[INSERT STATE NAME]:

VACCINE MANDATES &
VACCINE EXEMPTIONS

ICAN

Informed
Consent
Action
Network

PART I:

K-12 MANDATED VACCINES IN [INSERT STATE NAME]

ICAN

Informed
Consent
Action
Network

VACCINES MANDATED FOR K-12 IN [INSERT STATE NAME]

[INSERT IMAGE OF REQUIRED K-12 VACCINES]

ARGUMENT USED TO JUSTIFY MANDATES:

THE PRODUCTS PREVENT TRANSMISSION!

OTHERWISE, WHY NOT MANDATE HEART MEDICINE?

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Search

Heart Disease

CDC > Heart Disease Home

- Heart Disease Home
- About Heart Disease
- Know Your Risk for Heart Disease
- Prevent Heart Disease
- Heart Disease Facts
- Heart Disease Communications Kit
- American Heart Month 2023 Toolkits

Other DHDSP Web Sites

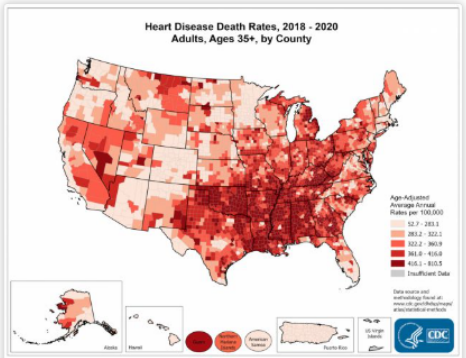
Heart Disease Facts

Print

Learn more about heart disease and its risk factors. It's important for everyone to know the facts about heart disease.

Heart Disease in the United States

- Heart disease is the **leading cause of death** for men, women, and people of most racial and ethnic groups in the United States.[1]
- **One person dies every 33 seconds** in the United States from cardiovascular disease.[1]
- About **695,000 people in the United States** died from heart disease in 2021—that's **1 in every 5 deaths**.[1,2]
- Heart disease cost the United States about **$239.9 billion** each year from 2018 to 2019.[3] This includes the cost of health care services, medicines, and lost productivity due to death.



Source: Interactive Atlas of Heart Disease and Stroke.

MOST SCHOOL-REQUIRED VACCINES DO **NOT** PREVENT TRANSMISSION OF THE DISEASE

PERTUSSIS

DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

December 30, 2021

Elizabeth Brehm
Siri & Glimstad
200 Park Ave, 17th Floor
New York, NY 10166
Via email: foia@sirillp.com

Dear Ms. Brehm:

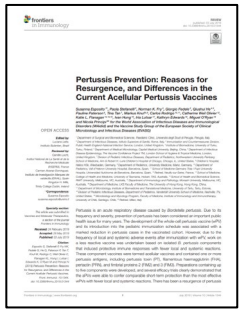
This letter is our final response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of September 28, 2020, assigned #20-02418-FOIA, for:

> *"Documents sufficient to reflect that acellular pertussis vaccines, while reducing symptoms from pertussis, do not prevent infection and transmission."*

Published scientific literature was used to inform the sentence in question ("Acellular pertussis vaccines may not prevent colonization (carrying the bacteria in your body without getting sick or spread of the bacteria."). For administrative convenience and to fully respond to your request, program staff have provided examples of literature that support the content of this sentence below.

Acellular pertussis vaccines protect against disease but fail to prevent infection and transmission in a nonhuman primate model.
https://pubmed.ncbi.nlm.nih.gov/24277828/

Pertussis Prevention: Reasons for Resurgence, and Differences in the Current Acellular Pertussis Vaccines
https://pubmed.ncbi.nlm.nih.gov/31333640/


Pertussis Prevention: Reasons for Resurgence, and Differences in the Current Acellular Pertussis Vaccines

PNAS

SEE COMMENTARY

Acellular pertussis vaccines protect against disease but fail to prevent infection and transmission in a nonhuman primate model

Jason M. Warfel, Li

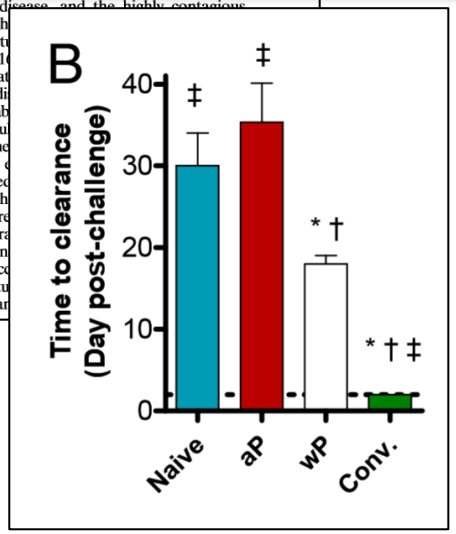
Center for Biologics Evaluation and Research, US Food and Drug Administration,

Division of Bacterial, Para

Edited by Rino Rappuoli

Pertussis is a highly contagious respiratory illness caused by the bacterial pathogen *Bordetella pertussis*. Pertussis rates in the United States have been rising and reached a 50-y high of 42,000 cases in 2012. Although pertussis resurgence is not completely understood, we hypothesize that current acellular pertussis (aP) vaccines fail to prevent colonization and transmission. To test our hypothesis, infant baboons were vaccinated at 2, 4, and 6 mo of age with aP or whole-cell pertussis (wP) vaccines and challenged with *B. pertussis* at 7 mo. Infection was followed by quantifying colonization in nasopharyngeal washes and monitoring leukocytosis and symptoms. Baboons vaccinated with aP were protected from severe pertussis-associated symptoms but not from colonization, did not clear the infection faster than naïve animals, and readily transmitted *B. pertussis* to unvaccinated contacts. Vaccination with wP induced a more rapid clearance compared with naïve and aP-vaccinated animals. By comparison, previously infected animals were not colonized upon secondary infection. Although all vaccinated and previously infected animals had robust serum anti-

therapeutic for established disease, and the highly contagious nature of pertussis. Although have been used to study pertu produce the human disease (1 developed a nonhuman primat (*Papio anubis*) and found the di pertussis. Upon challenge, bab spiratory colonization and leu 80,000 cells/mL, similar to the (1, 17). In addition, baboons ness characterized by repeated fits last on average >2 wk in th some severely infected childre 12 wk (1, 17). We also chara *B. pertussis* from infected to n transmission postulated to occ this is the only model of pertu and transmission of the humar



"aPVs [pertussis vaccine] … cannot avoid infection and transmission. … aPV pertussis vaccines do not prevent colonization. Consequently, they do not reduce the circulation of B. pertussis and do not exert any herd immunity effect."
https://pubmed.ncbi.nlm.nih.gov/31333640/

ICAN

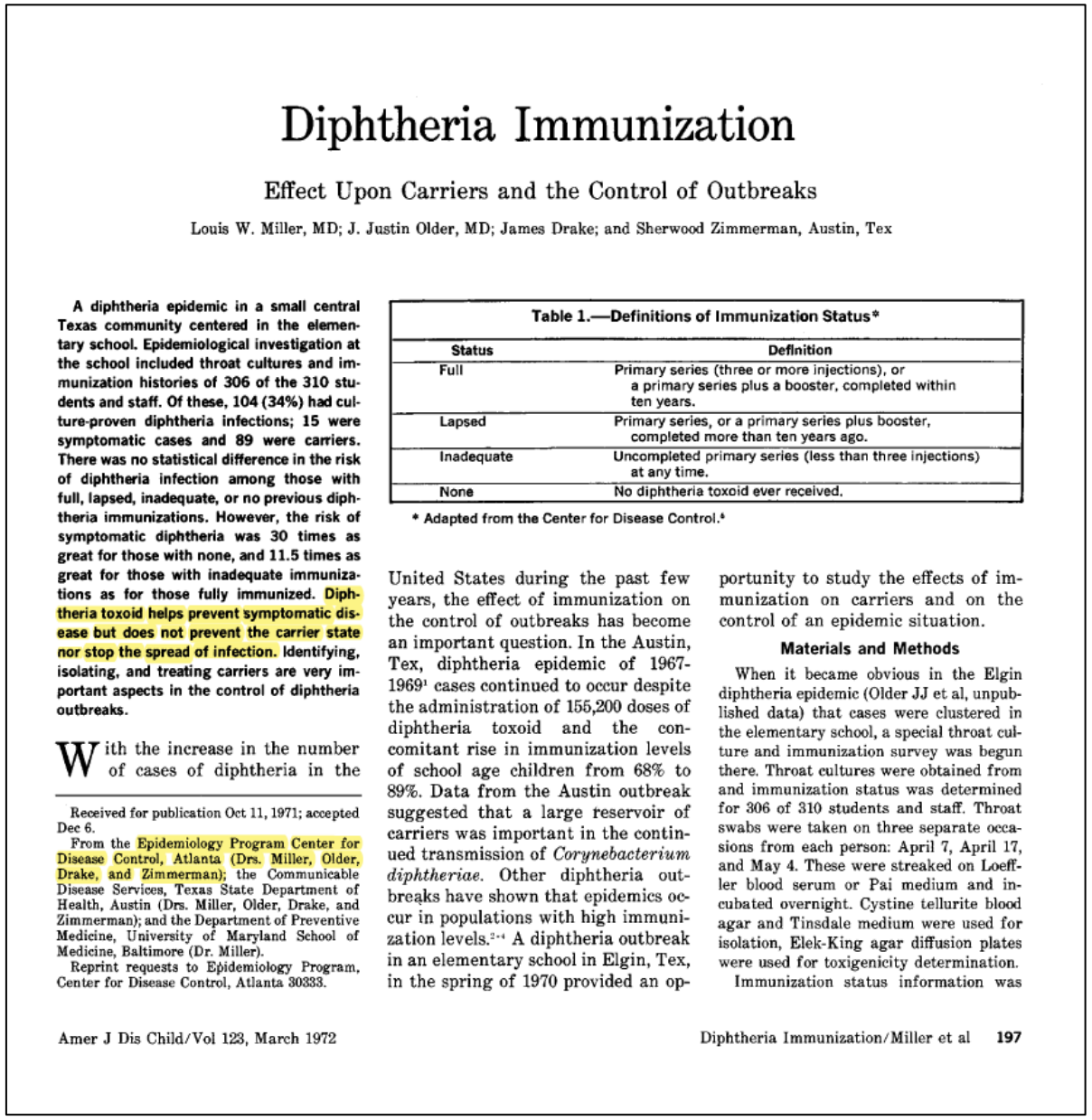
PERTUSSIS

A vaccine that reduces symptoms while allowing that person to transmit the disease makes that person more likely to transmit that disease.

Do we exclude children who are vaccinated for pertussis from school?

OF COURSE NOT!

DIPHTHERIA



Diphtheria Immunization

Effect Upon Carriers and the Control of Outbreaks

Louis W. Miller, MD; J. Justin Older, MD; James Drake; and Sherwood Zimmerman, Austin, Tex

A diphtheria epidemic in a small central Texas community centered in the elementary school. Epidemiological investigation at the school included throat cultures and immunization histories of 306 of the 310 students and staff. Of these, 104 (34%) had culture-proven diphtheria infections; 15 were symptomatic cases and 89 were carriers. There was no statistical difference in the risk of diphtheria infection among those with full, lapsed, inadequate, or no previous diphtheria immunizations. However, the risk of symptomatic diphtheria was 30 times as great for those with none, and 11.5 times as great for those with inadequate immunizations as for those fully immunized. Diphtheria toxoid helps prevent symptomatic disease but does not prevent the carrier state nor stop the spread of infection. Identifying, isolating, and treating carriers are very important aspects in the control of diphtheria outbreaks.

Table 1.—Definitions of Immunization Status*

Status	Definition
Full	Primary series (three or more injections), or a primary series plus a booster, completed within ten years.
Lapsed	Primary series, or a primary series plus booster, completed more than ten years ago.
Inadequate	Uncompleted primary series (less than three injections) at any time.
None	No diphtheria toxoid ever received.

* Adapted from the Center for Disease Control.[4]

With the increase in the number of cases of diphtheria in the United States during the past few years, the effect of immunization on the control of outbreaks has become an important question. In the Austin, Tex, diphtheria epidemic of 1967-1969[1] cases continued to occur despite the administration of 155,200 doses of diphtheria toxoid and the concomitant rise in immunization levels of school age children from 68% to 89%. Data from the Austin outbreak suggested that a large reservoir of carriers was important in the continued transmission of *Corynebacterium diphtheriae*. Other diphtheria outbreaks have shown that epidemics occur in populations with high immunization levels.[2-4] A diphtheria outbreak in an elementary school in Elgin, Tex, in the spring of 1970 provided an opportunity to study the effects of immunization on carriers and on the control of an epidemic situation.

Materials and Methods

When it became obvious in the Elgin diphtheria epidemic (Older JJ et al, unpublished data) that cases were clustered in the elementary school, a special throat culture and immunization survey was begun there. Throat cultures were obtained from and immunization status was determined for 306 of 310 students and staff. Throat swabs were taken on three separate occasions from each person: April 7, April 17, and May 4. These were streaked on Loeffler blood serum or Pai medium and incubated overnight. Cystine tellurite blood agar and Tinsdale medium were used for isolation, Elek-King agar diffusion plates were used for toxigenicity determination.

Immunization status information was

Received for publication Oct 11, 1971; accepted Dec 6.

From the Epidemiology Program Center for Disease Control, Atlanta (Drs. Miller, Older, Drake, and Zimmerman); the Communicable Disease Services, Texas State Department of Health, Austin (Drs. Miller, Older, Drake, and Zimmerman); and the Department of Preventive Medicine, University of Maryland School of Medicine, Baltimore (Dr. Miller).

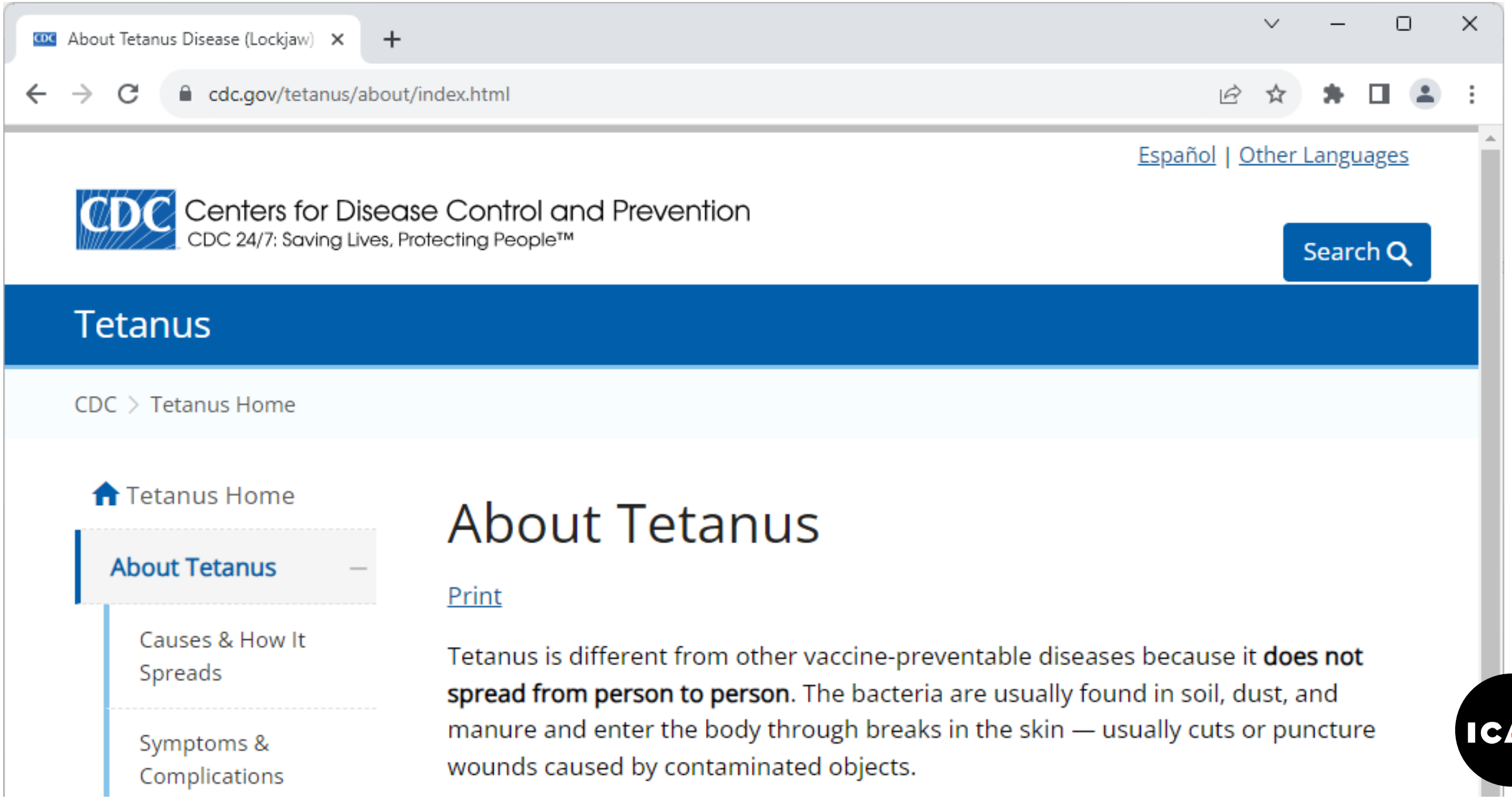
Reprint requests to Epidemiology Program, Center for Disease Control, Atlanta 30333.

"Diphtheria toxoid helps prevent symptomatic disease but does not prevent the carrier state nor stop the spread of infection … [T]he concept of herd immunity is not applicable in the prevention of diphtheria."

https://www.ncbi.nlm.nih.gov/pubmed/5026197

ICAN

TETANUS


About Tetanus Disease (Lockjaw)
cdc.gov/tetanus/about/index.html
Español | Other Languages
CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™
Search
Tetanus
CDC > Tetanus Home
Tetanus Home
About Tetanus
Causes & How It Spreads
Symptoms & Complications
About Tetanus
Print
Tetanus is different from other vaccine-preventable diseases because it does not spread from person to person. The bacteria are usually found in soil, dust, and manure and enter the body through breaks in the skin — usually cuts or puncture wounds caused by contaminated objects.

POLIO

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Search

U.S. National Authority for Containment of Poliovirus

Office of Readiness and Response > Poliovirus Containment

Poliovirus Containment

Poliovirus Disease & Poliovirus

Polio Disease and Poliovirus Containment

Print

Inactivated poliovirus vaccine

IPV protects people against all three types of poliovirus. IPV does not contain live virus and cannot cause disease. It protects people from polio disease but does not stop transmission of the virus.

ICAN

POLIO

Disadvantages

- IPV induces very low levels of immunity in the intestine. As a result, when a person immunized with IPV is infected with wild poliovirus, the virus can still multiply inside the intestines and be shed in the faeces, risking continued circulation.

  IPV does not stop transmission of the virus

https://polioeradication.org/polio-today/polio-prevention/the-vaccines/ipv/

ICAN

MENINGOCOCCAL

"Rates of meningococcal disease have declined in the United States since the 1990s and remain low today. Much of the decline occurred before the routine use of MenACWY vaccines. … [D]ata suggest MenACWY vaccines have provided protection to those vaccinated, but probably not to the larger, unvaccinated community (population or herd immunity)."

https://www.cdc.gov/vaccines/vpd/mening/public/index.html

HEPATITIS B

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

November 30, 2020

Elizabeth Brehm
Siri & Glimstad
200 Park Ave, 17th Floor
New York, NY 10166
Via email: foia@sirillp.com

Dear Ms. Brehm:

This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of November 9, 2020, for 'documentation sufficient to reflect any case(s) of transmission of Hepatitis B in an elementary, middle, or high school setting.'

A search of our records failed to reveal any documents pertaining to your request.

CHICKEN POX

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

VARIVAX®
Varicella Virus Vaccine Live
Suspension for intramuscular or subcutaneous injection
Initial U.S. Approval: 1995

- Evaluate individuals for immune competence prior to administration of VARIVAX if there is a family history of congenital or hereditary immunodeficiency. (5.1)
- Avoid close contact with high-risk individuals susceptible to varicella because of possible transmission of varicella vaccine virus. (5.3)
- Immune Globulins (IG) and other blood products should not be given concomitantly with VARIVAX. (5.4, 7.2)
- Avoid use of salicylates for 6 weeks following administration of VARIVAX to children and adolescents. (5.5, 7.1)

5.3 Risk of Vaccine Virus Transmission

Post-marketing experience suggests that transmission of varicella vaccine virus (Oka/Merck) resulting in varicella infection including disseminated disease may occur between vaccine recipients (who develop or do not develop a varicella-like rash) and contacts susceptible to varicella including healthy as well as high-risk individuals.

Due to the concern for transmission of vaccine virus, vaccine recipients should attempt to avoid whenever possible close association with susceptible high-risk individuals for up to six weeks following vaccination with VARIVAX. Susceptible high-risk individuals include:

- Immunocompromised individuals;
- Pregnant women without documented history of varicella or laboratory evidence of prior infection;
- Newborn infants of mothers without documented history of varicella or laboratory evidence of prior infection and all newborn infants born at <28 weeks gestation regardless of maternal varicella immunity.

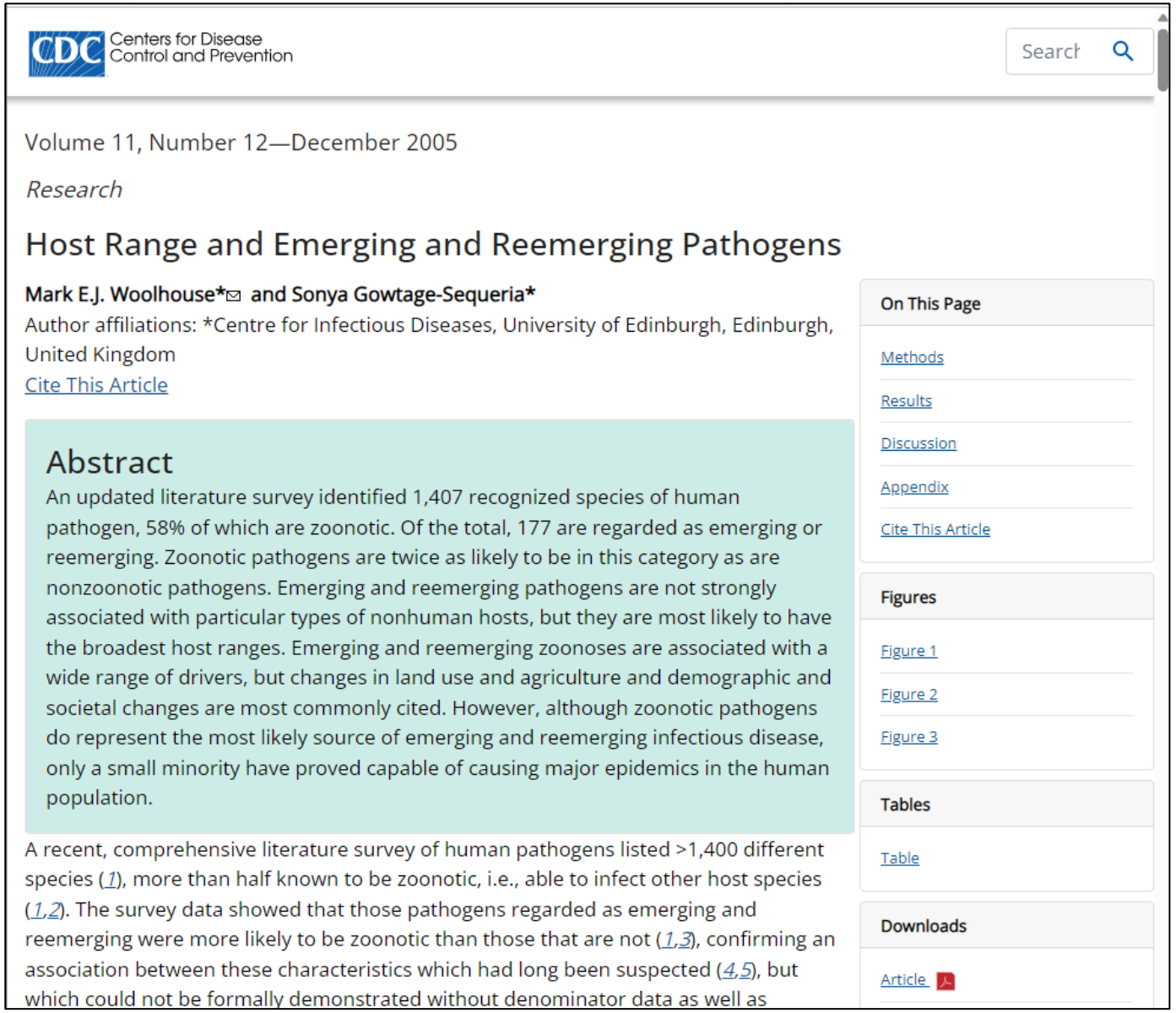
Do we exclude children vaccinated for chicken pox from school because they can transmit it for up to six weeks following vaccination?

OF COURSE NOT!

https://www.fda.gov/media/76008/download

ICAN

CHICKEN POX



CDC Centers for Disease Control and Prevention

Search

Volume 11, Number 12—December 2005

Research

Host Range and Emerging and Reemerging Pathogens

Mark E.J. Woolhouse*✉ and Sonya Gowtage-Sequeria*
Author affiliations: *Centre for Infectious Diseases, University of Edinburgh, Edinburgh, United Kingdom

Cite This Article

Abstract

An updated literature survey identified 1,407 recognized species of human pathogen, 58% of which are zoonotic. Of the total, 177 are regarded as emerging or reemerging. Zoonotic pathogens are twice as likely to be in this category as are nonzoonotic pathogens. Emerging and reemerging pathogens are not strongly associated with particular types of nonhuman hosts, but they are most likely to have the broadest host ranges. Emerging and reemerging zoonoses are associated with a wide range of drivers, but changes in land use and agriculture and demographic and societal changes are most commonly cited. However, although zoonotic pathogens do represent the most likely source of emerging and reemerging infectious disease, only a small minority have proved capable of causing major epidemics in the human population.

A recent, comprehensive literature survey of human pathogens listed >1,400 different species (*1*), more than half known to be zoonotic, i.e., able to infect other host species (*1*,*2*). The survey data showed that those pathogens regarded as emerging and reemerging were more likely to be zoonotic than those that are not (*1*,*3*), confirming an association between these characteristics which had long been suspected (*4*,*5*), but which could not be formally demonstrated without denominator data as well as

On This Page

Methods
Results
Discussion
Appendix
Cite This Article

Figures

Figure 1
Figure 2
Figure 3

Tables

Table

Downloads

Article

"literature survey identified 1,407 recognized species of human pathogen"

Children that can be harmed from chicken pox, can be from these 1,407 other pathogens, and are not in school.

MMR

"Everyone will die without MMR vaccine!"

Annual deaths pre-vaccine and pre-modern medicine:

Vaccine	Licensed	Appx. Annual Deaths in 3 Years Prior (U.S.)	Death Rate (U.S.)
Measles	1963	400	1 in 500,000
Mumps	1967	35	1 in 6,000,000
Rubella	1969	15	1 in 13,000,000
Total		**450**	**1 in 450,000**

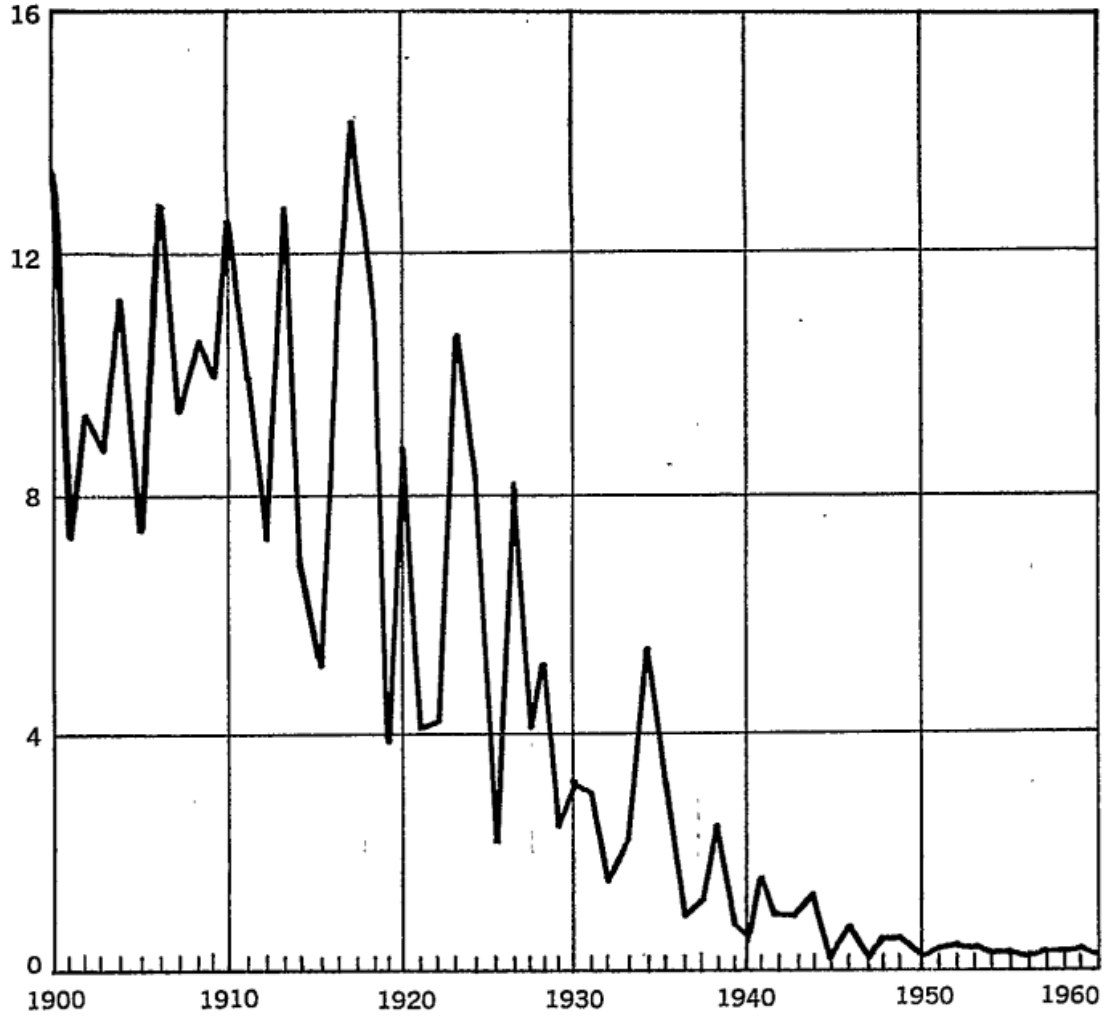
ICAN

MEASLES

First measles vaccine licensed in 1963

Figure 19.—Death Rates for Measles: Death-registration States, 1900–32, and United States, 1933–60

(Rates per 100,000 population).



https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf

MEASLES

Current MMR vaccine licensed in 1978: 834 children in trial, no control, & Only 42 days of safety review

Tabl_ _0

Clinical Complaints Reported Among Children Who Received a 0.5 Ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-0763 (Study #443)

Clinical Complaint	Total Vaccinees (102 Children) Days Post-Vaccination 0-4	5-12	13-18	19-28	29-42	No. with Complaint	Initially Seronegative to: Measles, Mumps and Rubella (68 Children) Days Post-Vaccination 0-4	5-12	13-18	19-28	29-42	No. with Complaint
Soreness at Injection Site	4 (4.2%)			1 (1.0)		5	2 (3.0)					2
Lymphadenopathy	2 (2.1)	3 (3.1)		2 (2.1)	2 (2.1)	6	1 (1.5)	1 (1.5)		2 (3.0)	2 (3.0)	3
Measles-Like Rash	1 (1.0)	9 (9.4)	6 (6.2)	1 (1.0)		11	1 (1.5)	7 (10.4)	5 (7.5)	1 (1.5)		9
Arthralgia			1 (1.0)	1 (1.0)		1			1 (1.5)	1 (1.5)		1
Myalgia		1 (1.0)				1		1 (1.5)				1
Irritability	3 (3.0)	3 (3.0)	1 (1.0)	1 (1.0)	1 (1.0)	4	2 (2.9)	2 (2.9)	1 (1.5)	1 (1.5)		3
Headache	2 (2.1)	2 (2.1)				2	2 (3.0)	2 (3.0)				2
Upper Respiratory Illness	38 (39.6)	37 (38.5)	24 (25.0)	35 (36.5)	32 (33.3)	64	28 (41.8)	27 (40.3)	20 (29.8)	25 (37.3)	20 (29.8)	46
Otitis	1 (1.0)	7 (7.3)	2 (2.1)	5 (5.2)	4 (4.2)	14	1 (1.5)	4 (6.0)	2 (3.0)	3 (4.5)	2 (3.0)	9
Ophthalmopathy	2 (2.1)	3 (3.1)	2 (2.1)	4 (4.2)	2 (2.1)	6	2 (3.0)	3 (4.5)	2 (3.0)	4 (6.0)	2 (3.0)	6
Gastrointestinal Illness	18 (18.7)	24 (25.0)	9 (9.4)	17 (17.7)	15 (15.6)	43	14 (20.9)	19 (28.4)	9 (13.4)	14 (20.9)	11 (16.4)	35
Anorexia	13 (13.5)	19 (19.8)	8 (8.3)	10 (10.4)	13 (13.5)	28	10 (14.9)	12 (17.9)	6 (9.0)	9 (13.4)	11 (16.4)	20
Fatigue				1 (1.0)		1				1 (1.5)		1
Rash-Chafing, Diaper, Heat, Herpes	4 (4.2)	4 (4.2)	1 (1.0)	4 (4.2)	5 (5.2)	12	3 (4.5)	4 (6.0)	1 (1.5)	3 (4.5)	3 (4.5)	9
Allergy, Asthma	1 (1.0)	2 (2.1)	3 (3.1)	2 (2.1)	3 (3.1)	6		1 (1.5)	2 (3.0)	1 (1.5)		3
Fever	1 (1.0)	1 (1.0)		2 (2.1)	1 (1.0)	4		1 (1.5)		1 (1.5)		2
Sudoresis	1 (1.0)					1	1 (1.5)					1
Teething	3 (3.0)			1 (1.0)	3 (3.0)	6	3 (4.4)			1 (1.5)	3 (4.4)	6
Persons with Complaints:	50 (52.1)	50 (52.1)	33 (34.4)	43 (44.8)	44 (45.8)	78	38 (56.7)	38 (56.7)	29 (43.3)	32 (47.8)	30 (44.8)	58
Persons with No Complaints:	46 (47.9)	46 (47.9)	63 (65.6)	53 (55.2)	52 (54.2)	18	29 (43.3)	29 (43.3)	38 (56.7)	35 (52.2)	37 (55.2)	9
Negative Physician Surveillance	6	6	6	6	6	6	1	1	1	1	1	1

Note: A similar trial was relied upon to license the original MMR in 1971

https://sirillp.com/MMR-clinical-trial

ICAN

MEASLES

Only 3 routine childhood vaccines in 1986: MMR, DTP, and OPV.

TABLE 1. Recommended schedule for active immunization of normal infants and children (See individual ACIP recommendations for details.)

Recommended age*	Vaccine(s)†	Comments
2 mo.	DTP-1,§ OPV-1¶	Can be given earlier in areas of high endemicity
4 mo.	DTP-2, OPV-2	6-wks-2-mo. interval desired between OPV doses to avoid interference
6 mo.	DTP-3	An additional dose of OPV at this time is optional for use in areas with a high risk of polio exposure
15 mo.**	MMR††	
18 mo.**	DTP-4, OPV-3	Completion of primary series
4-6 yr.§§	DTP-5, OPV-4	Preferably at or before school entry
14-16. yr	Td¶¶	Repeat every 10 years throughout life

*These recommended ages should not be construed as absolute, i.e. 2 mos. can be 6-10 weeks, etc.

†For all products used, consult manufacturer's package enclosure for instructions for storage, handling, and administration. Immunobiologics prepared by different manufacturers may vary, and those of the same manufacturer may change from time to time. The package insert should be followed for a specific product.

§DTP—Diphtheria and tetanus toxoids and pertussis vaccine.

¶OPV—Oral, attenuated poliovirus vaccine contains poliovirus types 1, 2, and 3.

**Simultaneous administration of MMR, DTP, and OPV is appropriate for patients whose compliance with medical care recommendations cannot be assured.

††MMR—Live measles, mumps, and rubella viruses in a combined vaccine (see text for discussion of single vaccines versus combination).

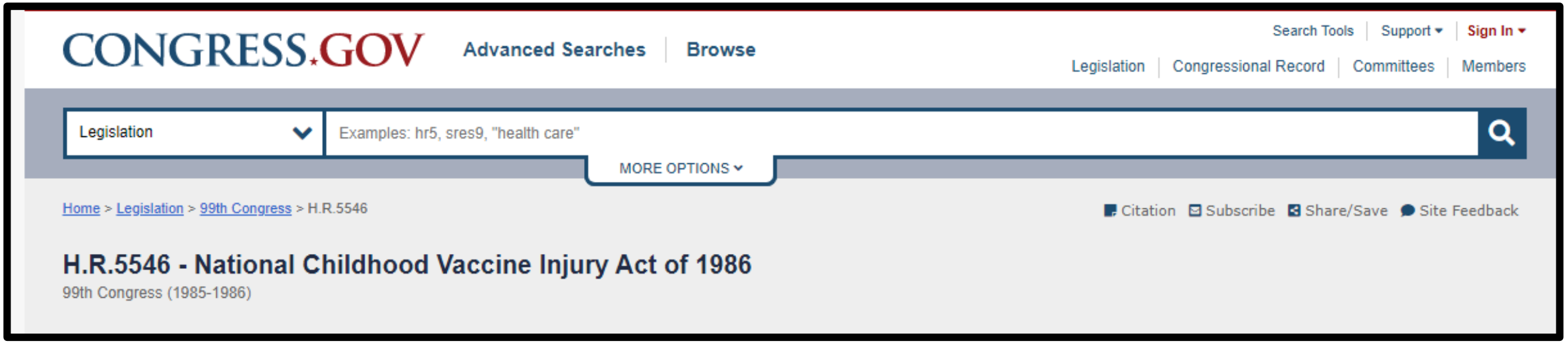
§§Up to the seventh birthday.

¶¶Td—Adult tetanus toxoid and diphtheria toxoid in combination, which contains the same dose of tetanus toxoid as DTP or DT and a reduced dose of diphtheria toxoid.

1983 childhood immunization schedule

ICAN

MEASLES



- 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")

- *Bruesewitz v. Wyeth*, 562 U.S. 223 ("[W]e hold that the National Childhood Vaccine Injury Act pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by a vaccine side effects.")

The 1986 Act: NO OTHER CONSUMER PRODUCT ENJOYS THIS DEGREE OF IMMUNITY

MEASLES

(NOT RISK FREE)

VACCINE INFORMATION STATEMENT

MMR (Measles, Mumps, and Rubella) 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

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible.

Getting MMR vaccine is much safer than getting measles, mumps, or rubella disease. Most people who get MMR vaccine do not have any problems with it.

After MMR vaccination, a person might experience:

Minor events:

- Sore arm from the injection
- Fever
- Redness or rash at the injection site
- Swelling of glands in the cheeks or neck

If these events happen, they usually begin within 2 weeks after the shot. They occur less often after the second dose.

Moderate events:

- Seizure (jerking or staring) often associated with fever
- Temporary pain and stiffness in the joints, mostly in teenage or adult women
- Temporary low platelet count, which can cause unusual bleeding or bruising
- Rash all over body

Severe events occur very rarely:

- Deafness
- Long-term seizures, coma, or lowered consciousness
- Brain damage

Other things that could happen after this vaccine:

- People sometimes faint after medical procedures,

a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 and get to the nearest hospital. Otherwise, call your health care provider.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

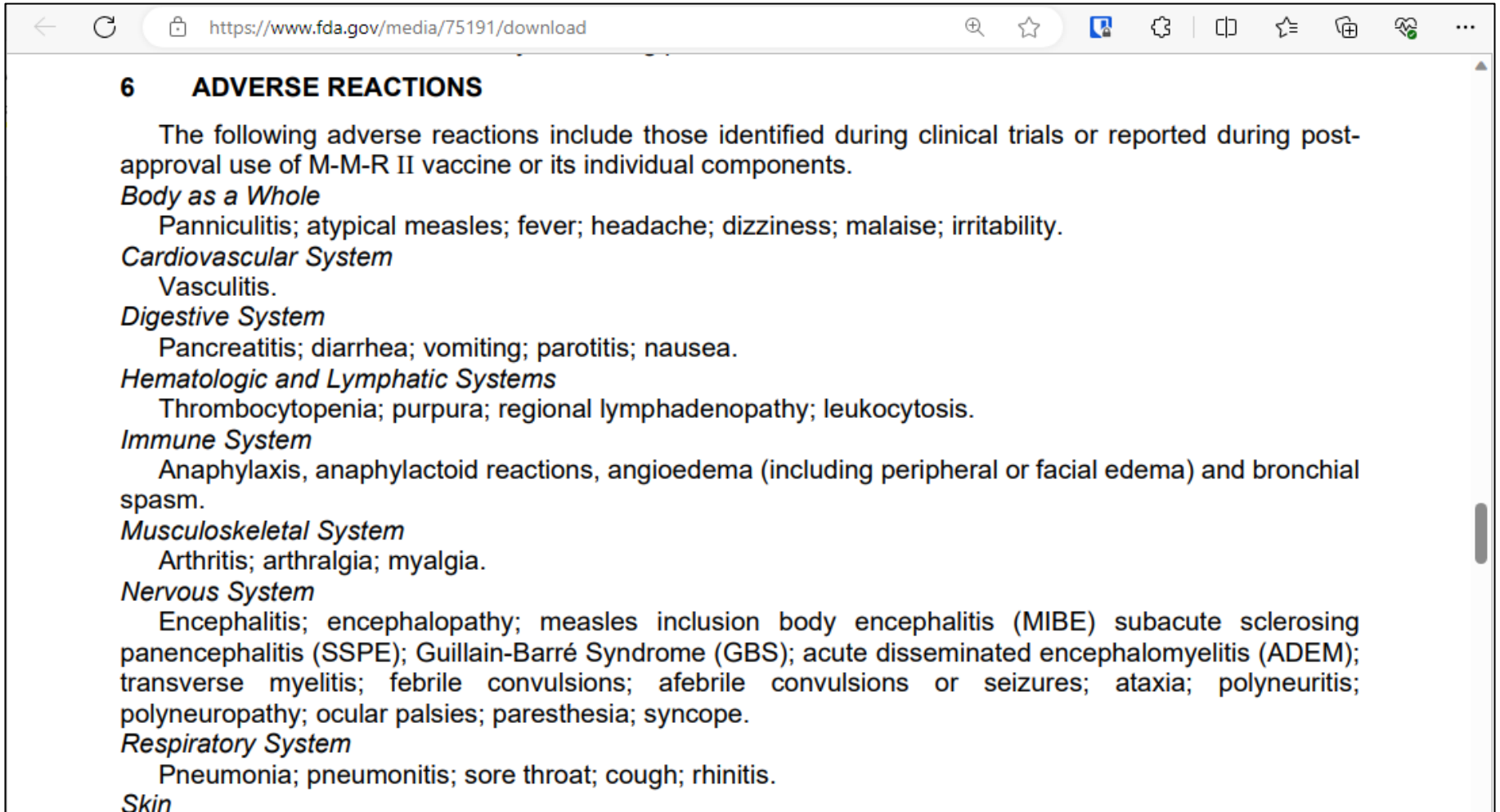
Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**. There is a time limit to file a claim for compensation.

7 How can I learn more?

ICAN

MEASLES

Federal law provides that package inserts for vaccines should include "***only*** **those adverse events for which there is some basis to believe there is a *causal relationship* between the drug and the occurrence of the adverse event.**" 21 CFR 201.57



6 ADVERSE REACTIONS

The following adverse reactions include those identified during clinical trials or reported during post-approval use of M-M-R II vaccine or its individual components.

Body as a Whole

Panniculitis; atypical measles; fever; headache; dizziness; malaise; irritability.

Cardiovascular System

Vasculitis.

Digestive System

Pancreatitis; diarrhea; vomiting; parotitis; nausea.

Hematologic and Lymphatic Systems

Thrombocytopenia; purpura; regional lymphadenopathy; leukocytosis.

Immune System

Anaphylaxis, anaphylactoid reactions, angioedema (including peripheral or facial edema) and bronchial spasm.

Musculoskeletal System

Arthritis; arthralgia; myalgia.

Nervous System

Encephalitis; encephalopathy; measles inclusion body encephalitis (MIBE) subacute sclerosing panencephalitis (SSPE); Guillain-Barré Syndrome (GBS); acute disseminated encephalomyelitis (ADEM); transverse myelitis; febrile convulsions; afebrile convulsions or seizures; ataxia; polyneuritis; polyneuropathy; ocular palsies; paresthesia; syncope.

Respiratory System

Pneumonia; pneumonitis; sore throat; cough; rhinitis.

Skin

Journal of the Pediatric Infectious Diseases Society
ORIGINAL ARTICLE

MEASLES

Immunogenicity and Safety of a Measles-Mumps-Rubella Vaccine Administered as a First Dose to Children Aged 12 to 15 Months: A Phase III, Randomized, Noninferiority, Lot-to-Lot Consistency Study

Supplementary Table 6. Incidence of unsolicited adverse events (Day 0–42), serious adverse events, AEs prompting emergency room visits and NOCDs (Day 0–180) (total vaccinated cohort).

n (%)	MMR-RIT (N=3714)	MMR II (N=1289)
Unsolicited AEs (≥1 symptom)	1857 (50.0)	618 (47.9)
Grade 3	225 (6.1)	85 (6.6)
SAEs (any, ≥1 SAE)	77 (2.1)	25 (1.9)
AEs prompting ER visit	375 (10.1)	134 (10.4)
NOCDs (any, ≥1 NOCD)	128 (3.4)	48 (3.7)

AE, adverse event; ER, emergency room; N, number of children with the documented dose; n (%), number (percentage) of children reporting the AE at least once; NOCDs, new onset chronic diseases (see definition in Patients and methods); SAE, serious AE.
Grade 3 unsolicited AEs were those preventing normal, everyday activities.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7192400/

ICAN

VACCINES MANDATED FOR K-12 IN [INSERT NAME OF STATE]

DTaP

IPV

Men

HepB

VAR

MMR

ICAN

PART II:

ELIMINATION OF THE MARKET FORCES ASSURING SAFETY

HOW IS PRODUCT SAFETY ASSURED?

MARKET FORCES!

REGULATORS

Eliminating market forces is a big deal!

VACCINE SCHEDULE EXPLODES

Guaranteed Market + No Liability =

1986

DTP (2 months)
OPV (2 months)

DTP (4 months)
OPV (4 months)

DTP (6 months)

MMR (15 months)

DTP (18 months)
OPV (18 months)

DTP (4 years)
OPV (4 years)

T (14 years)

2023

Hepatitis B (one day)

Hepatitis B (one month)

DTaP (2 months)
IPV (2 months)
Hib (2 months)
PCV (2 months)
Rotavirus (2 months)

DTaP (4 months)
IPV (4 months)
Hib (4 months)
PCV (4 months)
Rotavirus (4 months)

DTaP (6 months)
IPV (6 months)
Hepatitis B (6 months)
Hib (6 months)
PCV (6 months)
Covid-19 (6 months)
Rotavirus (6 months)
Influenza (6 months)

Covid-19 (8 months)

MMR (12 months)
Varicella (12 months)
Hib (12 months)
Hepatitis A (12 months)
PCV (12 months)
Covid-19 (12 months)

DTaP (15 months)

Hepatitis A (18 months)
Influenza (18 months)

Influenza (2 years)

Influenza (3 years)

Influenza (4 years)
DTaP (4 years)
MMR (4 years)
IPV (4 years)
Varicella (4 years)

Influenza (5 years)

Influenza (6 years)

Influenza (7 years)

Influenza (8 years)

Influenza (9 years)

Influenza (10 years)

HPV (11 years)
Men ACWY (11 years)
Influenza (11 years)
Tdap (11 years)

HPV (11 ½ years)

Influenza (12 years)

Influenza (13 years)

Influenza (14 years)

Influenza (15 years)

Men ACWY (16 years)
Influenza (16 years)

Influenza (17 years)

1983 CDC Vaccine Schedule: https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg
2023 CDC Vaccine Schedule: https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

ICAN

VACCINE SCHEDULE EXPLODES

Guaranteed Market + No Liability =

1986

Hepatitis B (one day)

Hepatitis B (one month)

DTaP (2 months)
IPV (2 months)
Hib (2 months)
PCV (2 months)
Rotavirus (2 months)
DTP (2 months)
OPV (2 months)

DTaP (4 months)
IPV (4 months)
Hib (4 months)
PCV (4 months)
Rotavirus (4 months)
DTP (4 months)
OPV (4 months)

DTaP (6 months)
IPV (6 months)
Hepatitis B (6 months)
Hib (6 months)
PCV (6 months)
Covid-19 (6 months)
Rotavirus (6 months)
Influenza (6 months)
DTP (6 months)

Covid-19 (8 months)

MMR (12 months)
Varicella (12 months)
Hib (12 months)
Hepatitis A (12 months)
PCV (12 months)
Covid-19 (12 months)

2023

DTaP (15 months)
MMR (15 months)

Hepatitis A (18 months)
Influenza (18 months)
DTP (18 months)
OPV (18 months)

Influenza (2 years)

Influenza (3 years)

Influenza (4 years)
DTaP (4 years)
MMR (4 years)
IPV (4 years)
Varicella (4 years)
DTP (4 years)
OPV (4 years)

Influenza (5 years)

Influenza (6 years)

Influenza (7 years)

Influenza (8 years)

Influenza (9 years)

Influenza (10 years)

HPV (11 years)
Men ACWY (11 years)
Influenza (11 years)
Tdap (11 years)

HPV (11 ½ years)

Influenza (12 years)

Influenza (13 years)

Influenza (14 years)
T (14 years)

Influenza (15 years)

Men ACWY (16 years)
Influenza (16 years)

Influenza (17 years)

1983 CDC Vaccine Schedule: https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg
2023 CDC Vaccine Schedule: https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

ICAN

PART III:
CLINICAL TRIALS

CLINICAL TRIALS

Why are placebo-controlled clinical trials critical?

THEY ARE HOW CAUSATION BETWEEN THE PRODUCT AND AN ADVERSE EVENT IS DETERMINED

ICAN

CLINICAL TRIALS

Impact of Eliminating Market Forces

Pfizer's Top 5 Selling Drugs of All Time*		
DRUG	**SAFETY REVIEW PERIOD**	**CONTROL USED**
Enbrel (Pfizer)	6.6 years	Placebo
Eliquis (Pfizer)	7.4 years+	Placebo
PCV13 (Pfizer)	½ year	PCV7
Lyrica (Pfizer)	2 years+	Placebo
Lipitor (Pfizer)	4.9 years+	Placebo

Vaccines in First 6 Months of Life (3x Each)**		
VACCINE	**SAFETY REVIEW PERIOD**	**CONTROL USED**
Hep-B (Merck)	5 days	None
IPV (Sanofi)	3 days	None
Hib (Merck)	3 days	Hib
DTaP (GSK)	28 days	DTP
PCV13 (Pfizer)	6 months	PCV7

* https://moneyinc.com/the-five-highest-selling-pfizer-drugs-of-all-time/
** https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf
Source for all data: https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

ICAN

CLINICAL TRIALS

Example: First Shot on CDC Schedule

Table 1 — COVID-19 vaccination recommendations have changed. Find the latest recommendations at www.cdc.gov/covidschedule

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2023

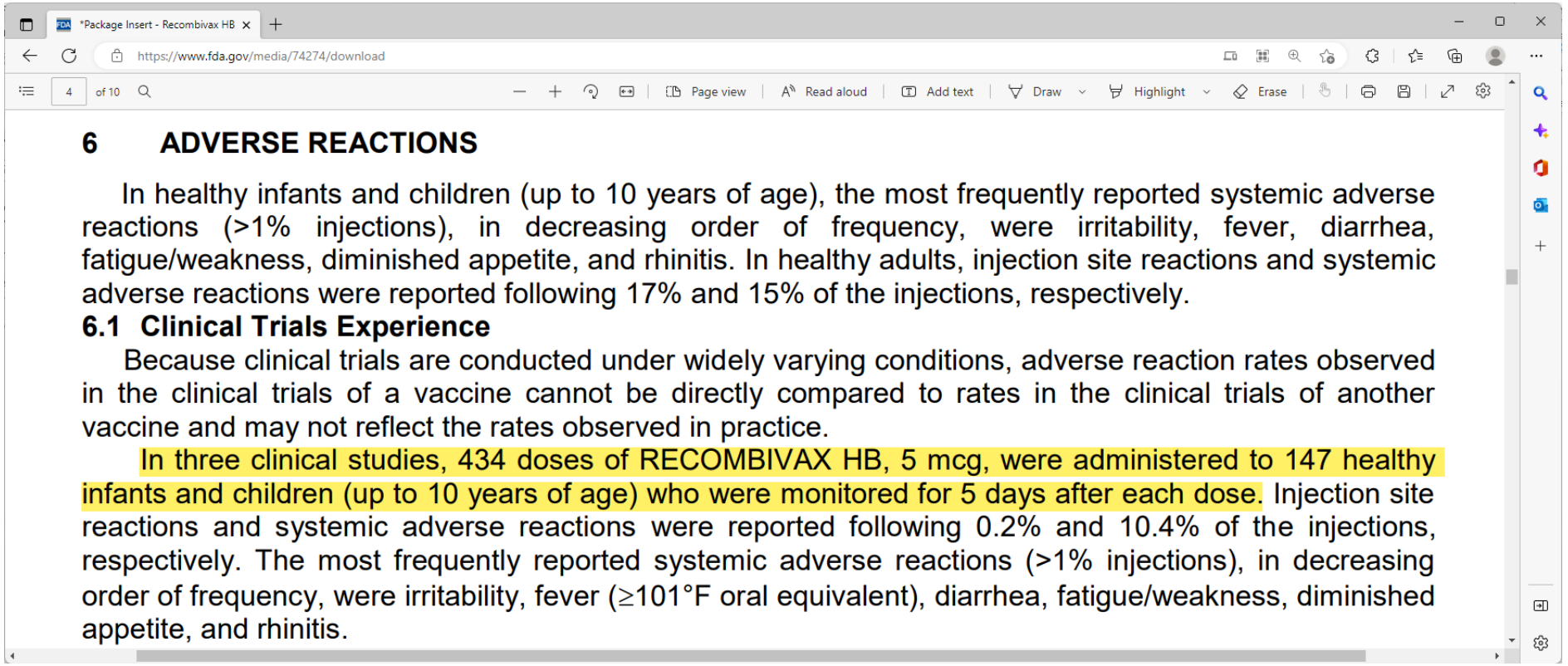
These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs
Hepatitis B (HepB)	1st dose	◄----- 2nd dose -----►			◄---------- 3rd dose ----------►												
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1st dose	2nd dose	See Notes												
Diphtheria, tetanus, acellular pertussis (DTaP <7 yrs)			1st dose	2nd dose	3rd dose			◄----- 4th dose -----►				5th dose					
***Haemophilus influenzae* type b (Hib)**			1st dose	2nd dose	See Notes		◄ 3rd or 4th dose, See Notes ►										
Pneumococcal conjugate (PCV13, PCV15)			1st dose	2nd dose	3rd dose		◄----- 4th dose -----►										
Inactivated poliovirus (IPV <18 yrs)			1st dose	2nd dose	◄---------- 3rd dose ----------►							4th dose					
COVID-19 (1vCOV-mRNA, 2vCOV-mRNA, 1vCOV-aPS)					2- or 3- dose primary series and booster (See Notes)												

ICAN

CLINICAL TRIALS

Clinical Trial for Hep B Vaccine



*Package Insert - Recombivax HB

https://www.fda.gov/media/74274/download

4 of 10 Page view Read aloud Add text Draw Highlight Erase

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

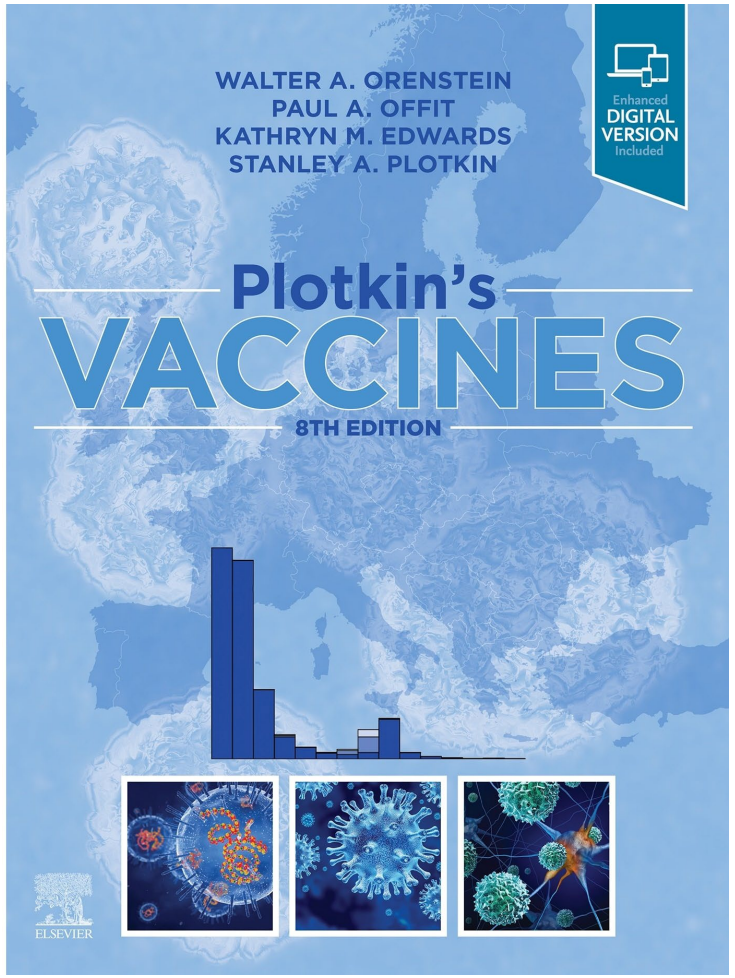
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

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.

Hep B Package Insert: https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states
Hep B Clinical Trial Report: https://icandecide.org/wp-content/uploads/2020/09/COMBINED-02.pdf
Hep B Petition to FDA to Withdraw Licensure https://www.regulations.gov/document/FDA-2020-P-1857-0001

ICAN

CLINICAL TRIALS



Full Deposition: https://thehighwire.com/page/1/?s=stanley+plotkin

CLINICAL TRIALS

Clinical trials for Covid-19 vaccines, by comparison, were robust.

CLINICAL TRIALS

www.google.com

Google “fda licensed vaccines” and first result is https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states which lists every licensed vaccine and trial data.

PART IV:
POST-LICENSURE SAFETY

POST-LICENSURE SAFETY

Maybe the trials were not great, but after licensure, these products were definitely studied! Right?!?!

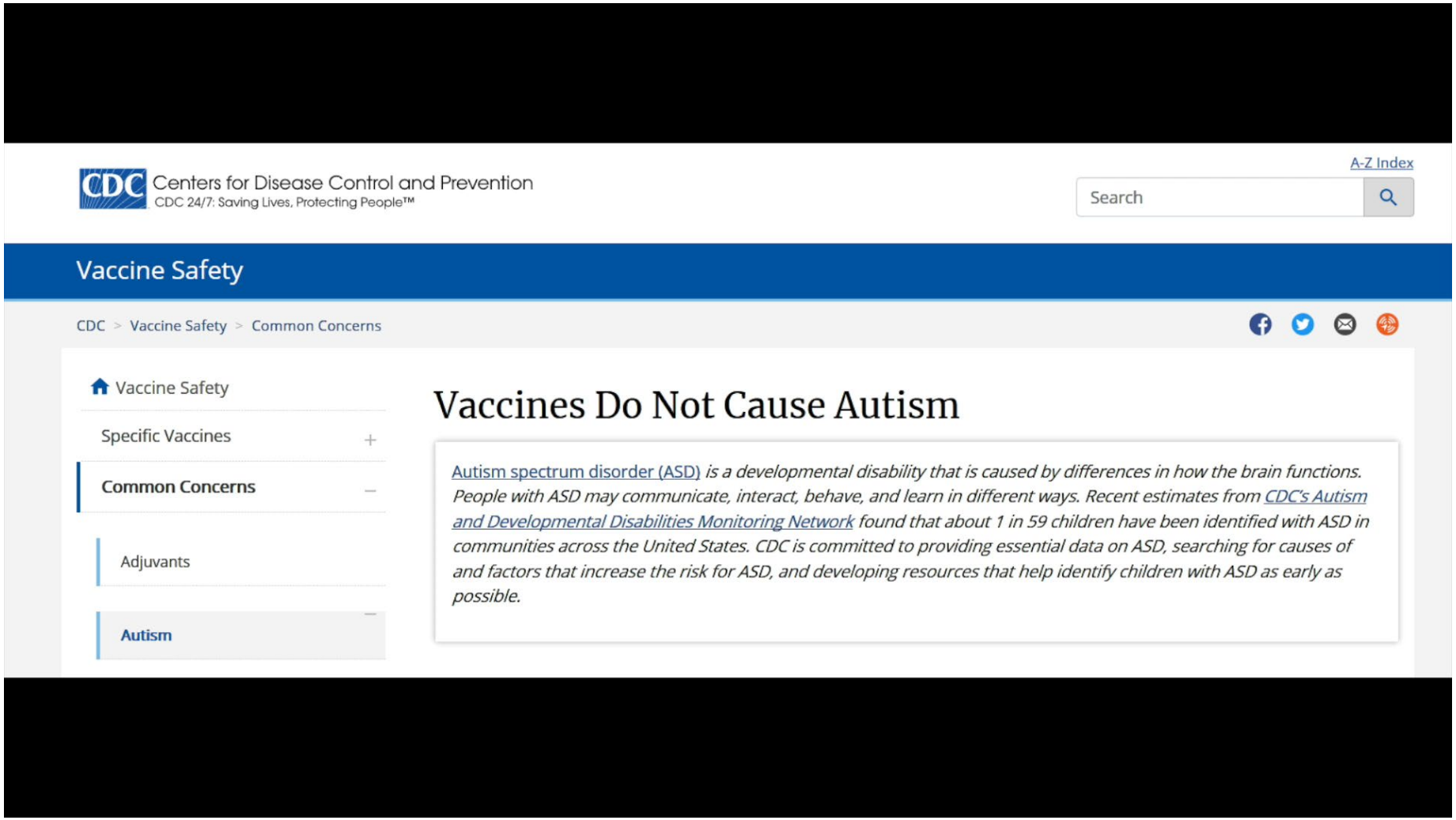
"Rest assured, vaccines do not cause _____!"

POST-LICENSURE SAFETY

If autism and vaccines was not properly studied, think about what that means regarding the over 100 other serious adverse events complained of after vaccines and how their safety was studied.

So, let's use autism as the litmus test.

POST-LICENSURE SAFETY



POST-LICENSURE SAFETY

Depending on the study, 40% to 70% of autism parents blame vaccines for their child's autism.

J Autism Dev Disord
DOI 10.1007/s10803-014-2310-8

ORIGINAL PAPER

Emergence of Autism Spectrum Disorder in Children from Simplex Families: Relations to Parental Perceptions of Etiology

0196-206X/06/2702-0156
Copyright © 2006 by Lippincott Williams & Wilkins, Inc.

Vol. 27, No. 2, April 2006
Printed in U.S.A.

Parental Perceptions and Use of Complementary and Alternative Medicine Practices for Children with Autistic Spectrum Disorders in Private Practice

JOHN W. HARRINGTON, M.D.
LAWRENCE ROSEN, M.D.
ANA GARNECHO, M.D.
Department of Pediatrics, New York Medical College
Maria Fareri Children's Hospital, Westchester Medical Center
PATRICIA A. PATRICK, M.P.H.
Department of Medicine, New York Medical College
Primary Care Research Unit, New York Medical College, Valhalla, NY

Introduction

Journal of Genetic Counseling, Vol. 15, No. 1, February 2006 (© 2006)
DOI: 10.1007/s10897-005-9002-7

Original Paper

Parental Perspectives on the Causes of an Autism Spectrum Disorder in their Children

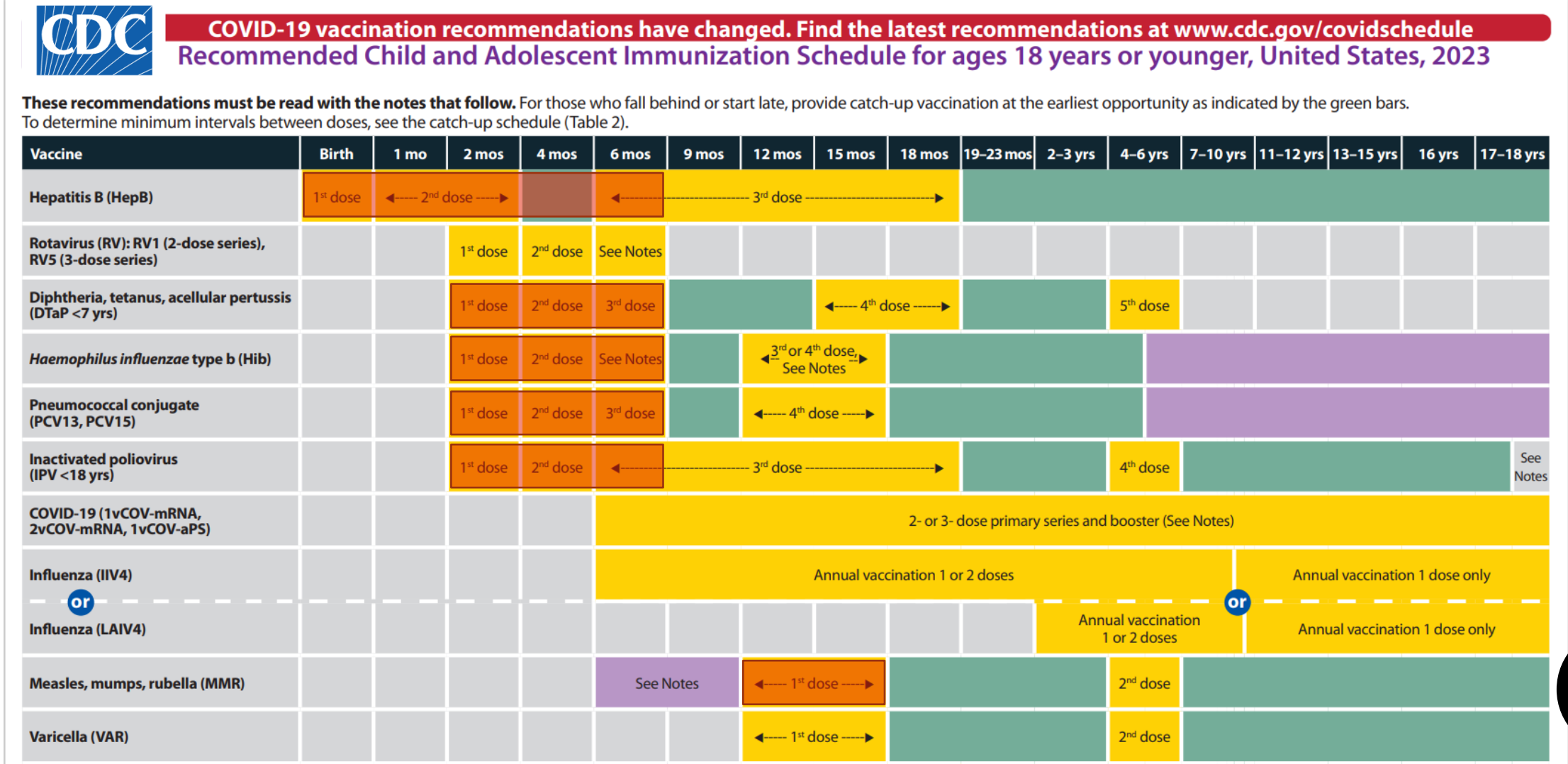
L. Mercer,[1,2] S. Creighton,[1,2] J. J. A. Holden,[2,3] and M. E. S. Lewis[1,2,4]

Published Online: 18 March 2006

ICAN

POST-LICENSURE SAFETY

Which vaccines do parents blame?



POST-LICENSURE SAFETY

YEAR

1986

1991

2008

2012

2018
2019
2020

2023

TITLE III—VACCINE COMPENSATION

National Childhood Vaccine Injury Act of 1986.
42 USC 201.

SEC. 301. SHORT TITLE.

This title may be cited as the "National Childhood Vaccine Injury Act of 1986".

SEC. 312. RELATED STUDIES.

42 USC 300aa-1 note.

(a) REVIEW OF PERTUSSIS VACCINES AND RELATED ILLNESSES AND CONDITIONS.—Not later than 3 years after the effective date of this title, the Secretary of Health and Human Services shall complete a review of all relevant medical and scientific information (including information obtained from the studies required under subsection (e)) on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the following illnesses and conditions:

(1) Hemolytic anemia.
(2) Hypsarrhythmia.
(3) Infantile spasms.
(4) Reye's syndrome.
(5) Peripheral mononeuropathy.
(6) Deaths classified as sudden infant death syndrome.
(7) Aseptic meningitis.
(8) Juvenile diabetes.
(9) Autism.
(10) Learning disabilities.
(11) Hyperactivity.

ICAN

POST-LICENSURE SAFETY

YEAR
1986
1991
2008
2012
2018
2019
2020
2023

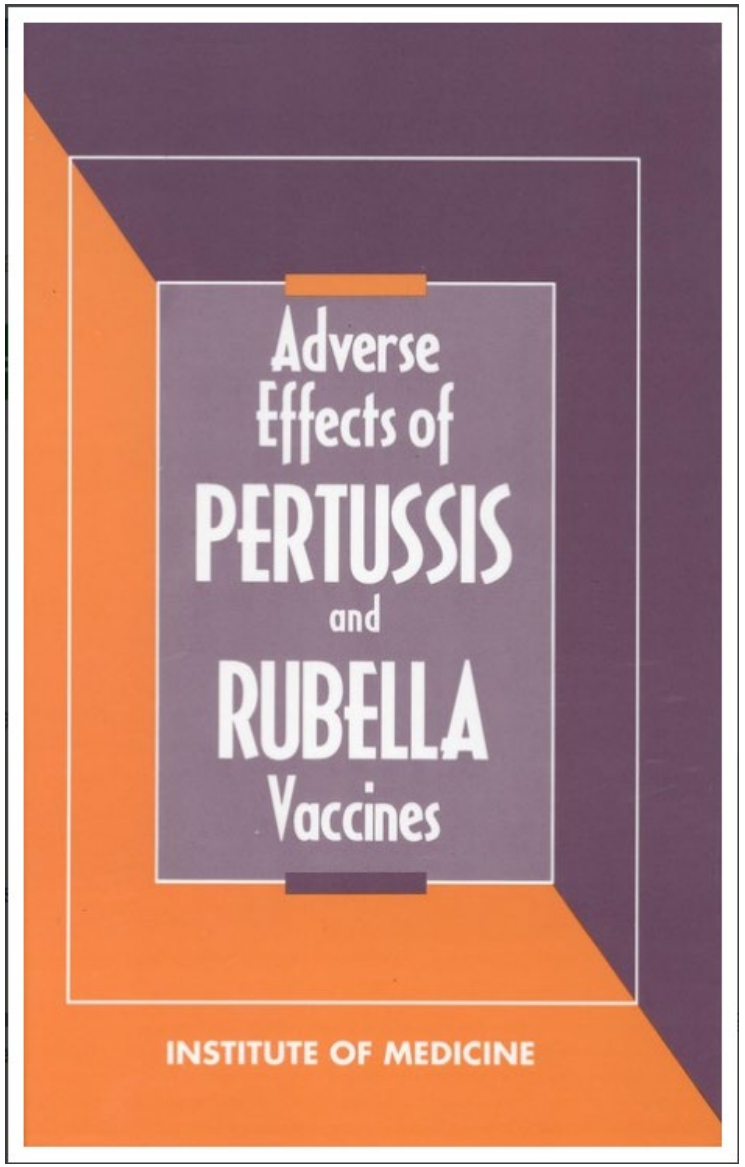


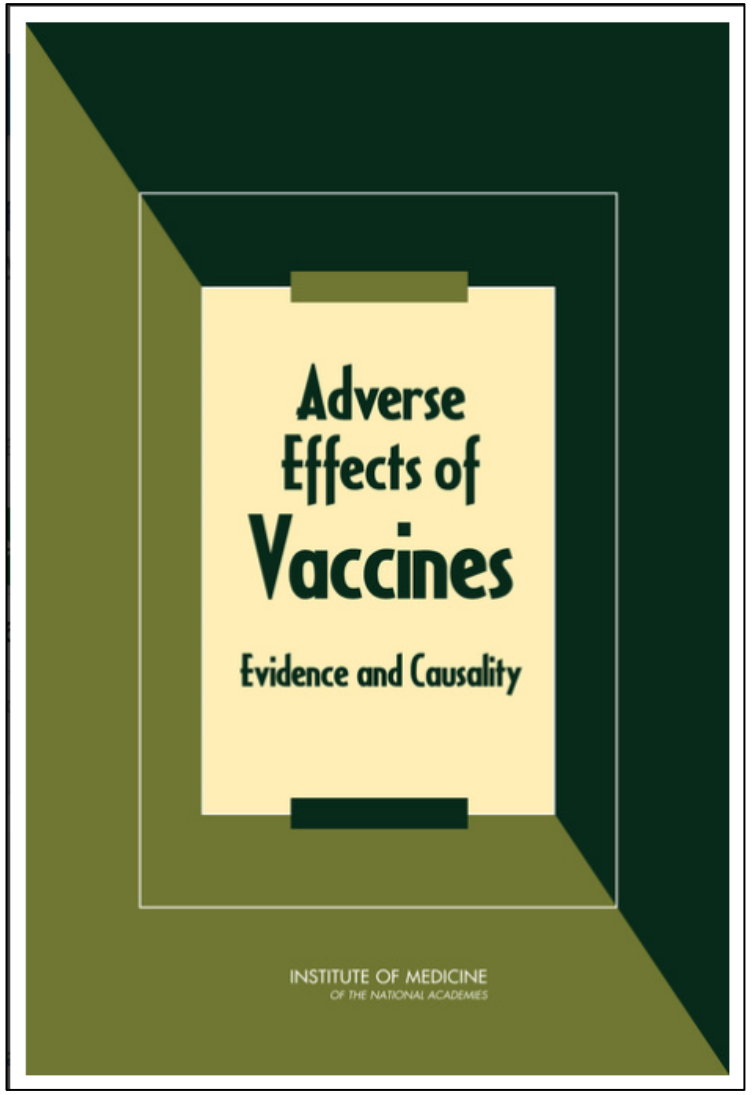
TABLE 1-2 Summary of Conclusions by Adverse Event for DPT[a] and RA 27/3 MMR[b] Vaccines

Conclusion	Adverse Events Reviewed: DPT Vaccine	Adverse Events Reviewed: RA 27/3 Rubella Vaccine
1. No evidence bearing on a causal relation[c]	Autism	
	or other rash Guillain-Barré syndrome Hemolytic anemia Juvenile diabetes Learning disabilities and attention-deficit disorder Peripheral mononeuropathy Thrombocytopenia	
3. Evidence does not indicate a causal relation[e]	Infantile spasms Hypsarrythmia Reye syndrome Sudden infant death syndrome	
4. Evidence is consistent with a causal relation[f]	Acute encephalopathy[g] Shock and "unusual shock-like state"	Chronic arthritis
5. Evidence indicates a causal relation[h]	Anaphylaxis Protracted, inconsolable crying	Acute arthritis

[c]No category of evidence was found bearing on a judgment about causation (all categories of evidence left blank in Table 1-1).

POST-LICENSURE SAFETY

YEAR
1986
1991
2008
2012
2018
2019
2020
2023



AUTISM

Epidemiologic Evidence

The committee reviewed one study to evaluate the risk of autism after the administration of DTaP vaccine. This one study (Geier and Geier, 2004) was not considered in the weight of epidemiologic evidence because it provided data from a passive surveillance system and lacked an unvaccinated comparison population.

Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.

Mechanistic Evidence

The committee did not identify literature reporting clinical, diagnostic, or experimental evidence of autism after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens alone or in combination.

Weight of Mechanistic Evidence

The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism as lacking.

Causality Conclusion

Conclusion 10.6: The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.

ICAN

POST-LICENSURE SAFETY

YEAR

1986

1991

2008

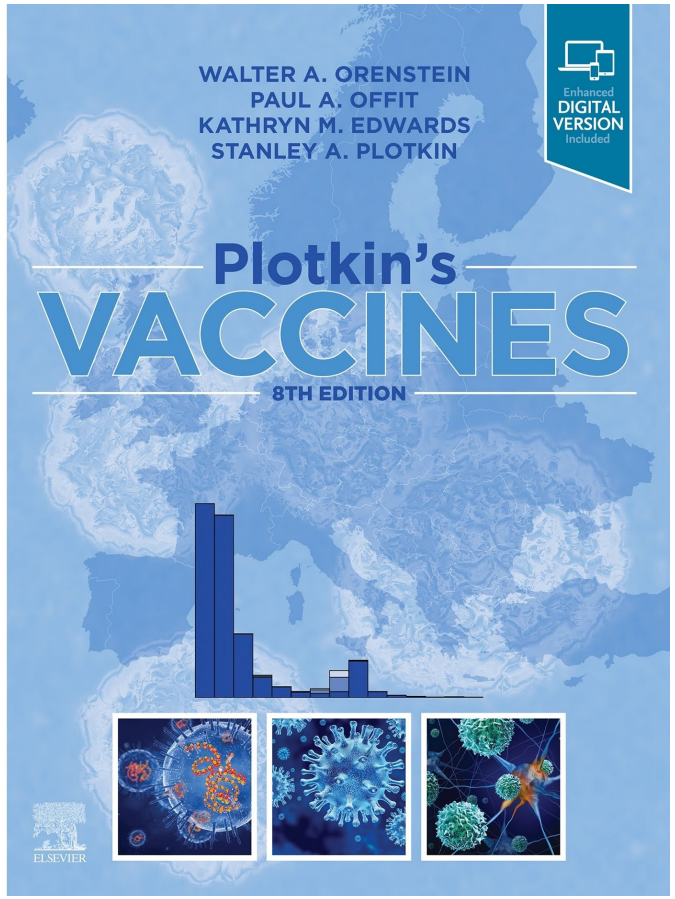
2012

2018

2019

2020

2023



[redacted]

Full Deposition: https://thehighwire.com/page/1/?s=stanley+plotkin

ICAN

POST-LICENSURE SAFETY

YEAR
1986
1991
2008
2012
2018
2019
2020
2023

FOIA to CDC demanding:

- "All studies relied upon by CDC to claim that the DTaP vaccine does not cause autism."
- "All studies relied upon by CDC to claim that neither Engerix-B nor Recombivax HB do not cause autism."
- "All studies relied upon by CDC to claim that Prevnar 13 does not cause autism."
- "All studies relied upon by CDC to claim that Hib vaccines do not cause autism."
- "All studies relied upon by CDC to claim that inactivated polio vaccine ('IPV') does not cause autism."
- "Copies of the studies the CDC relies upon to claim that the cumulative exposure of vaccines it recommends that babies be administered during the first six months of life do not cause autism."

https://icandecide.org/wp-content/uploads/2020/03/Stipulation-and-Order-Fully-Exec

ICAN

POST-LICENSURE SAFETY

YEAR

1986

1991

2008

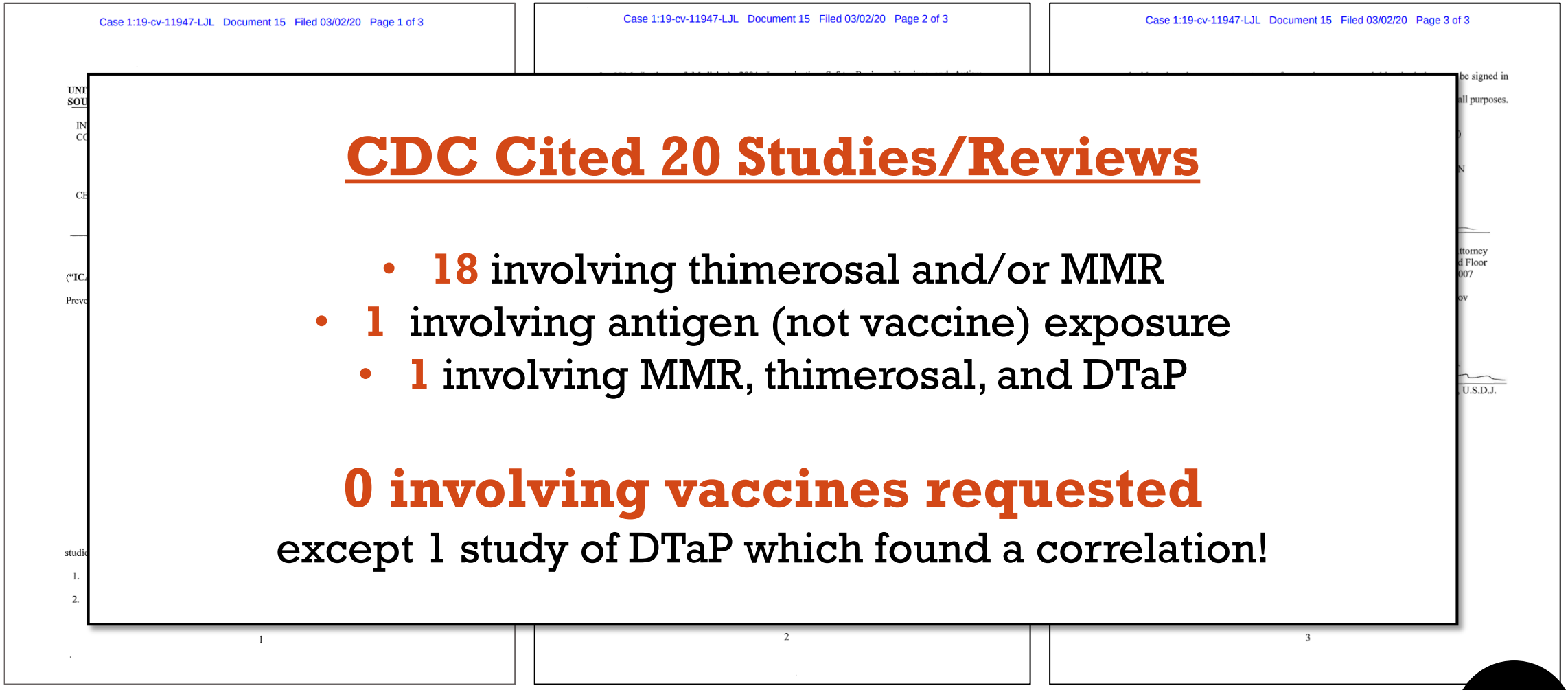
2012

2018

2019

2020

2023



https://icandecide.org/wp-content/uploads/2020/03/Stipulation-and-Order-Fully-Executed.pdf

ICAN

POST-LICENSURE SAFETY

YEAR

1986

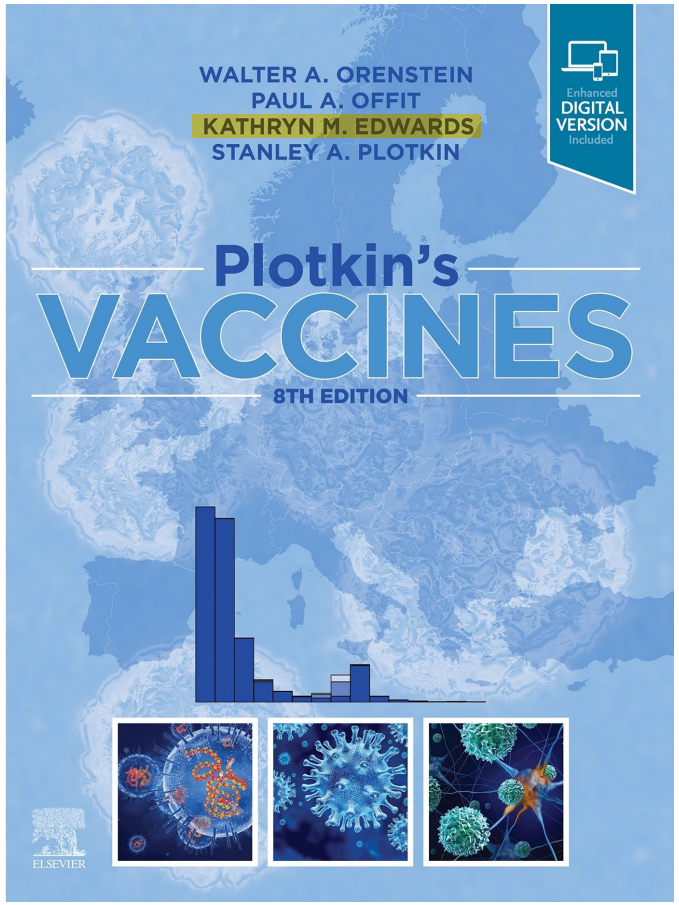
1991

2008

2012

2018
2019
2020

2023



Full Deposition: https://thehighwire.com/videos/the-deposition-of-the-godmother-of-vaccines-dr-kathryn-edwards/

ICAN

POST-LICENSURE SAFETY

Childhood Vaccines

YEAR	
1986	Hepatitis B (1 day) Hepatitis B (1 month)
1991	DTaP (2 months) Polio (2 months) Hib (2 months) PCV (2 months) Rotavirus (2 months)
2008	DTaP (4 months) Polio (4 months) Hib (4 months) PCV (4 months) Rotavirus (4 months)
2012	DTaP (6 months) Polio (6 months) Hepatitis B (6 months) Hib (6 months) PCV (6 months) Rotavirus (6 months) Influenza (6 months) **MMR (12 months)**
2018 2019 2020	Varicella (12 months) Hib (12 months) Hepatitis A(12 months) PCV (12 months) DTaP (15 months) Hepatitis A(18 months) Influenza (18 months) Influenza (2 years) Influenza (3 years) Influenza (4 years) DTaP (4 years) **MMR (4 years)** IPV (4 years) Varicella (4 years) Influenza (5 years) Influenza (6 years) Influenza (7 years) Influenza (8 years)
2023	Influenza (9 years) Influenza (10 years) HPV (11 years) Men ACWY (11 years) Influenza (11 years) TDaP (11 years) HPV (11 ½ years) Influenza (12 years) Influenza (13 years) Influenza (14 years) Influenza (15 years) Men ACWY (16 years) Influenza (16 years) Influenza (17 years) Influenza (18 years)

Vaccine Ingredients

(Partial List)

2-phenoxethanol
Complex fermentation medium
Eagle MEM modified medium
Enzymes
Formaldehyde
Gelatin
Glutaraldehyde
Guinea pig cell cultures
Hydrolyzed porcine gelatin
Human-diploid fibroblast cell cultures
Human embryonic lung cell cultures
Human serum albumin
Lactalbumin hydrolysate
Madin Darby Canine Kidney cell protein
Medium 199
Minimum Essential Medium
Modified Mueller's growth medium
Modified Stainer-Scholte liquid medium
MRC-5 human diploid cells
Neomycin
Neomycin Sulphate
Phenol polymyxin B
Polymyxin B Sulphate
Polysorbate 80
Soy Peptone
Stainer-Scholte medium
Streptomycin
WI-38 human diploid lung fibroblasts
Yeast
Yeast Protein
thimerosal

ICAN

POST-LICENSURE SAFETY

POST-LICENSURE SAFETY

Fede…es should
inclu… **is some**
basi… **ween the**
drug… 201.57

Chi… **r 100**
seri… harma
bec… **ere is**
a ca…

https://www.fda.gov/media/74274/download

Immune System Disorders

Hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria have been reported within the first few hours after vaccination. An apparent hypersensitivity syndrome (serum-sickness-like) of delayed onset has been reported days to weeks after vaccination, including: arthralgia/arthritis (usually transient), fever, and dermatologic reactions such as urticaria, erythema multiforme, ecchymoses and erythema nodosum *[see Warnings and Precautions (5.1)]*. Autoimmune diseases including systemic lupus erythematosus (SLE), lupus-like syndrome, vasculitis, and polyarteritis nodosa have also been reported.

Gastrointestinal Disorders

Elevation of liver enzymes; constipation

Nervous System Disorders

Guillain-Barré syndrome; multiple sclerosis; exacerbation of multiple sclerosis; myelitis including transverse myelitis; seizure; febrile seizure; peripheral neuropathy including Bell's Palsy; radiculopathy; herpes zoster; migraine; muscle weakness; hypesthesia; encephalitis

Skin and Subcutaneous Disorders

FDA Package Insert - SPIKEVAX.

https://www.fda.gov/media/155675/download

Cardiac Disorders: myocarditis, pericarditis
Immune System Disorders: anaphylaxis
Nervous System Disorders: syncope

Cardiac Disorders

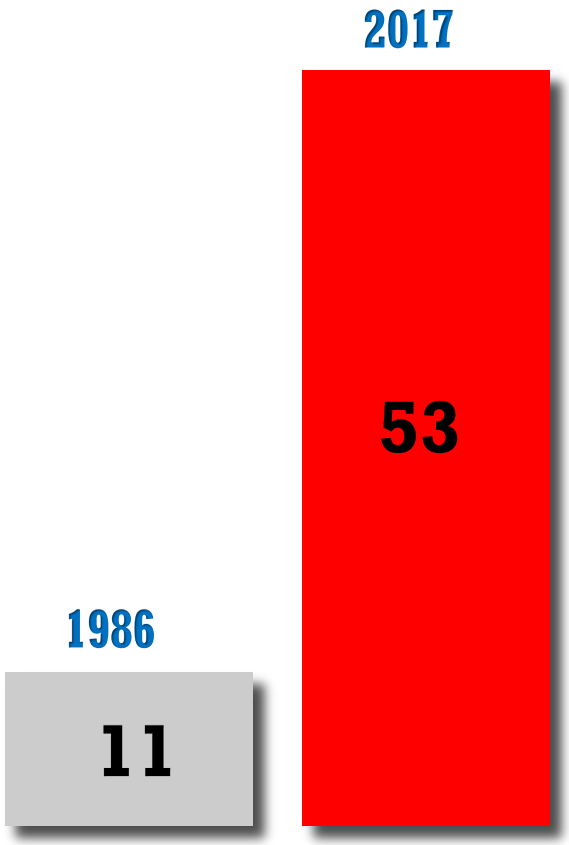
Syncope; tachycardia

www.icandecide.org/vaccine-safety-debate/
or www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

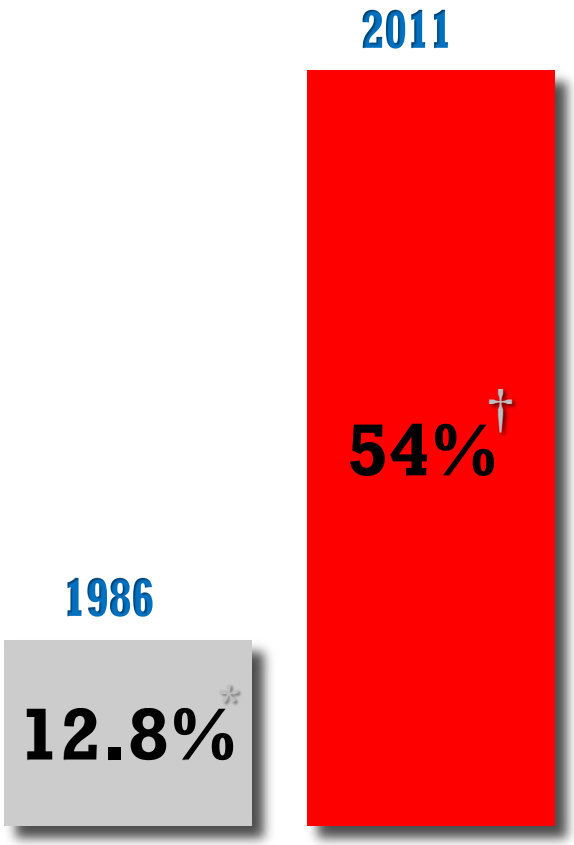
ICAN

POST-LICENSURE SAFETY

Number of Childhood Vaccines



Prevalence of Chronic Childhood Illness



* Cleave et. al, 2010, *Dynamics of Obesity and Chronic Health Conditions Among Children and Youth*, JAMA.

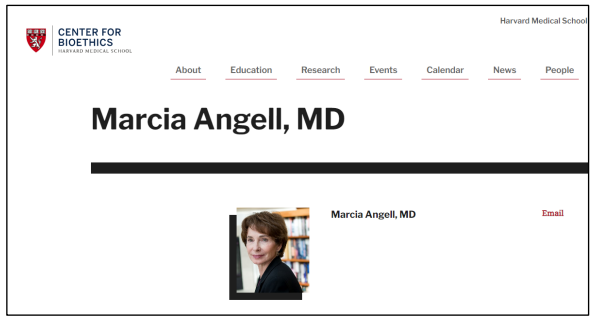
†Bethel et. al, 2011, *A National and State Profile of Leading Health Problems and Health Care Quality for US Children: Key Insurance Disparities and Across-State Variations*, Academic Pediatrics.

ICAN

POST-LICENSURE SAFETY

Pharma has Annual Kitty of Billions of Dollars

- Medical Journals
- Medical Associations
- Medical Schools
- Public Relations Firms
- News Advertising
- Lobbyists (1,400+)

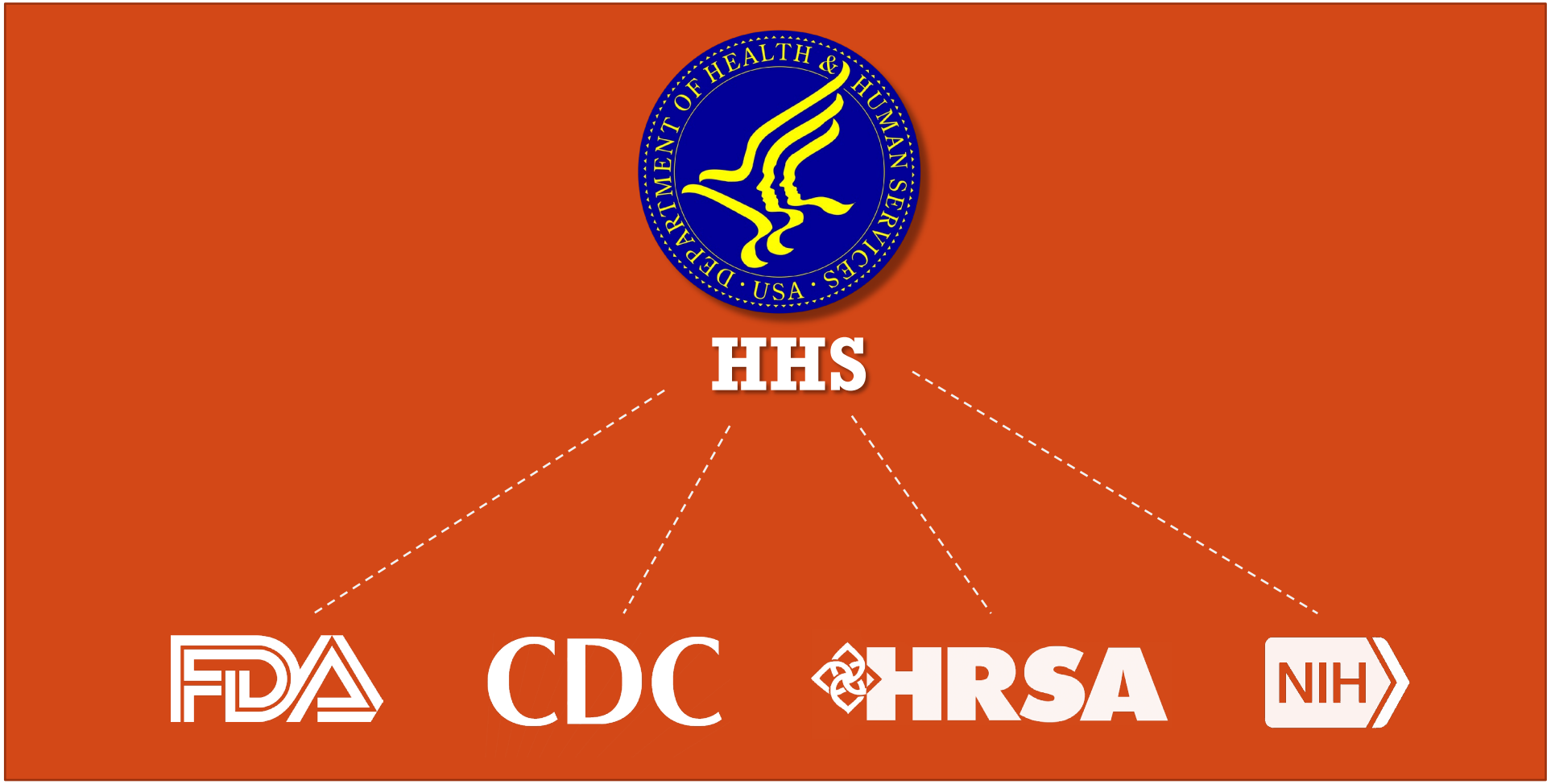


"It is no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of The New England Journal of Medicine."

PART V:
CONFLICTED REGULATORS

CONFLICTED REGULATORS

Who is responsible for vaccine safety?



ICAN

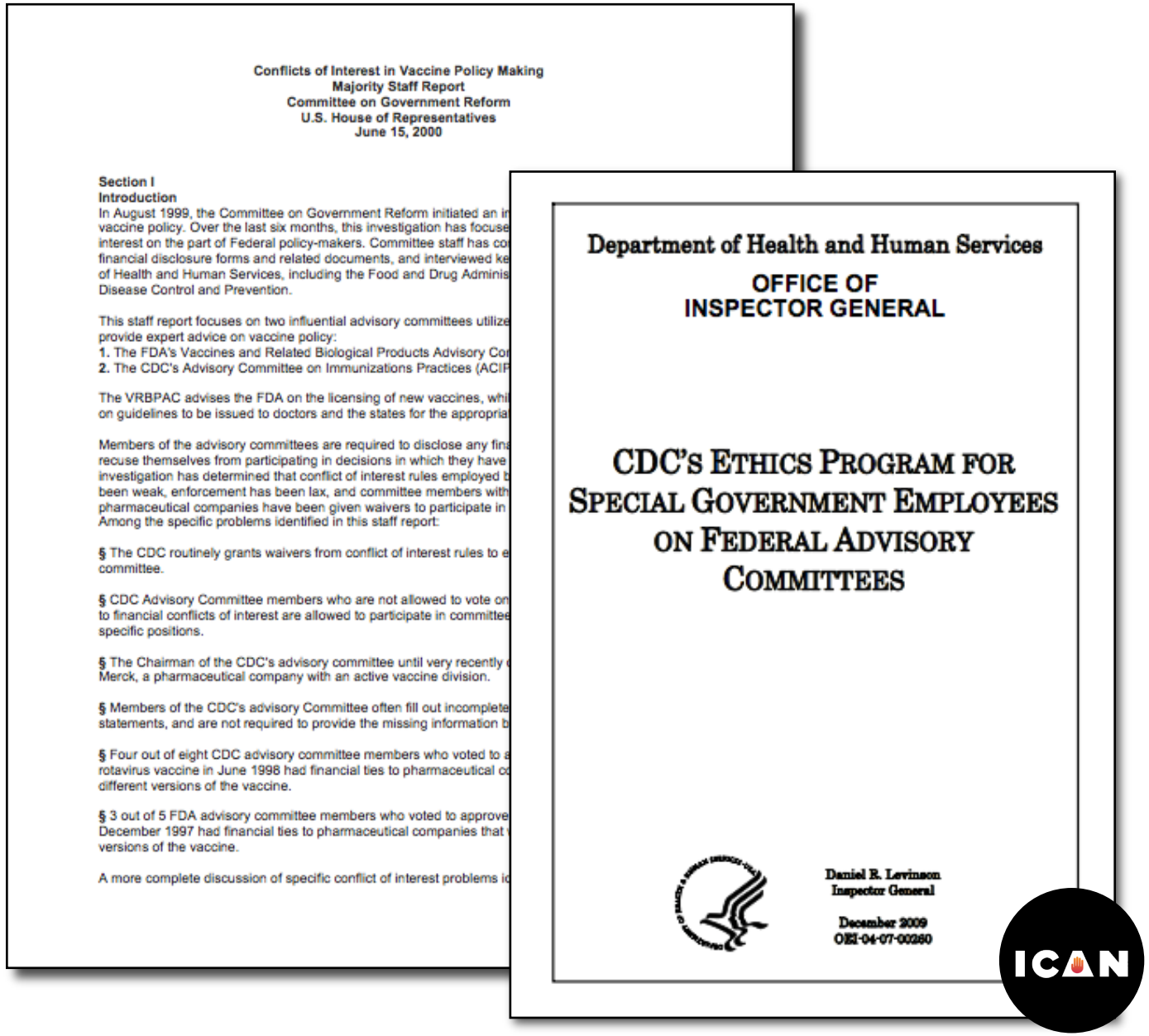
CONFLICTED REGULATORS

U.S. House Report (June 2000)

> **"The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry."**

HHS Inspector General (December 2009)

> **"CDC had a systemic lack of oversight of the ethics program" including finding that "58 percent of [committee members] had potential conflicts of interest that CDC did not identify" and "32 percent … had potential conflicts of intertest that CDC identified but did not resolve."**



Conflicts of Interest in Vaccine Policy Making
Majority Staff Report
Committee on Government Reform
U.S. House of Representatives
June 15, 2000

Section I
Introduction
In August 1999, the Committee on Government Reform initiated an in
vaccine policy. Over the last six months, this investigation has focuse
interest on the part of Federal policy-makers. Committee staff has co
financial disclosure forms and related documents, and interviewed ke
of Health and Human Services, including the Food and Drug Adminis
Disease Control and Prevention.

This staff report focuses on two influential advisory committees utilize
provide expert advice on vaccine policy:
1. The FDA's Vaccines and Related Biological Products Advisory Co
2. The CDC's Advisory Committee on Immunizations Practices (ACI

The VRBPAC advises the FDA on the licensing of new vaccines, whi
on guidelines to be issued to doctors and the states for the appropria

Members of the advisory committees are required to disclose any fin
recuse themselves from participating in decisions in which they have
investigation has determined that conflict of interest rules employed b
been weak, enforcement has been lax, and committee members with
pharmaceutical companies have been given waivers to participate in
Among the specific problems identified in this staff report:

§ The CDC routinely grants waivers from conflict of interest rules to e
committee.

§ CDC Advisory Committee members who are not allowed to vote on
to financial conflicts of interest are allowed to participate in committee
specific positions.

§ The Chairman of the CDC's advisory committee until very recently
Merck, a pharmaceutical company with an active vaccine division.

§ Members of the CDC's advisory Committee often fill out incomplete
statements, and are not required to provide the missing information b

§ Four out of eight CDC advisory committee members who voted to a
rotavirus vaccine in June 1998 had financial ties to pharmaceutical co
different versions of the vaccine.

§ 3 out of 5 FDA advisory committee members who voted to approve
December 1997 had financial ties to pharmaceutical companies that
versions of the vaccine.

A more complete discussion of specific conflict of interest problems i

Department of Health and Human Services
OFFICE OF
INSPECTOR GENERAL

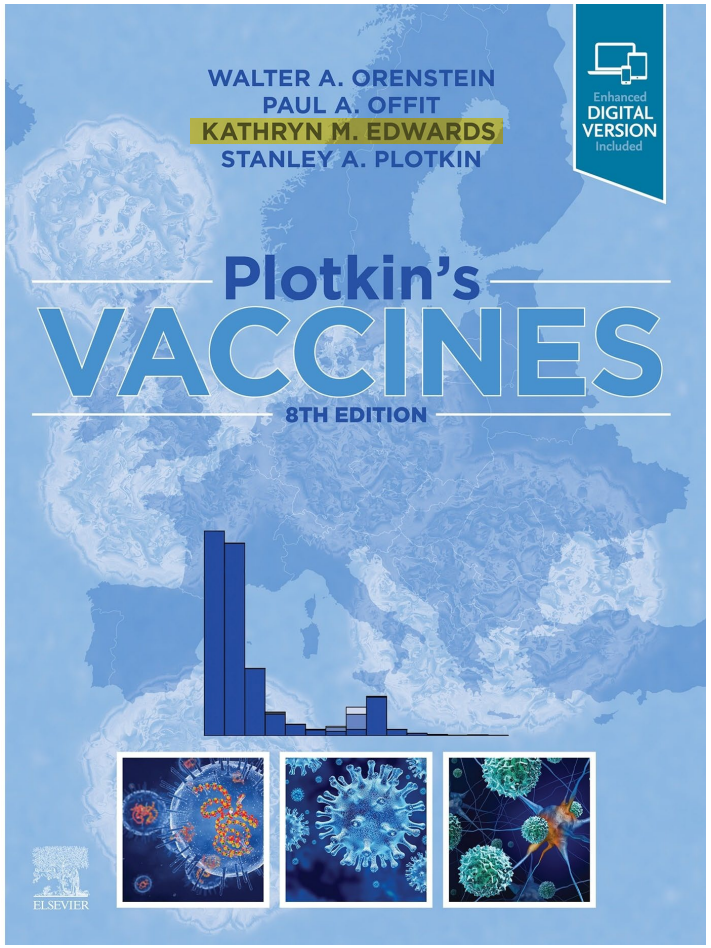
CDC'S ETHICS PROGRAM FOR SPECIAL GOVERNMENT EMPLOYEES ON FEDERAL ADVISORY COMMITTEES

Daniel R. Levinson
Inspector General

December 2009
OEI-04-07-00260

ICAN

CONFLICTED REGULATORS

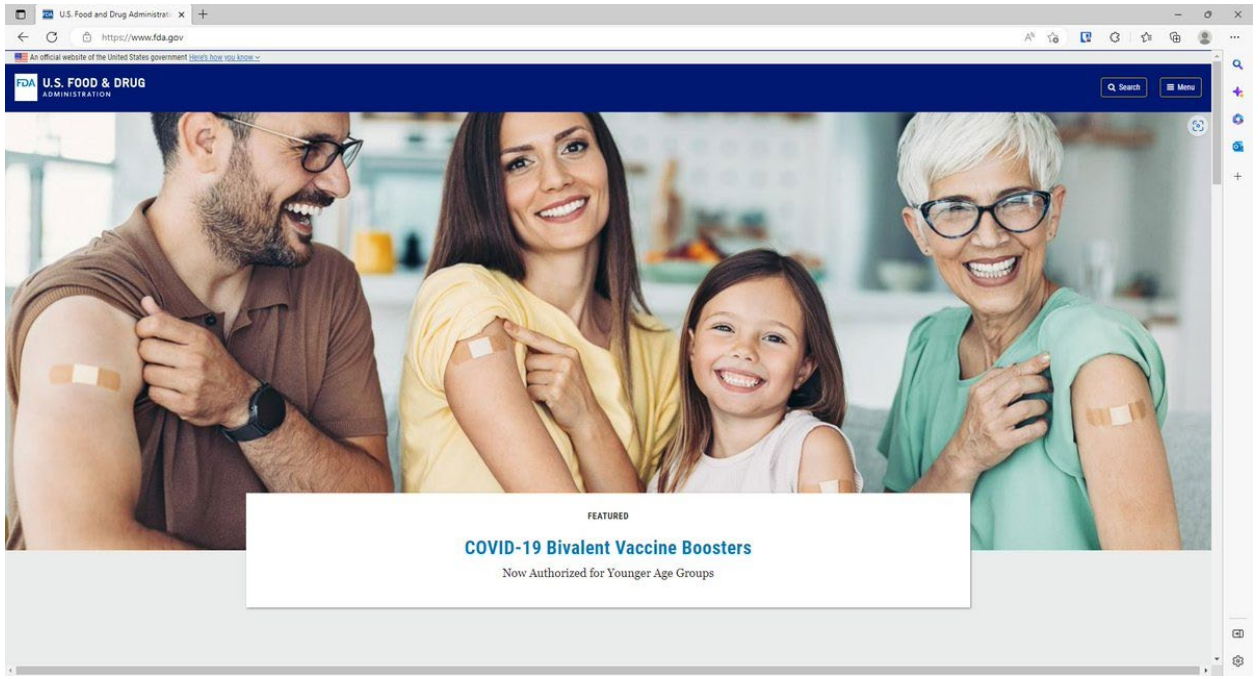


Full Deposition: https://thehighwire.com/videos/the-deposition-of-the-godmother-of-vaccines-dr-kathryn-edwards/

ICAN

CONFLICTED REGULATORS

FDA acts like a promotor, not regulator.



CONFLICTED REGULATORS

When gave immunity to pharma, made HHS responsible for safety. This section of law underpins all vaccine safety and failing to do the easy parts!

42 USCS § 300aa-27

Current through Public Law 117-362, approved January 5, 2023.

United States Code Service > TITLE 42. THE PUBLIC HEALTH AND WELFARE (Chs. 1 — 164) > CHAPTER 6A. PUBLIC HEALTH SERVICE (§§ 201 — 300aaa-13) > VACCINES (§§ 300aa — 300aa-34) > NATIONAL VACCINE INJURY COMPENSATION PROGRAM (§§ 300aa-10 — 300aa-34) > Assuring a Safer Childhood Vaccination Program in the United States (§§ 300aa-25 — 300aa-28)

§ 300aa-27. Mandate for safer childhood vaccines

(a) General rule. In the administration of this subtitle [42 USCS §§ 300aa-10 et seq.] and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on the effective date of this part [effective Dec. 22, 1987] and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

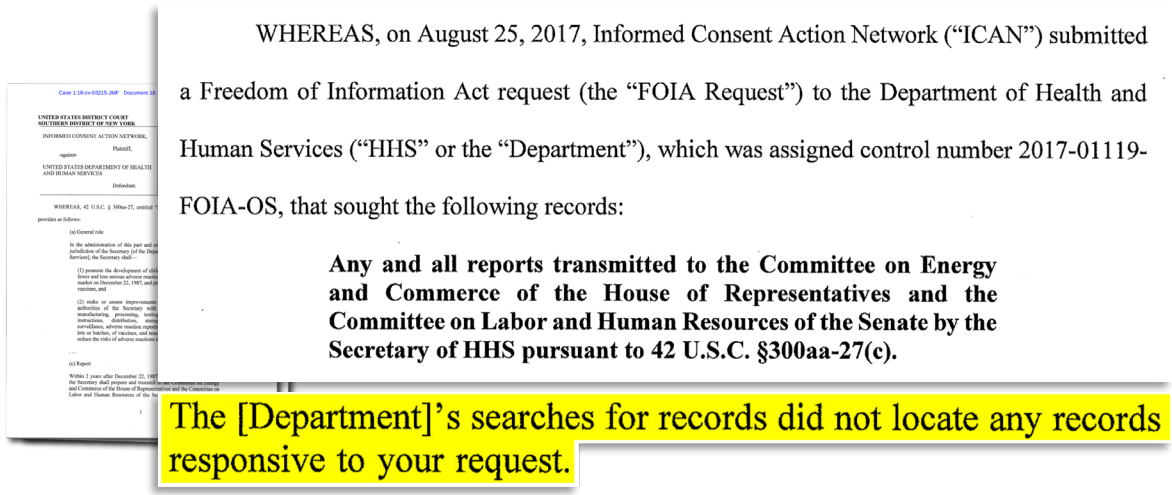
(b) Task force.

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

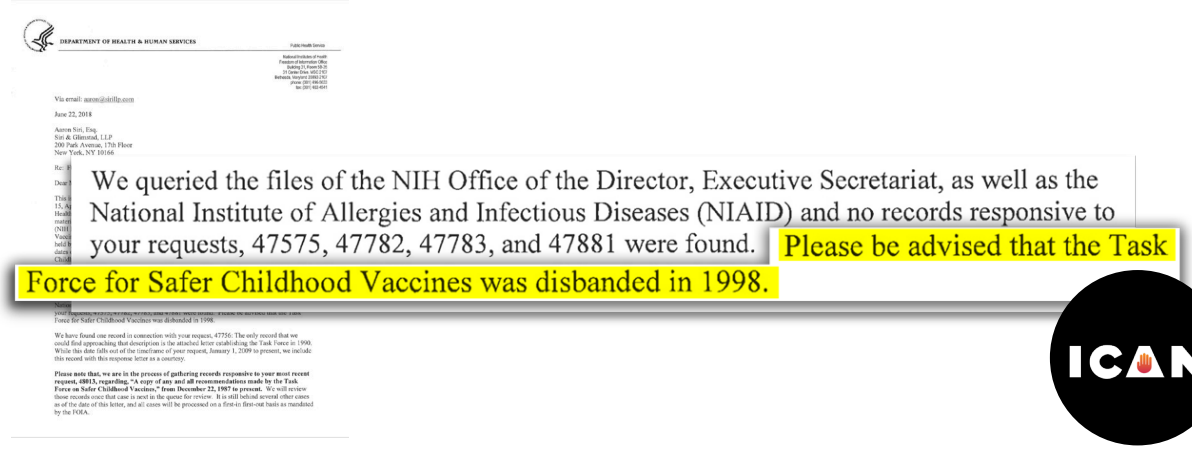
(c) Report. Within 2 years after the effective date of this part [effective Dec. 22, 1987], and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.



WHEREAS, on August 25, 2017, Informed Consent Action Network ("ICAN") submitted a Freedom of Information Act request (the "FOIA Request") to the Department of Health and Human Services ("HHS" or the "Department"), which was assigned control number 2017-01119-FOIA-OS, that sought the following records:

Any and all reports transmitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate by the Secretary of HHS pursuant to 42 U.S.C. §300aa-27(c).

The [Department]'s searches for records did not locate any records responsive to your request.



We queried the files of the NIH Office of the Director, Executive Secretariat, as well as the National Institute of Allergies and Infectious Diseases (NIAID) and no records responsive to your requests, 47575, 47782, 47783, and 47881 were found. Please be advised that the Task Force for Safer Childhood Vaccines was disbanded in 1998.

CONFLICTED REGULATORS

Why HHS Abandon Safety?

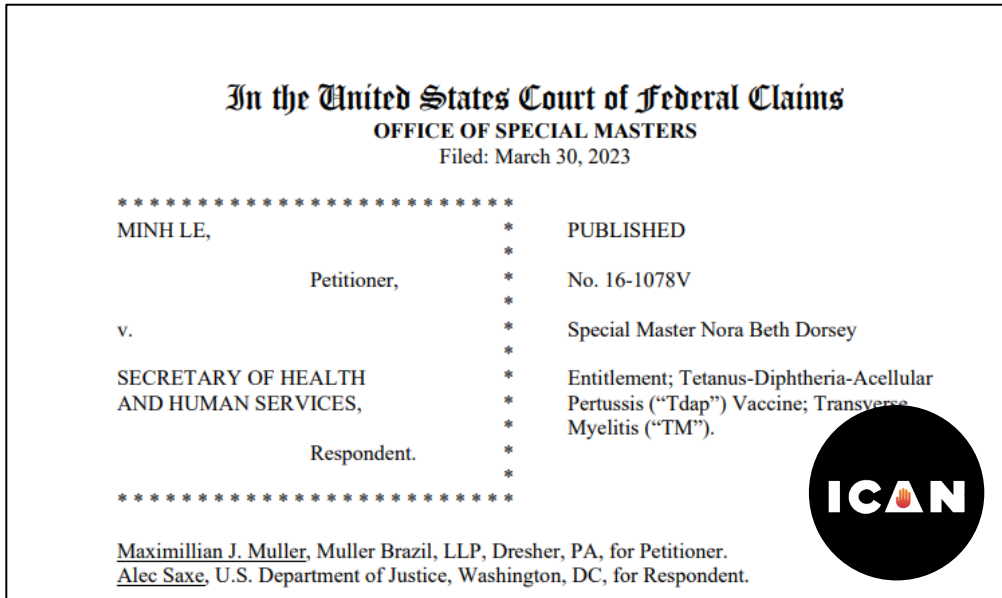
1. **Responsible for promoting vaccines.**

   Department of Transportation (promotes transportation) vs. National Transportation Safety Board (safety function)
   Department of Energy (promotes nuclear energy) vs. Nuclear Regulatory Commission (safety function)

2. **Responsible for defending vaccines against any claim of harm.**

   "In all proceedings brought by the filing of a petition [in Vaccine Court] the Secretary shall be named as the respondent." 42 USC § 300aa-12

3. **Revolving door & view themselves as partners with industry, not regulators.**



In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
Filed: March 30, 2023

MINH LE,	*	PUBLISHED
Petitioner,	*	No. 16-1078V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Entitlement; Tetanus-Diphtheria-Acellular Pertussis ("Tdap") Vaccine; Transverse Myelitis ("TM").
Respondent.	*	

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for Petitioner.
Alec Saxe, U.S. Department of Justice, Washington, DC, for Respondent.

ICAN

PART VI:
EXEMPTIONS

Pinned

Aaron Siri @AaronSiriSG · Dec 20, 2022

Mandates are the tool of bullies, criminals and dictators. If a patient refuses a medical product after being conveyed its benefits and risks, then that is called informed consent. They were informed and did not consent. Mandating over this objection is immoral and illiberal.

420 4,664 14.7K 703.9K

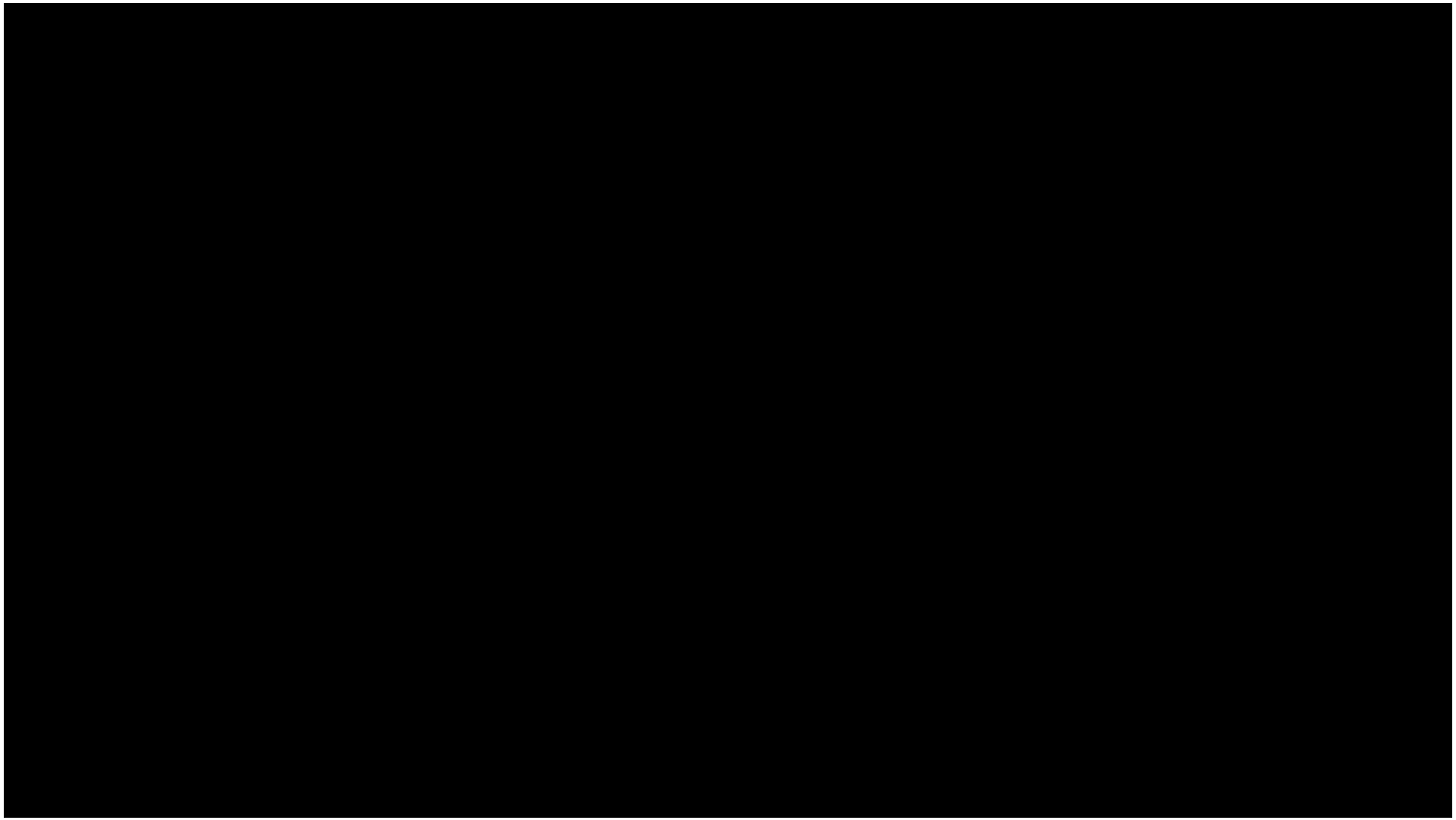
MANDATES ARE ONLY NECESSARY WHEN ONE CANNOT CONVINCE ON THE MERITS: WHEN SAFETY AND EFFICACY ARE QUESTIONABLE

ALL VACCINE MANDATES ARE ILLIBERAL

EXEMPTIONS ARE OFTEN LAST LINE OF DEFENSE

WHAT WAS FIRST AMENDMENT RELIGIOUS FREEDOM INTENDED TO PROTECT?

ABORTION AND VACCINES



Full Deposition: https://thehighwire.com/page/1/?s=stanley+plotkin