicken fibroblasts, $\beta$ -propiolactone, polygeline (processed bovine gelatin), human serum albumin, bovine serum, potassium glutamate, sodium EDTA, ovalbumin neomycin, chlortetracycline, amphotericin B
Rotavirus (RotaTeq)	sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal bovine serum, vero cells [DNA from porcine circoviruses (PCV) 1 and 2 has been detected in RotaTeq. PCV-1 and PCV-2 are not known to cause disease in humans.]
Rotavirus (Rotarix)	amino acids, dextran, Dulbecco's Modified Eagle Medium (sodium chloride, potassium chloride, magnesium sulfate, ferric (III) nitrate, sodium phosphate, sodium pyruvate, D-glucose, concentrated vitamin solution, L-cystine, L-tyrosine, amino acids solution, L-250 glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red), sorbitol, sucrose, calcium carbonate, sterile water, xanthan [Porcine circovirus type 1 (PCV-1) is present in Rotarix. PCV-1 is not known to cause disease in humans.]
Smallpox (Vaccinia – ACAM2000)	African Green Monkey kidney (Vero) cells, HEPES, human serum albumin, sodium chloride, neomycin, polymyxin B, Glycerin, phenol
Td (Tenivac)	aluminum phosphate, formaldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate



<b>Td (Mass Biologics)</b>	aluminum phosphate, formaldehyde, thimerosal, modified Mueller's media which contains bovine extracts, ammonium sulfate
<b>Tdap (Adacel)</b>	aluminum phosphate, formaldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, glutaraldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate, modified Mueller's growth medium
<b>Tdap (Boostrix)</b>	modified Latham medium derived from bovine casein, Fenton medium containing a bovine extract, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80
<b>Typhoid (inactivated – Typhim Vi)</b>	hexadecyltrimethylammonium bromide, formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, semi-synthetic medium
<b>Typhoid (Vivotif Ty21a)</b>	yeast extract, casein, dextrose, galactose, sucrose, ascorbic acid, amino acids, lactose, magnesium stearate, gelatin
<b>Varicella (Varivax) Frozen</b>	human embryonic lung cell cultures, guinea pig cell cultures, human diploid cell cultures (WI-38), human diploid cell cultures (MRC-5), sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, EDTA (Ethylenediaminetetraacetic acid), neomycin, fetal bovine serum
<b>Varicella (Varivax) Refrigerator Stable</b>	human embryonic lung cell cultures, guinea pig cell cultures, human diploid cell cultures (WI-38), human diploid cell cultures (MRC-5), sucrose, hydrolyzed gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
<b>Yellow Fever (YF-Vax)</b>	sorbitol, gelatin, sodium chloride, egg protein
<b>Zoster (Shingles – Zostavax) Frozen</b>	sucrose, hydrolyzed porcine gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride; MRC-5 cells, neomycin, bovine calf serum
<b>Zoster (Shingles – Zostavax) Refrigerator Stable</b>	sucrose, hydrolyzed porcine gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, MRC-5 cells, neomycin, bovine calf serum

A table listing vaccine excipients and media *by excipient* can be found in:  
 Grabenstein JD. ImmunoFacts: Vaccines and Immunologic Drugs – 2013  
 (38th revision). St Louis, MO: Wolters Kluwer Health, 2012.

**LATE**

**HB-2622**

Submitted on: 2/5/2018 3:10:14 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

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

Comments:

Chair Mizuno, Vice Chair Kobayashi, and House Committee members, thank you for this opportunity to provide testimony on HB2622.

As the President of the Hawaii Pharmacists Association, I strongly oppose this bill. This bill adds costly, burdensome, and unnecessary hurdles against making certain that all persons are vaccinated against dangerous vaccine-preventable diseases.

Vaccines are life-saving measures and any formidable steps that add burden to the family or individual will reduce immunization coverage levels and put everyone at risk for these diseases. With recent outbreaks in hepatitis A, mumps, and flu in Hawaii, many of us have witnessed firsthand the harmful effects on the health and economy of Hawaii when the community is not appropriately vaccinated.

Furthermore, these bills also do not take into consideration the important points below:

- The federal Vaccine Information Statement (VIS) requirement already ensures relevant information regarding vaccinations is provided to individuals and parents/guardians prior to vaccination. Providing a VIS for each vaccine administered is standard and accepted procedure in all vaccine-administration settings. All VIS are published by the CDC, and more information can be found here.
- Package inserts are not written in a manner that can be easily understood by a layperson. It is grossly impractical in a medical office or pharmacy setting to provide package inserts to patients. Many inserts can be between 25 and 36 pages of technical language. They are meant to be read by medical professionals.

- This would add an additional burden in terms of time, costs, and capacity for our healthcare providers, especially pediatricians.
- “Informed consent” is under the scope of the Hawaii Medical Board per HRS 671-3 and applies to a “proposed medical or surgical treatment or a diagnostic or therapeutic procedure” – none of which accurately describe immunizations.

For these reasons, I ask that you oppose this bill. It is a detriment and danger to the health and well-being of our families and communities in Hawaii.

Thank you for your consideration.

Patrick Uyemoto, Pharm.D.

President

Hawaii Pharmacists Association



**HAWAII MEDICAL ASSOCIATION**

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**LATE**

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

DATE: Tuesday, February 6, 2018  
TIME: 8:30am  
PLACE: Conference Room 329

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

**Re: HB 2622**

**Position: OPPOSE**

Chairs & Committee Members:

The HMA opposes this bill as unnecessary and potentially harmful.

**HMA OFFICERS**

President – William Wong, Jr., MD    President-Elect – Jerry Van Meter, MD    Secretary – Thomas Kosasa, MD  
Immediate Past President – Bernard Robinson, MD    Treasurer – Elizabeth A. Ignacio, MD  
Executive Director – Christopher Flanders, DO

**HB-2622**

Submitted on: 2/5/2018 3:59:52 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

**LATE**

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Laurie West		Support	Yes

Comments:

**HB-2622**

Submitted on: 2/5/2018 4:16:05 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Lois J Young	Ms.	Support	No

Comments:

Dear Sirs:

I believe it is the right of every human to know what is being injected into their bodies especially when it comes to vaccines. Each patient should be given scientific information regarding the ingredients in vaccines and also the option to accept or deny them. We need to be informed just like warning labels on cigarettes , household cleaners, or ingredients in processed foods. The consumer should be given the opportunity to choose.

Please vote yes and support INFORMED CONSENT, HB2622

Mahalo,

Lois Young

**HB-2622**

Submitted on: 2/5/2018 4:38:34 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
ANTHONY M GAIRNESE	APIC	Oppose	No

Comments:

I strongly oppose this bill

Tony Gairnese

**HB-2622**

Submitted on: 2/5/2018 4:40:59 PM

Testimony for HHS on 2/6/2018 8:30:00 AM



Submitted By	Organization	Testifier Position	Present at Hearing
Mary Wheaton	Willcox Hospital	Oppose	No

Comments:

According to the CDC, the majority — 85 percent — of this influenza season's pediatric flu **deaths** occurred in **children** who did not receive a flu shot. Of course I believe every parent and adult has the right to refuse vaccinations but the decision to refuse should be made after a conversation with their physician has occurred. As healthcare providers we already provide informed consent for all aspects of care we provide, sometimes in writing and always verbally. Adding an additional layer of paperwork would impose an undue burden on healthcare facilities while requiring patients to complete additional forms which would result in many individuals just walking away and not getting their children or themselves vaccinated because of time and inconvenience. Many patients do not understand the pros and cons of vaccinations as it applied to them simply by reading a form so a strong patient-doctor relationship and face to face conversations is the most successful method of providing informed consent. I oppose additional consent forms.



**LATE**

**HB-2622**

Submitted on: 2/5/2018 4:43:01 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Luann Casey		Oppose	No

Comments:

**LATE**

**HB-2622**

Submitted on: 2/5/2018 7:10:22 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Javier Mendez-Alvarez		Oppose	No

Comments:

**LATE**

Kalma K. Wong  
P.O. Box 240364  
Honolulu, HI 96824  
(808) 393-5218

February 5, 2018

Representative John M. Mizuno  
Chair, House Cmte on Health & Human Services  
Hawaii State Capitol, Room 439

Representative Bertrand Kobayashi  
Vice Chair, House Cmte on Health & Human Services  
Hawaii State Capitol, Room 403

RE: Testimony in SUPPORT of HB2622, Requires health care providers to obtain informed consent in writing from a person before administering a vaccination.

Dear Chair Mizuno, Vice Chair Kobayashi, and Members of the House Committee on Health & Human Services,

I am writing to express my SUPPORT of House Bill 2622, which requires health care providers to obtain informed consent in writing from a person before administering a vaccination. The bill also requires health care providers to gather patients' complete individual and family histories, as well as to provide the vaccine manufacturer's product insert sheet and information about the benefits and risks of each vaccine.

This important amendment to the Hawaii Revised Statutes regarding vaccination will only protect the health of the residents of this state. Although there may be some in the health care community who will object to this bill due to its inconvenience, those who understand that the health and safety of the patients should always ethically come first will applaud it. Patients have the right, at minimum, to be made aware of the side effects that are listed in the package insert of the vaccines. For example, a common flu vaccine given in Hawaii is the Afluria Quadrivalent. Under "**Warnings and Precautions**" of the package insert it states:

**5.1 Guillain-Barré Syndrome**

**If Guillain-Barré (GBS) has occurred within 6 weeks of previous influenza vaccination, the decision to give AFLURIA QUADRIVALENT should be based on careful consideration of the potential benefits and risks.**

Under "**Contraindications**" of the package insert it states:

**Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine including egg protein, or to a previous dose of any influenza vaccine.**

Guillain-Barré syndrome is a disorder in which the body's immune system attacks the nerves. Anaphylaxis is a potentially life-threatening allergic reaction to an allergen that can occur within minutes or even seconds.

The June 21, 2017 presentation, "End-of-Season Update: 2016-17 Influenza Vaccine Safety Monitoring, Advisory Committee on Immunization Practices" by Dr. Tom Shimabukuro of the Immunization Safety Office of the Centers for Disease Control and Prevention (CDC) stated that of the 4,236 voluntary reports of adverse vaccine events related to Quadrivalent Inactivated Influenza Vaccines, 258 (6%) were deemed "serious." A "serious" event includes death, life-threatening illness, hospitalization or prolongation of hospitalization or permanent disability. Of these, 51 (or almost 20% of the serious events) were reports of Guillain-Barré syndrome and 27 (or 10% of the serious events) were reports of anaphylaxis (<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2017-06/flu-04-shimabukuro.pdf>).

As adverse reactions are typically not thoroughly discussed when vaccines are given, this bill will help to ensure that both health care providers and their patients are more fully informed so that the most healthful decisions can be made. Please pass HB2622 to protect the health and safety of Hawaii's residents.

Sincerely,  
Kalma Wong

**LATE**

**HB-2622**

Submitted on: 2/5/2018 10:36:35 PM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Alec Wong-Miyasato		Support	No

Comments:

**LATE**

**HB-2622**

Submitted on: 2/6/2018 10:53:32 AM

Testimony for HHS on 2/6/2018 8:30:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Matthew Tuttle		Support	Yes

Comments:

We are not big given informed consent which is our right. We are not being told what is in the vaccines, we are not being given honest and complete information about the risks and side effects and we are not being given the package insert.

Informed consent is already required but it is not being done and their needs to be consequences for those healthcare provider's who do not give informed consent.