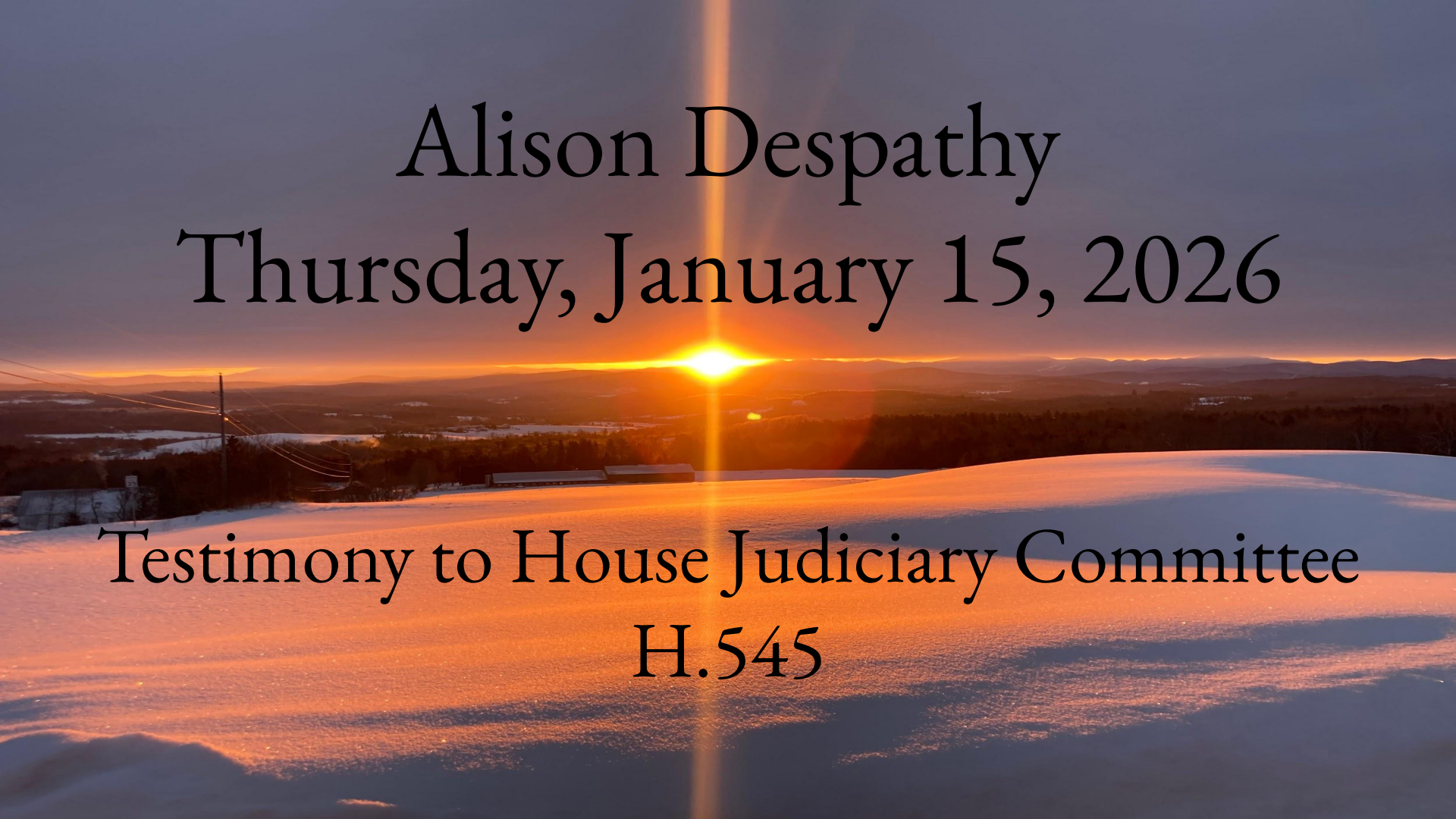


Alison Despathy
Thursday, January 15, 2026

Testimony to House Judiciary Committee
H.545

Kaylynne Matten 09/09/2004 - 12/06/2011

Kaylynne Matten lived in Barton, Vermont

Kaylynne died of myocarditis from a Fluzone vaccine at age 7. She received the vaccine 4 days prior to dying

The Matten's received $250,000 from the National Vaccine Injury Compensation Program (VCIP), for the death of their daughter.

It took over 10 years in the VCIP legal process for this "reimbursement"

Full Testimony Linked here

Kaylynne's Mom Nicole Matten's Testimony quotes -5/5/2015

"I was not told that vaccines can cause injuries or death, I was only told the shot would keep her healthy—but that was not the case."

"Pediatricians are denying that these things happen and if you ask me, doctors need to be better educated on adverse reactions of vaccines. They should also have to accept liability if the shot they give causes harm like it did for Kaylynne. They would give better information if they had to be responsible for their recommendations."

"Any and all vaccines should be subject to informed consent and full disclosure and exemptions (the right to say no) should always be available, since there is a risk."

$5,530,623,153.83

The amount paid since 1988 to those who have been injured by or lost loved ones because of a vaccine. This is paid by the National Vaccine Injury Compensation Program, established by the 1986 National Childhood Vaccine Injury Act.

HRSA Data and Statistics 09012025

NATIONAL VACCINE INJURY COMPENSATION PROGRAM

The National Vaccine Injury Compensation Program (VICP) is a federal program created in 1988 to compensate those who have been injured or killed by certain vaccines.

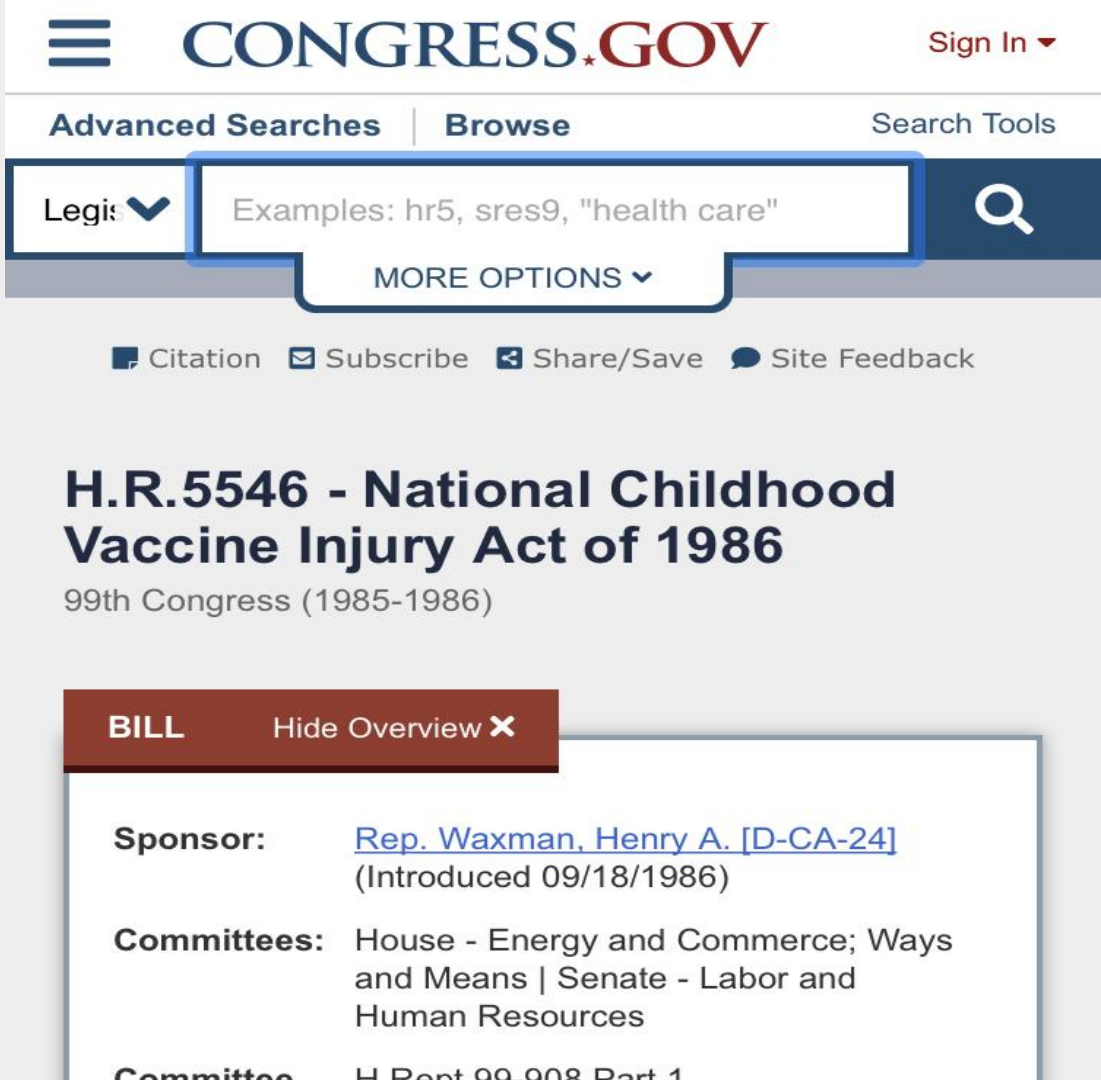
HRSA Data and Statistics 09012025

Health Resources and Services Administration is the agency that administers the National Vaccine Injury Compensation Program Established in 1988 after the National Childhood Vaccine Injury Act 0f 1986

Vaccine Injury Table Effective for Claims Filed on or After 1-3-2022

In 1986, President Reagan Signed the NCVIA

[H.R.5546 - 99th Congress (1985-1986): National Childhood Vaccine Injury Act of 1986 | Congress.gov | Library of Congress]



1986 National Childhood Vaccine Injury Act Broke Market Forces and Vaccine Safety

42 U.S.C. 300aa-11 –No person may bring a civil action for damages….against a vaccine administrator or manufacturer…for damages arising from a vaccine related injury or death associated with the administration of a vaccine.”

H.R.5546 - 99th Congress (1985-1986): National Childhood Vaccine Injury Act of 1986 | Congress.gov | Library of Congress
Siri-Testimony.pdf

How and Why Did This Happen

- 1985- US Senate Committee convened to deal with the lawsuits brought by parents whose children suffered brain injury and death from DPT vaccine
- Vaccine manufacturers were folding because the amount of liability payments exceeded the revenues
- Average claims ranged from $10- 45.6 million in a decade and 200 lawsuits were filed.
- In 1985, Lederle was the only vaccine manufacture left

Vaccine Crisis: An Emerging Societal Problem - JSTOR
TV Report On Vaccine Stirs Bitter Controversy - The Washington Post

The Law removed a person's ability to sue a vaccine manufacture for damages or death effectively removing market forces and safety demands

- Americans lost their constitutionally protected right to trial by jury for vaccine damage or death
- Instead of vaccine manufacturers being directed to make safer products they were granted full immunity for their products.
- There is no other product or company that has full immunity and this has compromised their duty to ensure safety of their products. Manufacturers of Drugs, planes, cars are all responsible for product safety
- Vaccines are given to children and the manufacturers cannot be sued

Pfizer's Four Most Profitable Drugs of All Time as of 2019[5]		
DRUG	**SAFETY FOLLOW UP**	**CONTROL USED**
Enbrel	6.6 years	Placebo
Eliquis	7.4 years+	Placebo
Lipitor	4.9 years+	Placebo
Lyrica	2 years+	Placebo

Siri-Testimony.pdf

VACCINE	SAFETY FOLLOW UP AFTER INJECTION	CONTROL USED
Hep-B (Merck)	5 days	None
IPV (Sanofi)	3 days	None
Hib (Merck)	3 days	Hib
DTaP (GSK)	28 days	DTP
Prevnar13 (Pfizer)	6 months	Prevnar

Siri-Testimony.pdf

ICAN
Informed Consent Action Network

None of the vaccine doses the CDC recommends for routine injection int were licensed by the FDA based on a long-term placebo-controlled trial

Type	Doses	Age Injected	Brand	Company[1]	Control	Placebo?	Safety Review After Injection[2]	Long	Source	Note
HepB	3	Birth 1M 6M	Recombivax HB	M	None	NO	5 days	NO	Package insert at § 6.1	Note that to license a vaccine for children, the FDA relies up
			Engerix B	G	None	NO	4 days	NO	Package insert at § 6.1	with children, not adults, because as the FDA explains, "I
										recognize that, because young children are still growing an
										thorough and robust clinical trials of adequate size are comple
										the immune response to a ... vaccine in this population. Childr
DTaP	15	2M 4M6M 15M 4Y	Infanrix	G	DTP	NO	30 days	NO	Package insert at § 6.1	DTP was also not licensed based on a placebo controlled trial
			Daptacel	S	DT or DTP	NO	Up to 2 months + 1 trial 6 months	NO	Package insert at § 6.1	The 6-month Daptacel trial had no control, 1,454 children and dose of DAPTACEL 3.9% subjects reported at least one serious
PCV	4	2M 4M 6M 12M	Prevnar 13, PCV-13	P	Prevnar 7	NO	6 months	NO	Package insert at § 6.1	Prevnar 7 trial's control was an "[i]nvestigational meningococca
										Prevnar 13 trial, "[s]erious adverse events reported following va
			Vaxneuvance PCV-15	M	Prevnar 13	NO	6 months	NO	Package insert at § 6.1	occurred in 8.2% among Prevnar 13 recipients and 7.2% an
										Vaxneuvance trial, "serious adverse events...were reported by 9.
			Prevnar 20, PCV-20	P	Prevnar 13	NO	6 months	NO	Package insert at § 6.1; Clinical Review	and by 8.9% of Prevnar 13 recipients" but deemed "safe" be
										numerical imbalances between vaccination groups." Prevnar
										"serious adverse events" and "newly diagnosed chronic medical
IPV	4	2M4M 6M 4Y	IPOL	S	None	NO	3 days	NO	Package insert at 14-17	IPOL is very different than the polio vaccine created by Jona
										1960s). Hence, trials of Salk's vaccine from the 1950s were not
Hib	3 or 4	2M 4M 6M 12M	ActHIB	S	HepB	NO	30 days	NO	Package insert at § 6.1; Basis of Approval at 8	Within 30 days of injection in the ActHIB trial, 3.4% experienc
										"[n]one was assessed by the investigators [Sonafi] as related t
			Hiberix	G	HibTITER or other vaccine	NO	31 days	NO	Package insert at § 6.1; Clinical review at 20-21	
			Liquid PedvaxHIB	M	Lyophilized PedvaxHIB	NO	3 days	NO	Package insert at 6-8	Lyophilized PedvaxHIB vaccine, used as the control for Liquid H in which controls were given placebo, OPV, and DTP but the PedvaxHIB was ever licensed.
RV[3]	2 or 3	2M 4M 6M	Rotarix	G	Dextran, Sorbitol, Amino Acids, Dulbecco's Modified Eagle Medium, and Sterilizer.	NO	31 days + 1 year for intussusception	NO	Package insert at § 6.1; Clinical review at 23-24	"[T]here were 68 (0.19%) deaths following...ROTARIX...and placebo.... The most common...cause...was pneumonia...obser ROTARIX and 10 (0.03%) placebo recipients." Its clinical review
			RotaTeq	M	Polysorbate 80, Tissue Culture Medium, Fetal Bovine Serum, and Sodium Phosphate	NO	42 days + 1 year for intussusception	NO	Package insert at § 6.1; Clinical reports at 445 etc.	of all components of Rotarix, but without any RV particles." T similarly admits its "placebo" contains multiple ingredients as se
Covid19	3	6M 7M 10M	Comirnaty	P	Placebo	YES	6 months	NO	Package insert at § 6.1	Comirnaty licensed for only 12+ (Spikevax, Moderna, only 18 and most vaccinated during the trial. All data 16+ is combined 1,131 vaccinated children, and one participant shows how this
Flu	19	6M 7M Yearly	Various	Varies	Flu shots change annually without any clinical trial	NO	Flu shots change annually without any clinical trial	NO	CDC 22-23 Flu Shots; FDA Flu Shots	The trials of the original flu shot formulations for children also (see pp. 13-14) even though some adult trials did. The one i placebo but, again, it changes every year and is not safety test
MMR	6	12M 4Y	M-M-R-II	M	None	NO	42 days	NO	Clinical reports	M-M-R-II trials totaled only 834 children and a third develope
			Priorix	G	M-M-R-II	NO	6 months	NO	Package insert at § 6.1; Sup materials at 12	third respiratory issues. In Priorix trial, both vaccine groups h events, emergency room visits, and new chronic diseases asthma, type I diabetes, celiac, and allergies). See Table 6 of th
VAR	2	12M 4Y	Varivax	M	45 mg of neomycin per milliliter	NO	70 days	NO	Package insert at § 6.1; Merck study at 2; Clinical reports	One controlled trial with 956 children, half Varivax and half n vaccinated and another 29 vaccinated 8 weeks later, during w the ear infections and 50% more respiratory infections.
HepA	2	12M 18M	Havrix	G	Engerix-B	NO	6 months	NO	Package insert at § 6.1	Trials for both occurred at the same time when there was n hence no excuse for not using a placebo control. It is also star
			Vaqta	M	AAHS and Thimerosal	NO	42 days	NO	Package insert at § 6.1; Merck study at 454	the control for Havrix, and an injection of cyto-and-neuro thimerosal, were used as a control for Vaqta instead of a salin
Tdap	3	11Y	Adacel	S	Td, for adults	NO	6 months	NO	Package insert at § 6.1	Due to reactions, Tdap (Adacel) given at 11Y has 12.5 times les
			Boostrix	G	Decavac or Adacel	NO	6 months	NO	Package insert at § 6.1	and 10 times less pertussis toxin (25mcg v 2.5mcg) than DTaP
HPV	2 or 3	9Y 9 ½Y	Gardasil 9	M	Gardasil 4 (see note)	NO	1 month in five trials, 6 months in one trial, and 4 years in one trial		Clinical review at 17-19	Gardasil 9 trial gave 306 people placebo after full series of Gardas received aluminum adjuvant, AAHS, except 320 people labele received all vaccine ingredients except antigens and AAHS. Acrc or aluminum adjuvant (used to induce autoimmunity) had a susp
Men4	2	11Y 16Y	Menactra	S	Menomune	NO	6 months	NO	Package insert at § 6.1	Incredibly, the safety section of the package insert for Meno was used as a control for the trial of Menactra. This provides safety pyramid scheme in which Menomune is licensed withou then used as the control to license Menactra; Menactra is the Menveo; and then Menveo is used as the control to license safety profile? Putting aside the limited 6-month safety Menomune's safety baseline was never established in a placeb
			Menveo	G	Menactra or other vaccine	NO	6 months	NO	Package insert at § 6.1	
			MenQuadfi	S	Menveo or other vaccine	NO	6 months	NO	Package insert at § 6.1	
MenB	0 or 2	10Y+ if indicated	Bexsero	G	See note	NO	30 days	NO	Summary basis at 14-15; Clinical review at 40	Bexsero's controls injected with aluminum hydroxide and, in saline injection followed by injection of Menveo and hence FDA not a "placebo control" trial. **Trumenba's trials had** no placeb
			Trumenba	P	See note	NO	30 days in 3 trials + 11M in 2 trials	NO	Summary basis at 4; Clinical review at 9-10	people in a dose ranging phase II study; otherwise, the Gardasil+placebo, dTaP-IPV+placebo, HepA+placebo, or Mena
PPSV23	0 to 2	2Y+ if indicated	Pneumovax 23	M	See note	NO	See note	NO	FDA documentation	Licensed for children 2 years and older but there is no indicat trial involving anyone younger than 16 years of age that the vaccine. See all FDA documentation for this vaccine linked.
DEN	0 or 3	6Y+ prior infected endemic areas	Dengvaxia	S	Placebo	YES	5 years	YES	Statistical review at 10; Package insert at 4	Finally, a longer-term placebo-controlled trial (35k+ children) harm and death – harms the above trials would likely miss – an infected are at increased risk for severe dengue." Hence, it is o in U.S.) to children 6+ who had dengue (Note: 5 years insuffici

[1] M=Merck; G=GSK; S=Sanofi; P=Pfizer.
[2] Note that for many trials with "6 months," the review was typically around 30 days after injection with a phone call at 6 months.

None of the vaccine doses the CDC recommends for routine injection were licensed by the FDA based on long-term placebo-controlled trials.

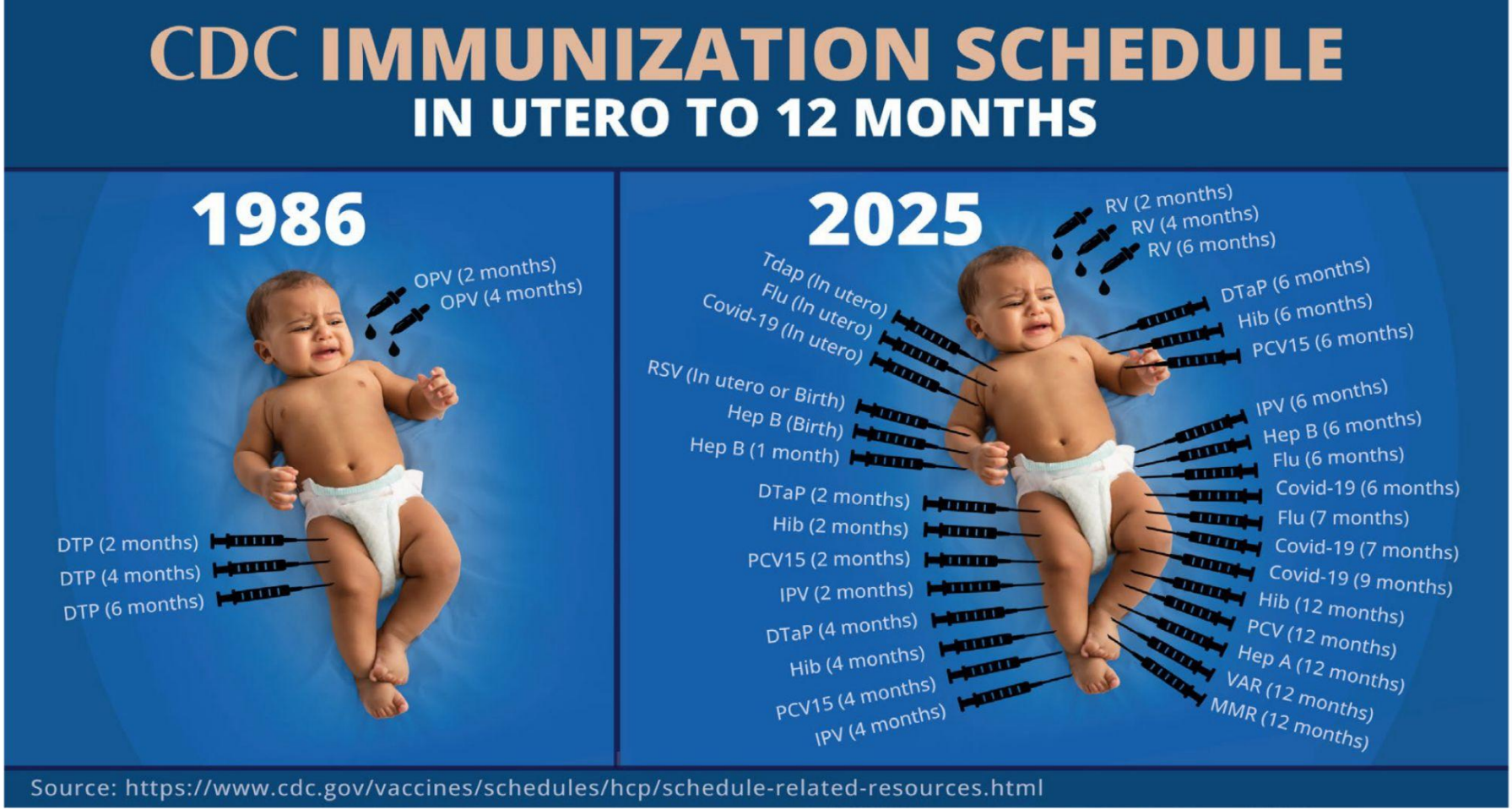
Childhood Vaccine Trials Summary Chart - ICAN - Informed Consent Action Network

A 2013 IOM report recommended that HHS "incorporate study of the safety of the overall childhood immunization schedule into its processes for setting priorities for research, recognizing stakeholder concerns, and establishing the priorities on the basis of epidemiological evidence, biological plausibility, and feasibility." and "continue to fund and support the Vaccine Safety Datalink project to study the safety of the recommended immunization schedule."

nationalacademies.org/read/13563/chapter/1

“In 1980, American children following the CDC immunization schedule received 23 vaccine doses in 7 shots against 7 different diseases (1 MMR, 5 DTP, 1 Td) plus 4 OPV drops. In 2024, the recommended number of routine vaccines had risen to at least 84 vaccine doses in at least 57 shots for 17 diseases, plus the RSV monoclonal antibody immunization for a total of 18 diseases. This is more than other developed nations.”

Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries



Vaccine Ingredients- aluminum, mercury, formaldehyde, squalene, antibiotics

[Common Ingredients in FDA-Approved Vaccines | FDA]

Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries

January 2, 2026

[Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries]

Universal Vaccine Recommendations Funded by the Government	Age at 1st Vaccine (months)	Rotavirus	Diphteria	Tetanus	Pertussis	Polio	Hib	Tuberculosis	Japanese Encephalitis	Hepatitis A	Hepatitis B	Pneumococcal	Measles	Mumps	Rubella	Varicella	HPV	Meningococcal	Influenza	Covid-19	# Vaccine Doses	# Diseases	# Mandated
Australia	0	2	6	6	6	4	4	..	..	..	4	3	2	2	2	1	1	2	5-6	..	50-51	15	13
Austria	2	2-3	5	5	5	5	3	..	..	..	4	3	2	2	2	..	2	1	17-18	..	58-60	14	0
Belgium	2	..	6	6	6	5	4	..	..	..	4	3	2	2	2	..	2	1	..	..	43	12	1
Canada	2	2-3	6	6	6	5	4	..	..	..	2-3	3-4	2	2	2	2	1	2	18-19	..	64-68	15	0
Denmark	3	..	4	4	4	4	3	..	..	..	..	3	2	2	2	..	2	..	..	..	30	10	0
Finland	2	3	5	5	5	4	3	..	..	..	..	3	2	2	2	2	2	..	6-7	..	44-45	13	0
France	2	2-3	5	5	5	5	3	..	..	..	3	3	2	2	2	..	2	6	..	..	45-46	13	11
Germany	1.5	2-3	5	5	5	4	3	..	..	..	3	3	2	2	2	2	2	4	..	..	44-45	14	1
Greece	2	2-3	6	6	6	4-5	4	..	..	2	3	3	2	2	2	2	2	5	5-6	..	56-58	16	0
Ireland	2	2	6	6	6	5	4	..	..	..	4	3	2	2	2	1	1	5	16	..	65	15	0
Italy	3	2	5	5	5	5	3	..	..	..	3	3	2	2	2	2	2	6	..	..	47	14	10
Japan	2	2-3	5	5	4	4	4	1	4	..	3	4	2	..	2	2	2-3	..	..	..	44-46	14	0
Netherlands	1.5	2	6	6	5	5	4	..	..	..	4	3	2	2	2	..	2	2	..	..	45	13	0
New Zealand	1.5	2	5	5	5	4	4	..	..	..	3	3	2	2	2	1	2	3	..	..	43	14	0
Norway	1.5	2	5	5	5	5	3	..	..	..	3	3	2	2	2	..	2	..	..	..	39	12	0
Portugal	0	..	6	6	5	5	4	..	..	..	3	3	2	2	2	..	2	4	..	..	44	12	0
Spain	2	2-3	5	5	4	4	3	..	..	..	3	3	2	2	2	2	1	6	4-5	..	48-50	15	0
Sweden	1.5	2-3	5	5	5	4	3	..	..	..	3	3	2	2	2	..	2	..	..	..	38-39	12	0
Switzerland	2	2	5	5	5	4	3	..	..	..	3	3	2	2	2	2	2	6	..	..	46	14	0
United Kingdom	2	2	6	6	5	6	4	..	..	..	4	2	2	2	2	2	1	4	14	..	62	15	0
# Recommended		17	20	20	20	20	20	1	1	1	18	20	20	19	20	12	20	15	8	0			
# Mandated		1	3	3	3	4	3	0	0	0	3	2	4	3	3	2	0	2	0	0			
USA 2024	0	2-3	6	6	6	4	3-4	..	..	2	3	4	2	2	2	2	2	2	18-19	18-19	84-88	17	12
USA Suggested	2	A	6	6	6	4	3-4	..	..	A	A	4	2	2	2	2	1	A	A	A	38-39	11	0

Table 2: The number of vaccines recommended for all children in peer nations, not including monoclonal antibodies. The number of vaccine doses is more than the number of injections or diseases covered. For example, the MMR shot contains three vaccine doses, one each for measles, mumps and rubella. Red

Hepatitis B Recombivax HB vaccine Timeline -case study

- Approved in 1986 by FDA
- First genetically modified virus used in a vaccine
- Studied for 5 days with 147 children up to 19 years of age
- October 12, 2017- Informed Consent Action Network sent a letter to HHS requesting the Hepatitis B safety data ICAN-HHS-Notice-1.pdf
- January 18, 2018 received a letter from HHS and FDA which failed to provide further clinical trial safety data Review-Copy.pdf
- Two more letters were submitted requesting the safety data ICAN-Reply-1.pdf and ignored
- ICAN submitted a FOIA demanding a copy of the clinical trials relied upon to license Recombivax HB
- Received a 1264 page document confirming the vaccine was only reviewed for a few days post injection
- FDA has refused to respond to further requested clinical trials data
- On September 4, 2020, Informed Consent Action Network filed a petition to the FDA "demanding that the licensure of the Hepatitis B vaccines be revoked or suspended until their safety, as required by law, is determined in a properly designed clinical trial of sufficient duration." Petition-Hep-B-FINAL.pdf

ICAN FILES FORMAL PETITION DEMANDING THAT THE FDA WITHDRAW ITS LICENSURE OF HEPATITIS B VACCINES - ICAN - Informed Consent Action Network

Duration of Pediatric Clinical Trials Submitted to the US Food and Drug Administration - PMC

Informed Consent Action Network statement on Petition

"There may be some uncertainty as to what is required under federal law to determine that a product is "safe" prior to licensure, but what is clear is that five days cannot possibly be sufficient to meet that requirement. Hence, if the FDA refuses to grant or timely respond to ICAN's petition, we intend to sue the FDA in federal court to demand that the license for these vaccines be revoke or suspend until a proper clinical trial is conducted."

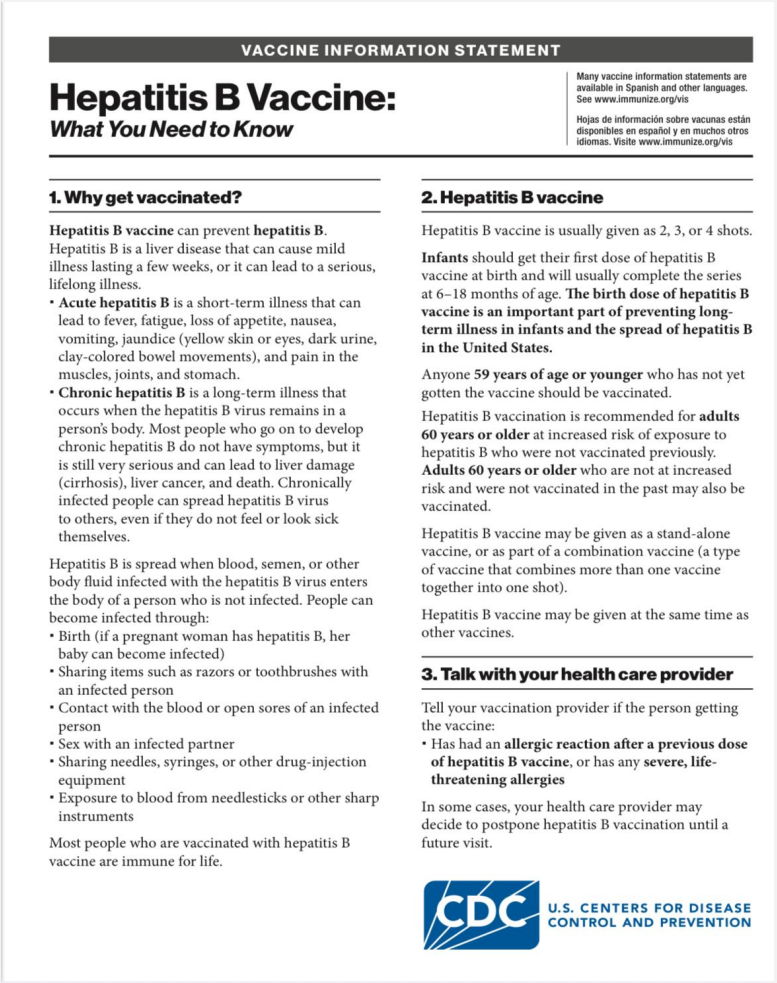
ICAN FILES FORMAL PETITION DEMANDING THAT THE FDA WITHDRAW ITS LICENSURE OF HEPATITIS B VACCINES - ICAN - Informed Consent Action Network

Informed Consent

The American Medical Association Code of Medical Ethics states that “Informed consent in medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well- considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.” Informed Consent | AMA-Code

In its Public Health Code of Ethics, the American Public Health Association asserts that “the effective and ethical practice of public health depends upon social and cultural conditions of respect for personal autonomy, self- determination, privacy, and the absence of domination in its many interpersonal and institutional forms.”
Public Health Code of Ethics

Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries



VACCINE INFORMATION STATEMENT

Hepatitis B Vaccine:
What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Hepatitis B vaccine can prevent **hepatitis B**. Hepatitis B is a liver disease that can cause mild illness lasting a few weeks, or it can lead to a serious, lifelong illness.

- **Acute hepatitis B** is a short-term illness that can lead to fever, fatigue, loss of appetite, nausea, vomiting, jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements), and pain in the muscles, joints, and stomach.
- **Chronic hepatitis B** is a long-term illness that occurs when the hepatitis B virus remains in a person's body. Most people who go on to develop chronic hepatitis B do not have symptoms, but it is still very serious and can lead to liver damage (cirrhosis), liver cancer, and death. Chronically infected people can spread hepatitis B virus to others, even if they do not feel or look sick themselves.

Hepatitis B is spread when blood, semen, or other body fluid infected with the hepatitis B virus enters the body of a person who is not infected. People can become infected through:

- Birth (if a pregnant woman has hepatitis B, her baby can become infected)
- Sharing items such as razors or toothbrushes with an infected person
- Contact with the blood or open sores of an infected person
- Sex with an infected partner
- Sharing needles, syringes, or other drug-injection equipment
- Exposure to blood from needlesticks or other sharp instruments

Most people who are vaccinated with hepatitis B vaccine are immune for life.

2. Hepatitis B vaccine

Hepatitis B vaccine is usually given as 2, 3, or 4 shots.

Infants should get their first dose of hepatitis B vaccine at birth and will usually complete the series at 6–18 months of age. **The birth dose of hepatitis B vaccine is an important part of preventing long-term illness in infants and the spread of hepatitis B in the United States.**

Anyone **59 years of age or younger** who has not yet gotten the vaccine should be vaccinated.

Hepatitis B vaccination is recommended for **adults 60 years or older** at increased risk of exposure to hepatitis B who were not vaccinated previously. **Adults 60 years or older** who are not at increased risk and were not vaccinated in the past may also be vaccinated.

Hepatitis B vaccine may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

Hepatitis B vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of hepatitis B vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone hepatitis B vaccination until a future visit.

CDC U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Hepatitis B Vaccine Information Sheet

“People sometimes use the term "informed consent" loosely when referring to VISs. VISs are written to fulfill the information requirements of the National Childhood Vaccine Injury Act, not as informed consent forms.”

“Some states have informed consent laws, covering either procedural requirements (e.g., whether consent may be oral or must be written) or substantive requirements (e.g., types of information required).”

VIS Frequently Asked Questions | Vaccines & Immunizations | CDC

Vaccine Information Statement: Hepatitis B Vaccine - What you need to know

Recombivax HB- Hep B vaccine given to babies on the first day of life

download (fda.gov)

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use RECOMBIVAX HB safely and effectively. See full prescribing information for RECOMBIVAX HB.

RECOMBIVAX HB® Hepatitis B Vaccine (Recombinant)
Suspension for intramuscular injection

6 ADVERSE REACTIONS

In healthy infants and children (up to 10 years of age), the most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever, diarrhea, fatigue/weakness, diminished appetite, and rhinitis. In healthy adults, injection site reactions and systemic adverse reactions were reported following 17% and 15% of the injections, respectively.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

In three clinical studies, 434 doses of RECOMBIVAX HB, 5 mcg, were administered to 147 healthy infants and children (up to 10 years of age) who were monitored for 5 days after each dose. Injection site reactions and systemic adverse reactions were reported following 0.2% and 10.4% of the injections, respectively. The most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever (≥101°F oral equivalent), diarrhea, fatigue/weakness, diminished appetite, and rhinitis.

Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries January 2, 2026

Tracy Beth Høeg, MD, Ph.D., Acting Director for the Center for Drug Evaluation and Research and FDA Ex Officio member to ACIP, and Martin Kulldorff, Ph.D., Chief Science and Data Officer for the Assistant Secretary for Planning and Evaluation, in consultation with experts at CDC, FDA, NIH, and CMS.

A successful childhood immunization program must be built on solid scientific evidence. This means:

1. **Approvals of new vaccines designed for mass uptake should be based on double blind placebo-controlled randomized trials.**
2. **For new vaccines, there must be a post market system in place to quickly detect unexpected adverse reactions.**
3. **In addition to acute adverse reactions, we must evaluate long-term effects on the immune system, such as asthma, autoimmune disease, neurological disorders, and non targeted infections. We have part of the infrastructure in place to this, but it has been underutilized.**
4. **In addition to individual vaccines, we must thoroughly evaluate the safety of the immunizations schedule, including cumulative effects, vaccine types and ingredients, the timing and order of vaccines and interaction effects. The IOM has long called for such studies but progress has been slow**

Considerations for H.545

1. Remove the liability shield in H.545.

2. Incorporate H.69 into H.545. Ensure the State, Legislators and Vermonters are informed of adverse events related to vaccines/immunizations. Early safety signals can prevent damage and death.
3.
4. H.69- Statement of purpose of bill as introduced: This bill proposes to require the Department of Health to submit an annual report to the General Assembly regarding adverse reactions reported to the Vaccine Adverse Event Reporting System. H-0069 As Introduced.pdf

5. Create a procedure for healthcare providers in Vermont administering vaccines in order to ensure and guarantee informed consent for patients and parents of children.

Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries January 2, 2026

Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries

To ensure a successful childhood vaccination program, the proposed updated schedule:

1. Recommends for all children all the vaccines for which there is consensus among peer nations.

2. Allows for more flexibility and choice, with less coercion, by reassigning non-consensus vaccines to certain high-risk groups and populations and/or based on shared clinical decision- making.

3. Ensures that all the diseases covered by the prior immunization schedule would still be available to anyone who wants them through their private health insurance, Medicaid, the Children's Health Insurance Program (CHIP), and/or the Vaccine for Children (VFC) Program. Among peer nations, the U.S. would continue to offer the greatest number of childhood vaccines for free to those who want them.

4. Is accompanied by a strengthening of vaccine research by launching double-blind placebo controlled randomized trials if appropriate and more observational studies to evaluate long- terms effects of individual vaccines and the vaccine schedule.

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