Immunization

Non-Medical Exemption Form (Religious and Personal Belief)

Vaccines are one of the greatest public health achievements of the past century and save an estimated 3 million children's lives every year. The Colorado Department of Public Health and Environment strongly supports vaccination as one of the easiest and most effective tools in preventing diseases that can cause serious illness and even death. For nearly all children, the benefits of preventing disease with a vaccine far outweigh the risks. Declining to follow the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) immunization schedule for number, space and timing of doses, may endanger an unvaccinated child's health and others who come into contact with him/her. Some vaccine-preventable diseases are common in other countries and unvaccinated children could easily get one of these diseases while traveling or from a traveler.

Colorado law C.R.S. § 25-4-902 requires all students attending any school in the state of Colorado to be vaccinated against certain vaccine-preventable diseases as established by Colorado Board of Health rule 6 CCR 1009-2, unless an exemption is filed. This law applies to students attending public, private and parochial kindergarten, elementary and secondary schools through 12th grade, colleges or universities, and child care facilities licensed by the Colorado Department of Human Services including child care centers, school-age child care centers, preschools, day camps, resident camps, day treatment centers, family child care homes, foster care homes, and Head Start programs. Prior to kindergarten, a non-medical exemption must be filed each time a student is due for vaccines according to the schedule developed by the ACIP.[1,2] From kindergarten through 12th grade, a non-medical exemption must be filed every year during the student's school enrollment/registration process.[1] Students with a recorded immunization exemption may be kept out of a child care facility or school during a disease outbreak; the length of time will vary depending on the type of the disease and the circumstances of the outbreak.

Please complete all required fields below; incomplete forms will not be accepted. *All fields are required unless noted optional.*

Type of Non-Medical Exemption Claimed: □ Personal Belief □ Religious

Student Information:

Last Name:	First Name:	(optional) Middle Name:
Gender: □ Female □ Male	Date of Birth:	
Street #:	Street Name:	Street Type (e.g. Ave.):
Unit #:	P.O. Box:	
City:	State:	Zip Code:
Email Address:		County:
Phone Number:		□ Home □ Cell

Parent/Guardian Completing This Form: □ Check if an emancipated student or student over 18 years old

Last Name:	First Name:	(optional) Middle Name:
Relationship to student: □ Mother □ Father □ Guardian		
Street #:	Street Name:	Street Type (e.g. Ave.):
Unit #:	P.O. Box:	
City:	State:	Zip Code:
Email Address:		County:
Phone Number:		□ Home □ Cell

School/Licensed Child Care Facility Information:

School Name/Licensed Child Care Facility:		
School District:		□ Check if Not Applicable
Address:		
City:	State:	Zip Code:
Phone Number:		Grade of Student:

[1] Colorado Board of Health rule 6 CCR 1009-2: https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=7698&fileName=6%20CCR%201009-2.

[2] 2018 Recommended Immunizations from Birth through 6 Years Old: www.cdc.gov/vaccines/parents/downloads/parent-ver-sch-0-6yrs.pdf. Based on this schedule, a non-medical exemption would be submitted at 2 months, 4 months, 6 months, 12 months and 18 months of age.

Vaccine Preventable Disease Information

The information provided below is to ensure parents/guardians/students are informed about the risks of not vaccinating.

Diphtheria, tetanus, pertussis (DTaP, Tdap) - Unvaccinated children may be at increased risk of developing diphtheria, tetanus and/or pertussis if exposed to these diseases. Serious symptoms and effects of diphtheria include heart failure, paralysis, breathing problems, coma, and death. Serious symptoms and effects of tetanus include "locking" of the jaw, difficulty swallowing and breathing, seizures, painful tightening of muscles in the head and neck, and death. Serious symptoms and effects of pertussis (whooping cough) include severe coughing fits that can cause vomiting and exhaustion, pneumonia, seizures, brain damage, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/dtap.pdf and http://www.cdc.gov/vaccines/hcp/vis/vis-statements/tdap.pdf

Haemophilus influenzae type b (Hib) - Unvaccinated children may be at increased risk of developing invasive Hib disease if exposed to this disease. Serious symptoms and effects include bacterial meningitis, pneumonia, severe swelling in the throat, brain damage, deafness, infections of the blood, joints, bones, and covering of the heart, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hib.pdf

Hepatitis B - Unvaccinated children may be at increased risk of developing hepatitis B if exposed to this disease. Serious symptoms and effects include jaundice, life-long liver problems such as liver damage, scarring, liver cancer, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hep-b.pdf

Inactivated poliovirus (IPV) - Unvaccinated children may be at increased risk of developing polio if exposed to this disease. Serious symptoms and effects include paralysis of muscles that control breathing, meningitis, permanent disability, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/ipv.pdf

Measles, mumps, rubella (MMR) - Unvaccinated children may be at increased risk of developing measles, mumps, and/or rubella if exposed to these diseases. Serious symptoms and effects of measles include pneumonia, seizures, brain damage, and death. Serious symptoms and effects of mumps include meningitis, painful swelling of the testicles or ovaries, sterility, deafness, and death. Serious symptoms and effects of rubella include rash, arthritis, and muscle or joint pain. If a pregnant woman gets rubella, she could have a miscarriage or her baby could be born with serious birth defects such as deafness, heart problems, and mental retardation. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.pdf

Pneumococcal conjugate (PCV13) - Unvaccinated children may be at increased risk of developing pneumococcal disease if exposed to this disease. Serious symptoms and effects include pneumonia, lung infections, blood infections, meningitis and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/pcv13.pdf.

Varicella (chickenpox) - Unvaccinated children may be at increased risk of developing varicella if exposed to this disease. Serious symptoms and effects include severe skin infections, pneumonia, brain damage, and death. For more information: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/varicella.pdf

Required Vaccines for School Entry - Place an "X" next to each vaccine you are declining.

	Diphtheria, tetanus, pertussis (DTaP)		Inactivated poliovirus (IPV)
	Tetanus, diptheria, pertussis (Tdap)		Measles, mumps, rubella (MMR)
	Haemophilus influenzae type b (Hib)		Pneumococcal conjugate (PCV13)
	Hepatitis B		Varicella (chickenpox)

Statement of Exemption

I am the parent/guardian of the above-named student or am the student himself/herself (emancipated or over 18 years of age) and am declining the vaccine(s) indicated above due to a religious or personal belief that is opposed to vaccines. The information I have provided on this form is complete and accurate.

- I may change my mind at any time and accept vaccination(s) for my child/myself in the future.
- I can review evidence-based vaccine information at www.colorado.gov/cdphe/immunization-education, or www.ImmunizeforGood.com for additional information on the benefits and risks of vaccines and the diseases they prevent.
- I can contact the Colorado Immunization Information System (CIIS) at www.ColoradoIIS.com or my health care provider to locate my child's/my immunization record.[3]

I acknowledge that I have read this document in its entirety.

Parent/Guardian/Student (emancipated or over 18 yrs old) signature: _____ Date: _____

(Optional) I authorize my/my student's school to share my/my student's immunization records with state/local public health agencies and the Colorado Immunization Information System, the state's secure, confidential immunization registry.

Parent/Guardian/Student (emancipated or over 18 yrs old) signature: _____ Date: _____

[3] Under Colorado law, you have the option to exclude your child's/your information from CIIS at any time. To opt out of CIIS, go to www.colorado.gov/cdphe/ciis-opt-out-procedures. Please be advised you will be responsible for maintaining your child's/your immunization records to ensure school compliance.

Good Afternoon,

Madam Chair Lontine and members of the committee, thank you for this opportunity. My name is Matt Baylor, I am here representing myself and my family and I oppose HB19-1312. As a Colorado parent I am concerned about student privacy. In order to have healthy kids and a healthy community we must protect our kids' privacy.

Our expectation of privacy has been codified in two different laws: FERPA and HIPAA. The Family Educational Rights and Privacy Act (FERPA) was enacted to protect students' personally identifiable information. The Health Insurance Portability and Accountability Act (HIPAA) defines and protects personal health information.

HB19-1312 causes great concern with both of these privacy protections. I will address them in the order they appear in the bill.

On page 6, line 10, this bill suggests medical providers offer information about opting-out of the immunization tracking system. In order to guard the spirit of HIPAA, participation in the immunization tracking system should be opt-in, not opt-out. I urge you to amend HB19-1312 to make the tracking system opt-in or oppose this legislation.

Simultaneously, on page 6, lines 12-13, it directs the provider to submit the medical exemption to the immunization tracking system. I ask that you clarify the language of HB19-1312 so that it is clear that parent and students control their data.

HB19-1312 on page 6, line 24 through page 7, line 19, requires students and their parents to disclose FERPA protected information in order to apply for the religious or personal belief exemption. FERPA already provides for the release of personally identifiable information in the event of a significant threat to the health and safety of our students. There is no need to disclose this information to any other agency since, according to FERPA, it is already readily available. I ask you to remove this requirement from HB19-1312 in order to continue the privacy protections afforded by FERPA.

Additionally, students and parents seeking a religious or personal belief exemption must opt-out of the immunization tracking system. To honor the privacy of health information as defined by HIPAA, HB19-1312's tracking system should be opt-in rather than opt-out.

HB19-1312 causes serious concerns for information protected by both HIPAA and FERPA. I urge you to either amend this bill so that it conforms to the privacy expectations codified in FERPA and HIPAA or oppose this bill in committee so that we ensure Colorado families have the assurance of privacy. We all have the same goal: healthy kids and a healthy community. Thank you for your time today.

Contraindications and Precautions

General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)

Printer friendly version [18 pages]

Updates

Major changes to the best practice guidance in this section include 1) enhancement of the definition of a "precaution" to include any condition that might confuse diagnostic accuracy and 2) recommendation to vaccinate during a hospitalization if a patient is not acutely moderately or severely ill.

General Principles

Contraindications (conditions in a recipient that increases the risk for a serious adverse reaction) and precautions to vaccination are conditions under which vaccines should not be administered. Because the majority of contraindications and precautions are temporary, vaccinations often can be administered later when the condition leading to a contraindication or precaution no longer exists. A vaccine should not be administered when a contraindication is present; for example, MMR vaccine should not be administered to severely immunocompromised persons (1). However, certain conditions are commonly misperceived as contraindications (i.e., are not valid reasons to defer vaccination).

National standards for pediatric vaccination practices have been established and include descriptions of valid contraindications and precautions to vaccination (2). Persons who administer vaccines should screen patients for contraindications and precautions to the vaccine before each dose of vaccine is administered (Table 4-1). Screening is facilitated by consistent use of screening questionnaires, which are available from certain state vaccination programs and other sources (e.g., the Immunization Action Coalition (http://www.immunize.org)).

Severely immunocompromised persons generally should not receive live vaccines (3). Because of the theoretical risk to the fetus, women known to be pregnant generally should not receive live, attenuated virus vaccines (4). Persons who experienced encephalopathy within 7 days after administration of a previous dose of pertussis-containing vaccine not

hospitalization (*15*). Likewise, patients admitted for elective procedures will not be acutely ill during all times during their hospitalization. Most studies that have explored the effect of surgery or anesthesia on the immune system were observational, included only infants and children, and were small and indirect, in that they did not look at the immune effect on the response to vaccination specifically (*16-35*). They do not provide convincing evidence that recent anesthesia or surgery significantly affect response to vaccines. Current, recent, or upcoming anesthesia/surgery/hospitalization is not a contraindication to vaccination (*16-35*). Efforts should be made to ensure vaccine administration during the hospitalization or at discharge. For patients who are deemed moderately or severely ill throughout the hospitalization, vaccination should occur at the earliest opportunity (i.e., during immediate post-hospitalization follow-up care, including home or office visits) when patients' clinical symptoms have improved.
A personal or family history of seizures is a precaution for MMRV vaccination; this is because a recent study found an increased risk for febrile seizures in children 12-23 months who receive MMRV compared with MMR and varicella vaccine (*36*).

Clinicians or other health-care providers might misperceive certain conditions or circumstances as valid contraindications or precautions to vaccination when they actually do not preclude vaccination (*2*) (Table 4-2). These misperceptions result in missed opportunities to administer recommended vaccines (*37*).

Routine physical examinations and procedures (e.g., measuring temperatures) are not prerequisites for vaccinating persons who appear to be healthy. The provider should ask the parent or guardian if the child is ill. If the child has a moderate or severe illness, the vaccination should be postponed.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use INFANRIX safely and effectively. See full prescribing information for INFANRIX.

INFANRIX (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed)
Suspension for Intramuscular Injection
Initial U.S. Approval: 1997

INDICATIONS AND USAGE

INFANRIX is a vaccine indicated for active immunization against diphtheria, tetanus, and pertussis as a 5-dose series in infants and children 6 weeks to 7 years of age. (1)

DOSAGE AND ADMINISTRATION

A 0.5-mL intramuscular injection given as a 5-dose series: (2.2)

- One dose each at 2, 4, and 6 months of age.
- One booster dose at 15 to 20 months of age and another booster dose at 4 to 6 years of age.

DOSAGE FORMS AND STRENGTHS

Single-dose vials and prefilled syringes containing a 0.5-mL suspension for injection. (3)

CONTRAINDICATIONS

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any diphtheria toxoid-, tetanus toxoid-, or pertussis-containing vaccine, or to any component of INFANRIX. (4.1)
- Encephalopathy within 7 days of administration of a previous pertussis-containing vaccine. (4.2)
- Progressive neurologic disorders. (4.3)

WARNINGS AND PRECAUTIONS

- If Guillain-Barré syndrome occurs within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give INFANRIX should be based on potential benefits and risks. (5.1)
- The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions. (5.2)
- Syncope (fainting) can occur in association with administration of injectable vaccines, including INFANRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope. (5.3)
- If temperature ≥105°F, collapse or shock-like state, or persistent, inconsolable crying lasting ≥3 hours have occurred within 48 hours after receipt of a pertussis-containing vaccine, or if seizures have occurred within 3 days after receipt of a pertussis-containing vaccine, the decision to give INFANRIX should be based on potential benefits and risks. (5.4)
- For children at higher risk for seizures, an antipyretic may be administered at the time of vaccination with INFANRIX. (5.5)
- Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including INFANRIX, to infants born prematurely should be based on consideration of the individual infant's medical status, and the potential benefits and possible risks of vaccination. (5.6)

ADVERSE REACTIONS

Rates of injection site reactions (pain, redness, swelling) ranged from 10% to 53%, depending on reaction and dose number, and were highest following Doses 4 and 5. Fever was common (20% to 30%) following Doses 1-3. Other common solicited adverse events were drowsiness, irritability/fussiness, and loss of appetite, reported in approximately 15% to 60% of subjects, depending on event and dose number. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

DRUG INTERACTIONS

Do not mix INFANRIX with any other vaccine in the same syringe or vial. (7.1)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 11/2018

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*Sections or subsections omitted from the full prescribing information are not listed.

2.4 Additional Dosing Information

If any recommended dose of pertussis vaccine cannot be given *[see Contraindications (4.2, 4.3), Warnings and Precautions (5.5)]*, Diphtheria and Tetanus Toxoids Adsorbed (DT) For Pediatric Use should be given according to its prescribing information.

3 DOSAGE FORMS AND STRENGTHS

INFANRIX is a suspension for injection available in 0.5-mL single-dose vials and 0.5-mL single-dose prefilled TIP-LOK syringes.

4 CONTRAINDICATIONS

4.1 Hypersensitivity

Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any diphtheria toxoid-, tetanus toxoid-, or pertussis-containing vaccine, or to any component of INFANRIX is a contraindication *[see Description (11)]*. Because of the uncertainty as to which component of the vaccine might be responsible, no further vaccination with any of these components should be given. Alternatively, such individuals may be referred to an allergist for evaluation if immunization with any of these components is being considered.

4.2 Encephalopathy

Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of administration of a previous dose of a pertussis-containing vaccine that is not attributable to another identifiable cause is a contraindication to administration of any pertussis-containing vaccine, including INFANRIX.

4.3 Progressive Neurologic Disorder

Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy, is a contraindication to administration of any pertussis-containing vaccine, including INFANRIX. Pertussis vaccine should not be administered to individuals with these conditions until a treatment regimen has been established and the condition has stabilized.

5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome

If Guillain-Barré syndrome occurs within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give any tetanus toxoid-containing vaccine, including INFANRIX, should be based on careful consideration of the potential benefits and possible risks. When a decision is made to withhold tetanus toxoid, other available vaccines should be given, as indicated.

5.2 Latex

The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic

reactions.

5.3 Syncope

Syncope (fainting) can occur in association with administration of injectable vaccines, including INFANRIX. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

5.4 Adverse Events following Prior Pertussis Vaccination

If any of the following events occur in temporal relation to receipt of a pertussis-containing vaccine, the decision to give any pertussis-containing vaccine, including INFANRIX, should be based on careful consideration of the potential benefits and possible risks:

- Temperature of ≥40.5°C (105°F) within 48 hours not due to another identifiable cause;
- Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours;
- Persistent, inconsolable crying lasting ≥3 hours, occurring within 48 hours;
- Seizures with or without fever occurring within 3 days.

5.5 Children at Risk for Seizures

For children at higher risk for seizures than the general population, an appropriate antipyretic may be administered at the time of vaccination with a pertussis-containing vaccine, including INFANRIX, and for the ensuing 24 hours to reduce the possibility of post-vaccination fever.

5.6 Apnea in Premature Infants

Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including INFANRIX, to infants born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination.

5.7 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the patient's immunization history for possible vaccine hypersensitivity. Epinephrine and other appropriate agents used for the control of immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur.

6 ADVERSE REACTIONS

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 with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. There is the possibility that broad use of INFANRIX could reveal adverse reactions not observed in clinical

trials.

Approximately 95,000 doses of INFANRIX have been administered in clinical studies. In these studies, 29,243 infants have received INFANRIX in primary series studies: 6,081 children have received a fourth consecutive dose of INFANRIX, 1,764 children have received a fifth consecutive dose of INFANRIX, and 559 children have received a dose of INFANRIX following 3 doses of PEDIARIX.

Solicited Adverse Events

In a U.S. study, 335 infants received INFANRIX, ENGERIX-B [Hepatitis B Vaccine (Recombinant)], inactivated poliovirus vaccine (IPV, Sanofi Pasteur SA), Haemophilus b (Hib) conjugate vaccine (Wyeth Pharmaceuticals Inc.), and pneumococcal 7-valent conjugate (PCV7) vaccine (Wyeth Pharmaceuticals Inc.) concomitantly at separate sites. All vaccines were administered at 2, 4, and 6 months of age. Data on solicited local reactions and general adverse events were collected by parents using standardized diary cards for 4 consecutive days following each vaccine dose (i.e., day of vaccination and the next 3 days) (Table 1). Among subjects, 69% were white, 16% were Hispanic, 8% were black, 4% were Asian, and 2% were of other racial/ethnic groups.

supplemented by spontaneous reporting by parents and a medical history after the first and second doses of vaccine. In the subset of 2,457, adverse events following the third dose of vaccine were reported via standardized diaries and spontaneous reporting at a follow-up visit. Adverse events in the remainder of the cohort were reported via report cards which were returned by mail approximately 28 days after the third dose of vaccine. Adverse events (rates per 1,000 doses) occurring within 7 days following any of the first 3 doses included: unusual crying (0.09), febrile seizure (0.0), afebrile seizure (0.13), and hypotonic-hyporesponsive episodes (0.01).

6.2 Postmarketing Experience

In addition to reports in clinical trials, worldwide voluntary reports of adverse events received for INFANRIX since market introduction are listed below. This list includes serious events and events that have a plausible causal connection to INFANRIX. These adverse events were reported voluntarily from a population of uncertain size; therefore, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccination.

Infections and Infestations

Bronchitis, cellulitis, respiratory tract infection.

Blood and Lymphatic System Disorders

Lymphadenopathy, thrombocytopenia.

Immune System Disorders

Anaphylactic reaction, hypersensitivity.

Nervous System Disorders

Encephalopathy, headache, hypotonia, syncope.

Ear and Labyrinth Disorders

Ear pain.

Cardiac Disorders

Cyanosis.

Respiratory, Thoracic, and Mediastinal Disorders

Apnea, cough.

Skin and Subcutaneous Tissue Disorders

Angioedema, erythema, pruritus, rash, urticaria.

General Disorders and Administration Site Conditions

Fatigue, injection site induration, injection site reaction, Sudden Infant Death Syndrome.

Alert: Due to routine maintenance on the OSHA website, some pages are temporarily unavailable. To file a complaint with OSHA or to ask a safety and health question, call 1-800-321-6742 (OSHA).

Hospital eTool

Administration
Central Supply
Clinical Services
Dietary
Emergency
Engineering
Healthcare Wide Hazards
Heliport
Housekeeping
ICU
Laboratory
Laundry
Pharmacy
Surgical Suite
Expert Systems

Healthcare Wide Hazards
Gluteraldehyde

Potential Hazard

Exposure of employees to glutaraldehyde. Glutaraldehyde is a toxic chemical that is used as a cold sterilant to disinfect and clean heat-sensitive medical, surgical and dental equipment. It is found in products such as Cidex, Aldesen, Hospex, Sporicidin, Omnicide, Matricide, Wavicide and others. Glutaraldehyde is also used as a tissue fixative in histology and pathology labs and as a hardening agent in the development of x-rays.

Glutaraldehyde Tray

The National Institute for Occupational Safety and Health (NIOSH) suggests ways in which health care workers may be exposed to glutaraldehyde including:

- Hospital staff who work in areas with a cold sterilizing procedure that uses glutaraldehyde (e.g., gastroenterology or cardiology departments).
- Hospital staff who work in operating rooms, dialysis departments, endoscopy units, and intensive care units, where glutaraldehyde formulations are used in infection control procedures.
- Central Supply workers who use glutaraldehyde as a sterilant.
- Research Technicians, researchers, and pharmacy personnel who either prepare the alkaline solutions or fix tissues in histology and pathology labs.
- Laboratory workers who sterilize bench tops with glutaraldehyde solutions.
- Workers who develop x-rays.

Glutaraldehyde is used in a limited number of applications, rather than as a general disinfectant. Specific applications include use as a disinfecting agent for respiratory therapy equipment, bronchoscopes, physical therapy whirlpool tubs, surgical instruments, anesthesia equipment parts, x-ray tabletops, dialyzers, and dialysis treatment equipment (Air contaminants).

Health effects of glutaraldehyde exposure include:

- **Short term (acute) effects:** Contact with glutaraldehyde liquid and vapor can severely irritate the eyes, and at higher concentrations burns the skin. Breathing glutaraldehyde can irritate the nose, throat, and respiratory tract, causing coughing and wheezing, nausea, headaches, drowsiness, nosebleeds, and dizziness.
- **Long-term (chronic) effects:** Glutaraldehyde is a sensitizer. This means some workers will become very sensitive to glutaraldehyde and have strong reactions if they are exposed to even small amounts. Workers may get sudden asthma attacks with difficult breathing, wheezing, coughing, and tightness in the chest. Prolonged exposure can cause a skin allergy and chronic eczema, and afterwards, exposure to small amounts produces severe itching and skin rashes. It has been implicated as a possible cause of occupational asthma.

Possible Solutions

Limit exposure to glutaraldehyde through work practice, engineering controls and personal protective equipment (PPE) including:

- Make sure that rooms in which glutaraldehyde is to be used are well ventilated and large enough to ensure adequate dilution of vapor, with a minimum air exchange rate of 10 air

changes per hour.

- Ideally, install local exhaust ventilation such as properly functioning laboratory fume hoods (capture velocity of at least 100 feet per minute) to control vapor.
- Keep glutaraldehyde baths under a fume hood where possible.

- Use only enough glutaraldehyde to perform the required disinfecting procedure.
- Store glutaraldehyde in closed containers in well ventilated areas. Air-tight containers are available. Post signs to remind staff to replace lids after using product.
- Use specially designed, mobile, compact, disinfectant soaking stations to facilitate sterilization of heat sensitive equipment such as endoscopes, or GI scopes. These soaking stations provide an enclosed area for sterilizing trays, and remove fumes from glutaraldehyde and other disinfectants.
- Use appropriate PPE covered under [29 CFR 1910.132(a)] including:
  - Use gloves that are impervious to glutaraldehyde such as those made of Butyl Rubber, Nitrile, and Viton®, which have been shown to provide full shift protection from glutaraldehyde.
  - For shorter exposures, you can use gloves made of polyethylene. Do not use Neoprene and PVC gloves because they do not provide adequate protection against glutaraldehyde and may actually absorb it.
  - Do not use latex surgical exam gloves for skin protection against glutaraldehyde, except in situations where only short-term, incidental contact is expected.
  - Wear lab coats, aprons, or gowns made of appropriate materials such as polypropylene to provide additional protection.
  - Wear splash-proof goggles and/or full face shields when working with glutaraldehyde to protect eyes.
- All employees who may be exposed to above the ceiling threshold limit value (TLV) of 0.05 ppm, should use appropriate respirators for glutaraldehyde vapor during routine or emergency work. Respirator requirements are found in the OSHA respiratory protection standard [29 CFR 1910.134]
- Provide eye wash fountains for immediate emergency use [29 CFR 1910.151(c)].
  - Use eye wash fountains and emergency showers if there is skin contact with glutaraldehyde. Flush area with water for at least 15 minutes to remove chemical.
  - Change into clean clothes if clothing becomes contaminated.
- Clean up spills immediately.
  - Refer to ANSI/AAMI [1996] for further information about emergency procedures in the event of a large spill.
- Do not eat, drink, or smoke in any area where glutaraldehyde is handled or stored.
- Use a vacuum or wet method to reduce dust while cleaning up pure glutaraldehyde. Do not dry sweep.
- Use less toxic products if feasible and available, or other processes for sterilization.
- Automate the transfer of pure glutaraldehyde or pump liquid glutaraldehyde from drums or other storage containers to appropriate containers and operations, avoiding exposure to glutaraldehyde by keeping it in a contained process.
- Hazard Communication Standard [29 CFR 1910.1200] requires employers to ensure that the hazards of all chemicals are evaluated and that this information is transmitted to the employees by means of a hazards communication program which includes, labeling, material safety data sheets, and employee training.

For additional information, see **Healthcare Wide Hazards - PPE**, and **Hazardous Chemicals**.

Additional Information:

- Best Practices for the Safe Use of Glutaraldehyde in Health Care. OSHA Publication 3258-08N, (2006).
- OSHA does not currently have a required permissible exposure level (PEL) for glutaraldehyde.
  - The American Conference of Government Industrial Hygienists (ACGIH) has a recommended ceiling Threshold Limit Value (TLV) of 0.05 ppm (parts per million). This represents an airborne concentration that should not be exceeded during any part of the work shift.

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.
If in doubt about whether a PI has been updated since this table was prepared, check the FDA's website at:
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

Vaccine	Contains
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, plasdone C, anhydrous lactose, microcrystalline cellulose, polacrilin potassium, 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
DT (Sanofi)	aluminum phosphate, isotonic sodium chloride, formaldehyde, casein, cystine, maltose, uracil, inorganic salts, vitamins, dextrose
DTaP (Daptacel)	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
DTaP (Infanrix)	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)
DTaP-IPV (Kinrix)	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
DTaP-IPV (Quadracel)	modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, formaldehyde, 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

Vaccine	Contains
DTaP-HepB-IPV (Pediarix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, glutaraldehyde, 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.
DTaP-IPV/Hib (Pentacel)	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. 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
Hib (ActHIB)	sodium chloride, modified Mueller and Miller medium (the culture medium contains milk-derived raw materials [casein derivatives]), formaldehyde, sucrose
Hib (Hiberix)	saline, synthetic medium, formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB)	complex fermentation media, amorphous aluminum hydroxyphosphate sulfate, sodium chloride
Hep A (Havrix)	MRC-5 human diploid cells, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic
Hep A (Vaqta)	MRC-5 diploid fibroblasts, amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride
Hep B (Engerix-B)	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate
Hep B (Recombivax)	soy peptone, dextrose, amino acids, mineral salts, phosphate buffer, formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein
Hep B (Heplisav-B)	vitamins and mineral salts, yeast protein, yeast DNA, deoxycholate, phosphorothioate linked oligodeoxynucleotide, phosphate buffered saline, sodium phosphate, dibasic dodecahydrate, monobasic dehydrate, polysorbate 80
Hep A/Hep B (Twinrix)	MRC-5 human diploid cells, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein
Human Papillomavirus (HPV) (Gardasil 9)	vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein
Influenza (Afluria) Trivalent & Quadrivalent	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)
Influenza (Fluad)	squalene, polysorbate 80, sorbitan trioleate, sodium citrate dehydrate, citric acid monohydrate, neomycin, kanamycin, barium, egg proteins, cetyltrimethylammonium bromide (CTAB), formaldehyde
Influenza (Fluarix) Quadrivalent	octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride
Influenza (Flublok) 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) Quadrivalent	Madin Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethlyammonium bromide, and β-propiolactone, Thimerosal (multi-dose vials)
Influenza (Flulaval) Quadrivalent	ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials), phosphate-buffered saline solution
Influenza (Fluzone) Quadrivalent	formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials)

Vaccine	Contains
Influenza (Fluzone) High Dose	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde
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 (MenB – Bexsero)	aluminum hydroxide, *E. coli*, histidine, sucrose, deoxycholate, kanamycin
Meningococcal (MenB – Trumenba)	defined fermentation growth media, polysorbate 80, aluminum phosphate, 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-propriolactone
Rabies (RabAvert)	chicken fibroblasts, β-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)	Vero cells, 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-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, 2% human serum albumin, 0.7% sodium chloride USP, 5% Mannitol USP, neomycin, polymyxin B, 50% Glycerin USP, 0.25% phenol USP
Td (Tenivac)	aluminum phosphate, formaldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate, sodium chloride, water

Vaccine	Contains
Td (Mass Biologics)	aluminum phosphate, formaldehyde, thimerosal, modified Mueller's media which contains bovine extracts, ammonium sulfate
Tdap (Adacel)	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
Tdap (Boostrix)	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
Typhoid (Typhim Vi)	hexadecyltrimethylammonium bromide, formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, semi-synthetic medium, sodium chloride, sterile water
Typhoid (Vivotif Ty21a)	yeast extract, casein, dextrose, galactose, sucrose, ascorbic acid, amino acids, lactose, magnesium stearate. gelatin
Varicella (Varivax) *Frozen*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, sodium phosphate monobasic, potassium phosphate monobasic, potassium chloride, EDTA, neomycin, fetal bovine serum
Varicella (Varivax) *Refrigerator Stable*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, urea, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
Yellow Fever (YF-Vax)	sorbitol, gelatin, sodium chloride, egg protein
Zoster (Shingles) (Zostavax) *Frozen*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed porcine gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride; neomycin, bovine calf serum
Zoster (Shingles) (Zostavax) *Refrigerator Stable*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed porcine gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
Zoster (Shingles) (Shingrix)	sucrose, sodium chloride, dioleoyl phosphatidylcholine (DOPC), 3-*O*-desacl-4'monophosphoryl lipid A (MPL), QS-21 (a saponin purified from plant extract *Quillaja saponaria* Molina), potassium dihydrogen phosphate, cholesterol, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, dipotassium phosphate, polysorbate 80

A table listing vaccine excipients and media *by excipient* is published by the Institute for Vaccine Safety at Johns Hopkins University, and can be found at http://www.vaccinesafety.edu/components-Excipients.htm.

Updates:

Trumenba: (added Aluminum phosphate)
RotaTeq: PI dated 2/2017
Rotarix: 6/11/18 (PI dated xx/xxxx)
Smallpox: 3/2018
Td (Tenivac): April 2013
Td (Mass Biologics): April 2009 (no change)
Tdap (Adacel): xxx/2017 (no change)
Tdap (Boostrix): 6/12/2018 (PI dated xx/xxxx) (no change)
Typhim Vi: March 2014 (added sodium chloride & buffered saline)
Ty21a: September 2013
Varicella Frozen: 2/2017
Varicella Refrigerator Stable: 2/2017
YF Vax: June 2016
Zostivax Frozen: xx/2018
Zostivax Refrigerator Stable: xx/2018
Shingrix: 10/2017

National Vaccine Injury Compensation Program

- **Established in 1988, following the National Childhood Vaccine Injury Act of 1986.**
- **Protects vaccine industry** who threatened to cease vaccine production due to public concern over vaccine manufacturing practices and the safety of vaccines.
- **Removes all liability from vaccine manufacturers** for injuries or side effects related to their medical products, and instead shifts 'nancial responsibility to the American taxpayer.
- **Created a liability-free marketplace for exponential growth** as evidenced by a major increase in vaccines added to the recommended CDC vaccine schedule.

BEFORE LIABILITY PROTECTION | **AFTER LIABILITY PROTECTION**

* In the case of infants born after 2004, their birth to 18 year doses exceed the numbers shown here.

24 Doses

1985

Diptheria
Tetanus
Pertussis
Measles
Mumps
Rubella
Polio

28 Doses

1989

Diptheria
Tetanus
Pertussis
Measles
Mumps
Rubella
Polio

ADDED
Haemophilus Influenzae B

32 Doses

1994

Diptheria
Tetanus
Pertussis
Measles
Mumps
Rubella
Polio
HIB

ADDED
Hepatitis B

36 Doses

2000

Diptheria
Tetanus
Pertussis
Measles
Mumps
Rubella
Polio
HIB
Hepatitis B

ADDED
Varicella
Hepatitis A

49+ Doses*

2005

Diptheria
Tetanus
Pertussis
Measles
Mumps
Rubella
Polio
HIB
Hepatitis B
Varicella
Hepatitis A

ADDED
Pneumococcal Influenza YEARLY

54+ Doses*

2010

Diptheria
Tetanus
Pertussis
Measles
Mumps
Rubella
Polio
HIB
Hepatitis B
Varicella
Hepatitis A
Pneumococcal Influenza

ADDED
Rotavirus
HPV

69+ Doses*

2016

Diptheria
Tetanus
Pertussis
Measles
Mumps
Rubella
Polio
HIB
Hepatitis B
Varicella
Hepatitis A
Pneumococcal Influenza
Rotovirus
HPV

ADDED
Meningococcal B

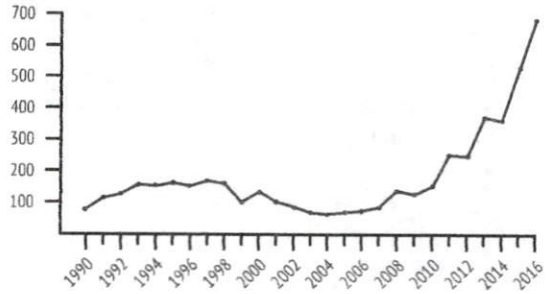
Liability Claims Due to Vaccine Injury, Paid by U.S. Taxpayers

$4,099,185,250

Total as of Feb 2019

Health Resources & Services Administration

Paid Claims by Year



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www.cohealthchoice.org

Source: Health Resources & Services Administration
U.S. Department of Health and Human Services

J Pediatric Infect Dis Soc 2019 Feb 22[Online ahead of print]

The 112-Year Odyssey of Pertussis and Pertussis Vaccines-Mistakes Made and Implications for the Future

James D Cherry

PMID: 30793754

Abstract

Effective diphtheria, tetanus toxoids, whole-cell pertussis (DTwP) vaccines became available in the 1930s, and they were put into routine use in the United States in the 1940s. Their use reduced the average rate of reported pertussis cases from 157 in 100 000 in the prevaccine era to <1 in 100 000 in the 1970s. Because of alleged reactions (encephalopathy and death), several countries discontinued (Sweden) or markedly decreased (United Kingdom, Germany, Japan) use of the vaccine. During the 20th century, *Bordetella pertussis* was studied extensively in animal model systems, and many "toxins" and protective antigens were described. A leader in B pertussis research was Margaret Pittman of the National Institutes of Health/US Food and Drug Administration. She published 2 articles suggesting that pertussis was a pertussis toxin (PT)-mediated disease. Dr Pittman's views led to the idea that less-reactogenic acellular vaccines could be produced. The first diphtheria, tetanus, pertussis (DTaP) vaccines were developed in Japan and put into routine use there. Afterward, DTaP vaccines were developed in the Western world, and definitive efficacy trials were carried out in the 1990s. These vaccines were all less reactogenic than DTwP vaccines, and despite the fact that their efficacy was less than that of DTwP vaccines, they were approved in the United States and many other countries. DTaP vaccines replaced DTwP vaccines in the United States in 1997. In the last 13 years, major pertussis epidemics have occurred in the United States, and numerous studies have shown the deficiencies of DTaP vaccines, including the small number of antigens that the vaccines contain and the type of cellular immune response that they elicit. The type of cellular response a predominantly, T2 response results in less efficacy and shorter duration of protection. Because of the small number of antigens (3-5 in DTaP vaccines vs >3000 in DTwP vaccines), linked-epitope suppression occurs. Because of linked-epitope suppression, all children who were primed by DTaP vaccines will be more susceptible to *pertussis throughout their lifetimes, and there is no easy way to decrease this increased lifetime* susceptibility.

Keywords: DTaP; DTwP; cellular response; linked-epitope suppression.

J Manipulative Physiol Ther. 2000 Feb;23(2):81-90.

Effects of diphtheria-tetanus-pertussis or tetanus vaccination on allergies and allergy-related respiratory symptoms among children and adolescents in the United States.

Hurwitz EL[1], Morgenstern H.

Author information

Abstract

BACKGROUND: Findings from animal and human studies confirm that diphtheria and tetanus toxoids and pertussis (DTP) and tetanus vaccinations induce allergic responses; associations between childhood vaccinations and subsequent allergies have been reported recently.

OBJECTIVE: The association of DTP or tetanus vaccination with allergies and allergy-related respiratory symptoms among children and adolescents in the United States was assessed.

METHODS: Data were used from the Third National Health and Nutrition Examination Survey on infants aged 2 months through adolescents aged 16 years. DTP or tetanus vaccination, lifetime allergy history, and allergy symptoms in the past 12 months were based on parental or guardian recall. Logistic regression modeling was performed to estimate the effects of DTP or tetanus vaccination on each allergy.

RESULTS: The odds of having a history of asthma was twice as great among vaccinated subjects than among unvaccinated subjects (adjusted odds ratio, 2.00; 95% confidence interval, 0.59 to 6.74). The odds of having had any allergy-related respiratory symptom in the past 12 months was 63% greater among vaccinated subjects than unvaccinated subjects (adjusted odds ratio, 1.63; 95% confidence interval, 1.05 to 2.54). The associations between vaccination and subsequent allergies and symptoms were greatest among children aged 5 through 10 years.

CONCLUSIONS: DTP or tetanus vaccination appears to increase the risk of allergies and related respiratory symptoms in children and adolescents. Although it is unlikely that these results are entirely because of any sources of bias, the small number of unvaccinated subjects and the study design limit our ability to make firm causal inferences about the true magnitude of effect.

PMID: 10714532

[Indexed for MEDLINE]

↓ Full text

Pertussis epidemic despite high levels of vaccination coverage with acellular pertussis vaccine.

Sala-Farré MR, et al. Enferm Infecc Microbiol Clin. 2015.
Show full citation

Abstract

INTRODUCTION: We describe the pertussis epidemic, based only on confirmed whooping cough cases. We have analyzed data on the diagnosis, epidemiology and vaccine history in order to understand the factors that might explain the trends of the disease.

METHODS: A descriptive study of the confirmed pertussis cases reported during 2011 in the Vallès region (population 1,283,000). Laboratory criteria for confirmed pertussis cases include isolation of Bordetella pertussis from a clinical specimen or detection of B. pertussis by PCR in nasopharyngeal swabs.

RESULTS: A total of 421 pertussis confirmed cases were reported, which was the highest incidence reported in the last decade (33 cases/100,000 people/year in 2011). The highest incidence rate was among infants less than 1 year old (448/100,000), followed by children 5-9 years old (154/100,000). Pertussis cases aged 2 months-1 year were 90% vaccinated following the current DTaP schedule for their age group in Catalonia, and cases of 5-9 years were 87% fully vaccinated with 5 doses of DTaP vaccine. There were no deaths, although 8% of cases were hospitalized. Pertussis was more severe in infants, 30% required hospitalization despite having received the vaccine doses corresponding to their age. Children of 5-9 years were most often identified as primary cases in households or school clusters.

CONCLUSION: Despite high levels of vaccination coverage, pertussis circulation cannot be controlled at all. The results question the efficacy of the present immunization programmes.

PMID: 24216286 [Indexed for MEDLINE]

Full text

EMERGING INFECTIOUS DISEASES

Emerg Infect Dis. 2000 Jul-Aug; 6(4): 348–357.
doi: 10.3201/eid0604.000404

PMCID: PMC2640897
PMID: 10905967

Reemergence of pertussis in the highly vaccinated population of the Netherlands: observations on surveillance data.

H. E. de Melker, J. F. Schellekens, S. E. Neppelenbroek, F. R. Mooi, H. C. Rümke, and M. A. Conyn-van Spaendonck

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Abstract

We analyzed pertussis reporting, death, hospitalization, and serodiagnostic data from 1976 to 1998 to help explain the cause of the 1996 pertussis outbreak in the Netherlands. The unexpected outbreak was detected by an increase in pertussis reporting and by other surveillance methods. In 1996, according to reporting and serologic data, the increase in pertussis incidence among (mostly unvaccinated) children less than 1 year of age was similar to the increase in hospital admissions. Among older (mostly vaccinated) persons, the increase in hospital admissions was relatively small. The increase in pertussis incidence was higher among vaccinated than among unvaccinated persons of all ages. This resulted in lower estimates of vaccine effectiveness. The proportion of pertussis infections resulting in recognizable symptoms may have increased among vaccinated persons because of a mismatch of the vaccine strain and circulating Bordetella pertussis strains. The small immunogenicity profile of the Dutch vaccine may have resulted in greater vulnerability to antigenic changes in B. pertussis.

Full Text

The Full Text of this article is available as a PDF (104K).

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These references are in PubMed. This may not be the complete list of references from this article.

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Severe tetanus in immunized patients with high anti-tetanus titers.

Crone NE, et al. Neurology. 1992.
Show full citation

Abstract

Severe (grade III) tetanus occurred in three immunized patients who had high serum levels of anti-tetanus antibody. The disease was fatal in one patient. One patient had been hyperimmunized to produce commercial tetanus immune globulin. Two patients had received immunizations 1 year before presentation. Anti-tetanus antibody titers on admission were 25 IU/ml to 0.15 IU/ml by hemagglutination and ELISA assays; greater than 0.01 IU/ml is considered protective. Even though one patient had seemingly adequate anti-tetanus titers by in vitro measurement (0.20 IU), in vivo mouse protection bioassays showed a titer less than 0.01 IU/ml, implying that there may have been a hole in her immune repertoire to tetanus neurotoxin but not to toxoid. This is the first report of grade III tetanus with protective levels of antibody in the United States. The diagnosis of tetanus, nevertheless, should not be discarded solely on the basis of seemingly protective anti-tetanus titers.

PMID: 1565228 [Indexed for MEDLINE]

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[Characteristics of Clostridium tetani and laboratory diagnosis of tetanus].
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See all

April 10, 2019

Good Afternoon,

My name is Cynthia Shelden, I reside in the county of Jefferson and the unincorporated town of Morrison. I have lived in Colorado for 21 years. I am an educator with a Master's Degree in Curriculum and Instruction. I am a wife of 25 years and mother of 3 children. Those 3 children have all been vaccinated and thus contribute to so-called "herd immunity" statistics. However, their pediatrician decided to put them on a delayed schedule when my middle daughter suffered a febrile seizure from the MMR vaccine. They, like many children, did not receive all their vaccines by kindergarten. This is actually quite common and reveals the fallacy of the fear tactic talking point in the Legislative Declaration regarding Colorado being last in kindergarten vaccine rates. (Section 1 - f). That same daughter has also been diagnosed with a little-known allergy to food dyes, red 40, blue lake, yellow 5, etc. This particular child cannot process foreign substances within her body as the rest of us do. She becomes violently ill and has been in the ER two other times for severe reactions. **It is because of this, that our pediatrician decided it was in her best interest, as well as the best interest of my other two children, to delay, and spread out, their vaccinations** and only administer them individually, no double and triple shots in one visit. None of my children are a "threat" to anyone in this room, within their schools, nor out in general public. What is a **"threat"** to our children, is **this bill**. Specifically:

1) This bill removes a doctor's rights to decide what does and does not go into my, or my child's, body such as our doctor has done. And it further forces doctors to violate the vow of "First do no harm". This blatant **overreach of power** is clear **abuse of power**.
2) YOU are taking away MY rights and MY privacy to allow MY pediatrician to make informed medical decisions on behalf of MY children by requiring medical exemptions, or delayed schedules, be submitted to the Health Department for bureaucratic approval. This is a private matter between patient/parent/practitioner.
3) As a consumer I'd like to ask you how is it OK for the State to coerce sovereign citizens to purchase and use a liability-free product from companies that, historically, have been less than forthcoming about the safety and efficacy of their products
4) And as a taxpayer, I leave you with these questions:
    - ❑ How do you plan to review all of the medical needs of these submissions individually?
    - ❑ Which credentialled medical professionals will review these submissions?
    - ❑ How do you plan to pay for the review of these submissions?
    - ❑ How do you plan to pay for the HIPPA and FERPA violation lawsuits that are sure to follow? Especially if schools will be required to report the names of non-compliers (Section 4)

The law in Colorado on Patient Rights: 6 CCR 1011-1 Chap 02-6.104 – PATIENT RIGHTS POLICY(1/28/16)

PATIENT RIGHTS POLICY (1) The health care entity shall develop and implement a policy regarding patient rights. The policy shall ensure that each patient or, where appropriate, patient designated representative has the right to: (a) participate in all decisions involving the patient's care or treatment; (b) be informed about whether the health care entity is participating in teaching programs, and to provide informed consent prior to being included in any clinical trials relating to the patient's care. (c) refuse any drug, test, procedure, or treatment and to be informed of risks and benefits of this action; (d) to care and treatment, in compliance with state statute, that is respectful, recognizes a person's dignity, cultural values and religious beliefs, and provides for personal privacy to the extent possible during the course of treatment; (e) know the names, professional status, and experience of the staff that are providing care or treatment to the patient; (f) receive, upon request: (i) prior to initiation of care or treatment, the estimated average charge to the patient for non-emergent care. This includes reasonable assistance with determining the charges which may include deductibles and co-payments that would not be covered by a third-party payer based on the coverage information supplied by the patient or patient designated representative. In discharging its responsibility hereunder, a health care entity may provide the estimated charge for an average patient with a similar diagnosis and inform the patient or the patient designated representative that there are variables that may alter the estimated charge. (ii) the health care entity's general billing procedures. (iii) an itemized bill that identifies treatment and services by date. The itemized bill shall enable patients to validate the charges for items and services provided and shall include contact information, including a telephone number for patient billing inquiries. The itemized bill shall be made available either within 10 business days of the request, or 30 days after discharge for inpatients, or 30 days after the service is rendered for outpatients – whichever is later. (g) give informed consent for all treatment and procedures. It is the responsibility of the licensed independent practitioner and other health professionals to obtain informed consent for procedures that they provide to the patient. (h) register complaints with the health care entity and the Department and to be informed of the procedures for registering complaints including contact information. (i) be free of abuse and neglect. To effectuate this patient right, the health care entity shall develop and implement policies and procedures to prevent, detect, investigate, and respond to incidents of abuse or neglect. Prevention includes, but is not limited to, adequate staffing to meet the needs of the patients, screening employees for records of abuse and neglect and protecting patients from abuse during investigation of allegations. Detection includes, but is not limited to, establishing a reporting system and training employees regarding identifying, reporting, and intervening in incidences of abuse and neglect. The health care entity shall investigate, in a timely

manner, all allegations of abuse or neglect and implement corrective actions in accordance with such investigations. (j) be free of the inappropriate use of restraints. Inappropriate use includes improper application of a restraint or the usage of a restraint as a means of coercion, discipline, convenience, or retaliation by staff. A health care entity that does not use restraints shall include a written statement in their policies and procedures to that effect. A health care entity that does use restraints shall develop and implement policies and procedures regarding: (i) the provision of training on the use of restraints. (ii) ongoing individual patient assessment to determine: when a medical condition or symptom indicates use of restraint to protect the patient or others from harm; the least restrictive intervention; and the discontinuation of the intervention at the earliest possible time. (iii) documentation of the use of restraint in the patient's medical record. (k) except in emergent situations, patients shall only be accepted for care and services when the facility can meet their identified and reasonable anticipated care, treatment, and service needs. (l) care delivered by the health care entity in accordance with the needs of the patient. (m) confidentiality of medical records. (n) receive care in a safe setting. (o) disclosure as to whether referrals to other providers are entities in which the health care entity has a financial interest. (p) to formulate advance directives and have the health care entity comply with such directives, as applicable and in compliance with applicable state statute. (2) The health care entity shall disclose the policy regarding patient rights prior to treatment or upon admission, where possible. For any patient care or treatment course requiring multiple patient encounters, disclosure provided at the beginning of such care or treatment course shall meet the intent of the regulations. (3) Each health care entity shall post a clear and unambiguous notice in a public location in the health care entity specifying that complaints may be registered with the health care entity, the Department, and with the appropriate oversight board at the Department of Regulatory Agencies (DORA). Upon request, the health care entity shall provide the patient and any interested person with contact information for registering complaints.

Colorado Revised Statutes Title 13 Courts and Court Procedure § 13-22-107 Legislative declaration--definitions--children--waiver by parent of prospective negligence claims

Search Colorado Revised Statutes

(1)(a) The general assembly hereby finds, determines, and declares it is the public policy of this state that:

(I) Children of this state should have the maximum opportunity to participate in sporting, recreational, educational, and other activities where certain risks may exist;

(II) Public, private, and non-profit entities providing these essential activities to children in Colorado need a measure of protection against lawsuits, and without the measure of protection these entities may be unwilling or unable to provide the activities;

(III) Parents have a fundamental right and responsibility to make decisions concerning the care, custody, and control of their children. The law has long presumed that parents act in the best interest of their children.

(IV) Parents make conscious choices every day on behalf of their children concerning the risks and benefits of participation in activities that may involve risk;

(V) These are proper parental choices on behalf of children that should not be ignored. So long as the decision is voluntary and informed, the decision should be given the same

dignity as decisions regarding schooling, medical treatment, and religious education; and

(VI) It is the intent of the general assembly to encourage the affordability and availability of youth activities in this state by permitting a parent of a child to release a prospective negligence claim of the child against certain persons and entities involved in providing the opportunity to participate in the activities.

(b) The general assembly further declares that the Colorado supreme court's holding in case number 00SC885, 48 P.3d 1229 (Colo. 2002) , has not been adopted by the general assembly and does not reflect the intent of the general assembly or the public policy of this state.

(2) As used in this section, unless the context otherwise requires:

(a) "Child" means a person under eighteen years of age.

(b) For purposes of this section only, "parent" means a parent, as defined in section 19-1-103(82), C.R.S ., a person who has guardianship of the person, as defined in section 19-1-103(60), C.R.S ., a person who has legal custody, as defined in section 19-1-103(73), C.R.S ., a legal representative, as defined in section 19-1-103(73.5), C.R.S ., a physical custodian, as defined in section 19-1-103(84), C.R.S ., or a responsible person, as defined in section 19-1-103(94), C.R.S .

(3) A parent of a child may, on behalf of the child, release or waive the child's prospective claim for negligence.

Patient bill of rights

Patient Bill of Rights

The law in Colorado on Patient Rights:

PATIENT RIGHTS POLICY

(1) The health care entity shall develop and implement a policy regarding patient rights. The policy shall ensure that each patient or, where appropriate, patient designated representative has the right to:
(a) participate in all decisions involving the patient's care or treatment;
(b) be informed about whether the health care entity is participating in teaching programs, and to provide informed consent prior to being included in any clinical trials relating to the patient's care.
(c) refuse any drug, test, procedure, or treatment and to be informed of risks and benefits of this action;
(d) to care and treatment, in compliance with state statute, that is respectful, recognizes a person's dignity, cultural values and religious beliefs, and provides for personal privacy to the extent possible during the course of treatment;
(e) know the names, professional status, and experience of the staff that are providing care or treatment to the patient;
(f) receive, upon request:

(i) prior to initiation of care or treatment, the estimated average charge to the patient for non-emergent care. This includes reasonable assistance with determining the charges which may include deductibles and co-payments that would not be covered by a third-party payer based on the coverage information supplied by the patient or patient designated representative. In discharging its responsibility hereunder, a health care entity may provide the estimated charge for an average patient with a similar diagnosis and inform the patient or the patient designated representative that there are variables that may alter the estimated charge.

(ii) the health care entity's general billing procedures.

(iii) an itemized bill that identifies treatment and services by date. The itemized bill shall enable patients to validate the charges for items and services provided and shall include contact information, including a telephone number for patient billing inquiries. The itemized bill shall be made available either within 10 business days of the request, or 30 days after discharge for inpatients, or 30 days after the service is rendered for outpatients - whichever is later.

(g) give informed consent for all treatment and procedures. It is the responsibility of the licensed independent practitioner and other health professionals to obtain informed consent for procedures that they provide to the patient.
(h) register complaints with the health care entity and the Department and to be informed of the procedures for registering complaints including contact information.

(i) be free of abuse and neglect. To effectuate this patient right, the health care entity shall develop and implement policies and procedures to prevent, detect, investigate, and respond to incidents of abuse or neglect. Prevention includes, but is not limited to, adequate staffing to meet the needs of the patients, screening employees for records of abuse and neglect and protecting patients from abuse during investigation of allegations. Detection includes, but is not limited to,

establishing a reporting system and training employees regarding identifying, reporting, and intervening in incidences of abuse and neglect. The health care entity shall investigate, in a timely manner, all allegations of abuse or neglect and implement corrective actions in accordance with such investigations.

(j) be free of the inappropriate use of restraints. Inappropriate use includes improper application of a restraint or the usage of a restraint as a means of coercion, discipline, convenience, or retaliation by staff. A health care entity that does not use restraints shall include a written statement in their policies and procedures to that effect. A health care entity that does use restraints shall develop and implement policies and procedures regarding:

(i) the provision of training on the use of restraints.

(ii) ongoing individual patient assessment to determine: when a medical condition or symptom indicates use of restraint to protect the patient or others from harm; the least restrictive intervention; and the discontinuation of the intervention at the earliest possible time.

(iii) documentation of the use of restraint in the patient's medical record.

(k) except in emergent situations, patients shall only be accepted for care and services when the facility can meet their identified and reasonable anticipated care, treatment, and service needs.

(l) care delivered by the health care entity in accordance with the needs of the patient.

(m) confidentiality of medical records.

(n) receive care in a safe setting.

(o) disclosure as to whether referrals to other providers are entities in which the health care entity has a financial interest.

(p) to formulate advance directives and have the health care entity comply with such directives, as applicable and in compliance with applicable state statute.

(2) The health care entity shall disclose the policy regarding patient rights prior to treatment or upon admission, where possible. For any patient care or treatment course requiring multiple patient encounters, disclosure provided at the beginning of such care or treatment course shall meet the intent of the regulations.

(3) Each health care entity shall post a clear and unambiguous notice in a public location in the health care entity specifying that complaints may be registered with the health care entity, the Department, and with the appropriate oversight board at the Department of Regulatory Agencies (DORA). Upon request, the health care entity shall provide the patient and any interested person with contact information for registering complaints.

6 CCR 1011-1 Chap 02-6.104 - PATIENT RIGHTS POLICY(1/28/16)

An Open Letter to Legislators Currently Considering Vaccine Legislation from Tetyana Obukhanych, PhD

Dear Legislator:

My name is Tetyana Obukhanych. I hold a PhD in Immunology. I am writing this letter in the hope that it will correct several common misperceptions about vaccines in order to help you formulate a fair and balanced understanding that is supported by accepted vaccine theory and new scientific findings.

Do unvaccinated children pose a higher threat to the public than the vaccinated?

It is often stated that those who choose not to vaccinate their children for reasons of conscience endanger the rest of the public, and this is the rationale behind most of the legislation to end vaccine exemptions currently being considered by federal and state legislators country-wide.

You should be aware that the nature of protection afforded by many modern vaccines – and that includes most of the vaccines recommended by the CDC for children – is not consistent with such a statement.

I have outlined below the recommended vaccines that cannot prevent transmission of disease either because they are not designed to prevent the transmission of infection (rather, they are intended to prevent disease symptoms), or because they are for non-communicable diseases.

People who have not received the vaccines mentioned below pose no higher threat to the general public than those who have, implying that discrimination against non-immunized children in a public school setting may not be warranted.

1. IPV (inactivated poliovirus vaccine) cannot prevent transmission of poliovirus. (see appendix for the scientific study, Item #1). Wild poliovirus has been non-existent in the USA for at least two decades. Even if wild poliovirus were to be re-imported by travel, vaccinating for polio with IPV cannot affect the safety of public spaces. Please note that wild poliovirus eradication is attributed to the use of a different vaccine, OPV or oral poliovirus vaccine. Despite being capable of *preventing wild poliovirus transmission, use of OPV was phased out long ago in the* USA and replaced with IPV due to safety concerns.

2. Tetanus is not a contagious disease, but rather acquired from deep-puncture wounds contaminated with C. tetani spores. Vaccinating for tetanus (via the DTaP combination vaccine) cannot alter the safety of public spaces; it is intended to *render personal protection only*.

3. While intended to prevent the disease-causing effects of the diphtheria toxin, the diphtheria toxoid vaccine (also contained in the DTaP vaccine) is not designed to prevent colonization and transmission of C. diphtheriae. Vaccinating for diphtheria cannot alter the safety of public spaces; it is likewise intended for personal protection only.

4. The acellular pertussis (aP) vaccine (the final element of the DTaP combined vaccine), now in use in the USA, replaced the whole cell pertussis vaccine in the late 1990s, which was followed by an unprecedented resurgence of whooping cough. An experiment with deliberate pertussis infection in primates revealed that the aP vaccine is not capable of preventing colonization and transmission of B. pertussis. The FDA has issued a warning regarding this crucial finding. [1]

Furthermore, the 2013 meeting of the Board of Scientific Counselors at the CDC revealed additional alarming data that pertussis variants (PRN-negative strains) currently circulating in the USA acquired a selective advantage to infect those who are up-to-date for their DTaP boosters, meaning that people who are up-to-date are more likely to be infected, and thus contagious, than people who are not vaccinated.

5. Among numerous types of H. influenzae, the Hib vaccine covers only type b. Despite its sole intention to reduce symptomatic and asymptomatic (disease-less) Hib carriage, the introduction of the Hib vaccine has inadvertently shifted strain dominance towards other types of H. influenzae (types a through f). These types have been causing invasive disease of high severity and increasing incidence in adults in the era of Hib vaccination of children (see appendix for the scientific study, Item #4). The general population is more vulnerable to the invasive disease now than it was prior to the start of the Hib vaccination campaign. Discriminating against children who are not vaccinated for Hib does not make any scientific sense in the era of non-type b H. influenzae disease.

6. Hepatitis B is a blood-borne virus. It does not spread in a community setting, especially among children who are unlikely to engage in high-risk behaviors, such as needle sharing or sex. Vaccinating children for hepatitis B cannot significantly alter the safety of public spaces. Further, school admission is not prohibited for children who are chronic hepatitis B carriers. To prohibit school admission for those who are simply unvaccinated - and do not even carry hepatitis B - would constitute unreasonable and illogical discrimination.

In summary, a person who is not vaccinated with IPV, DTaP, HepB, and Hib vaccines due to reasons of conscience poses no extra danger to the public than a person who is. No discrimination is warranted.

How often do serious vaccine adverse events happen?

It is often stated that vaccination rarely leads to serious adverse events.

Unfortunately, this statement is not supported by science.

A recent study done in Ontario, Canada, established that vaccination actually leads to an emergency room visit for 1 in 168 children following their 12-month vaccination appointment and for 1 in 730 children following their 18-month vaccination appointment (see appendix for a scientific study, Item #5).

When the risk of an adverse event requiring an ER visit after well-baby vaccinations

is demonstrably so high, vaccination must remain a choice for parents, who may understandably be unwilling to assume this immediate risk in order to protect their children from diseases that are generally considered mild or that their children may never be exposed to.

Can discrimination against families who oppose vaccines for reasons of conscience prevent future disease outbreaks of communicable viral diseases, such as measles?

Measles research scientists have for a long time been aware of the "measles paradox." I quote from the article by Poland & Jacobson (1994) "Failure to Reach the Goal of Measles Elimination: Apparent Paradox of Measles Infections in Immunized Persons." Arch Intern Med 154:1815-1820:

"The apparent paradox is that as measles immunization rates rise to high levels in a population, measles becomes a disease of immunized persons." [2]

Further research determined that behind the "measles paradox" is a fraction of the population called LOW VACCINE RESPONDERS. Low-responders are those who respond poorly to the first dose of the measles vaccine. These individuals then mount a weak immune response to subsequent RE-vaccination and quickly return to the pool of "susceptibles'' within 2-5 years, despite being fully vaccinated. [3]

Re-vaccination cannot correct low-responsiveness: it appears to be an immuno-genetic trait. [4] The proportion of low-responders among children was estimated to be 4.7% in the USA. [5]

Studies of measles outbreaks in Quebec, Canada, and China attest that outbreaks of measles still happen, even when vaccination compliance is in the highest bracket (95-97% or even 99%, see appendix for scientific studies, Items #6&7). This is because even in high vaccine responders, vaccine-induced antibodies wane over time. Vaccine immunity does not equal life-long immunity acquired after natural exposure.

It has been documented that vaccinated persons who develop breakthrough measles are contagious. In fact, two major measles outbreaks in 2011 (in Quebec, Canada, and in New York, NY) were re-imported by previously vaccinated individuals. [6] [7]

Taken together, these data make it apparent that elimination of vaccine exemptions, currently only utilized by a small percentage of families anyway, will neither solve the problem of disease resurgence nor prevent re-importation and outbreaks of previously eliminated diseases.

Is discrimination against conscientious vaccine objectors the only practical solution?

The majority of measles cases in recent US outbreaks (including the recent Disneyland outbreak) are adults and very young babies, whereas in the pre-vaccination era, measles occurred mainly between the ages 1 and 15.

Natural exposure to measles was followed by lifelong immunity from re-infection,

whereas vaccine immunity wanes over time, leaving adults unprotected by their childhood shots. Measles is more dangerous for infants and for adults than for school-aged children.

Despite high chances of exposure in the pre-vaccination era, measles practically never happened in babies much younger than one year of age due to the robust maternal immunity transfer mechanism.

The vulnerability of very young babies to measles today is the direct outcome of the prolonged mass vaccination campaign of the past, during which their mothers, themselves vaccinated in their childhood, were not able to experience measles naturally at a safe school age and establish the lifelong immunity that would also be transferred to their babies and protect them from measles for the first year of life.

Luckily, a therapeutic backup exists to mimic now-eroded maternal immunity. Infants as well as other vulnerable or immunocompromised individuals, are eligible to receive immunoglobulin, a potentially life-saving measure that supplies antibodies directed against the virus to prevent or ameliorate disease upon exposure (see appendix, Item #8).

In summary:

1) due to the properties of modern vaccines, non-vaccinated individuals pose no greater risk of transmission of polio, diphtheria, pertussis, and numerous non-type b H. influenzae strains than vaccinated individuals do, non-vaccinated individuals pose virtually no danger of transmission of hepatitis B in a school setting, and tetanus is not transmissible at all;

2) there is a significantly elevated risk of emergency room visits after childhood vaccination appointments attesting that vaccination is not risk-free;

3) outbreaks of measles cannot be entirely prevented even if we had nearly perfect vaccination compliance; and

4) an effective method of preventing measles and other viral diseases in vaccine-ineligible infants and the immunocompromised, immunoglobulin, is available for those who may be exposed to these diseases.

Taken together, these four facts make it clear that discrimination in a public school setting against children who are not vaccinated for reasons of conscience is completely unwarranted as the vaccine status of conscientious objectors poses no undue risk to the public.

Sincerely Yours,

~ Tetyana Obukhanych, PhD

Tetyana Obukhanych earned her Ph.D. in Immunology at the Rockefeller University, New

York, NY with her research dissertation focused on immunologic memory. She was subsequently involved in laboratory research as a postdoctoral research fellow at Harvard Medical School and Stanford University School of Medicine

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

1 Why get vaccinated?

Measles, mumps, and **rubella** are viral diseases that can have serious consequences. Before vaccines, these diseases were very common in the United States, especially among children. They are still common in many parts of the world.

Measles

- Measles virus causes symptoms that can include fever, cough, runny nose, and red, watery eyes, commonly followed by a rash that covers the whole body.
- Measles can lead to ear infections, diarrhea, and infection of the lungs (pneumonia). Rarely, measles can cause brain damage or death.

Mumps

- Mumps virus causes fever, headache, muscle aches, tiredness, loss of appetite, and swollen and tender salivary glands under the ears on one or both sides.
- Mumps can lead to deafness, swelling of the brain and/or spinal cord covering (encephalitis or meningitis), painful swelling of the testicles or ovaries, and, very rarely, death.

Rubella (also known as German Measles)

- Rubella virus causes fever, sore throat, rash, headache, and eye irritation.
- Rubella can cause arthritis in up to half of teenage and adult women.
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

These diseases can easily spread from person to person. Measles doesn't even require personal contact. You can get measles by entering a room that a person with measles left up to 2 hours before.

Vaccines and high rates of vaccination have made these diseases much less common in the United States.

2 MMR vaccine

Children should get 2 doses of MMR vaccine, usually:

- First dose: 12 through 15 months of age
- Second dose: 4 through 6 years of age

Infants who will be traveling outside the United States when they are between 6 and 11 months of age should get a dose of MMR vaccine before travel. This can provide temporary protection from measles infection, but will not give permanent immunity. The child should still get 2 doses at the recommended ages for long-lasting protection.

Adults might also need MMR vaccine. Many adults 18 years of age and older might be susceptible to measles, mumps, and rubella without knowing it.

A third dose of MMR might be recommended in certain mumps outbreak situations.

There are no known risks to getting MMR vaccine at the same time as other vaccines.

There is a combination vaccine called **MMRV** that contains both chickenpox and MMR vaccines. MMRV is an option for some children 12 months through 12 years of age. There is a separate Vaccine Information Statement for MMRV. Your health care provider can give you more information.

3 Some people should not get this vaccine

Tell your vaccine provider if the person getting the vaccine:

- **Has any severe, life-threatening allergies.** A person who has ever had a life-threatening allergic reaction after a dose of MMR vaccine, or has a severe allergy to any part of this vaccine, may be advised not to be vaccinated. Ask your health care provider if you want information about vaccine components.
- **Is pregnant, or thinks she might be pregnant.** Pregnant women should wait to get MMR vaccine until after they are no longer pregnant. Women should avoid getting pregnant for at least 1 month after getting MMR vaccine.
- **Has a weakened immune system** due to disease (such as cancer or HIV/AIDS) or medical treatments (such as radiation, immunotherapy, steroids, or chemotherapy).
- **Has a parent, brother, or sister with a history of immune system problems.**
- **Has ever had a condition that makes them bruise or bleed easily.**
- **Has recently had a blood transfusion or received other blood products.** You might be advised to postpone MMR vaccination for 3 months or more.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

- **Has tuberculosis.**
- **Has gotten any other vaccines in the past 4 weeks.** Live vaccines given too close together might not work as well.
- **Is not feeling well.** A mild illness, such as a cold, is usually not a reason to postpone a vaccination. Someone who is moderately or severely ill should probably wait. Your doctor can advise you.

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, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting and injuries caused by a fall. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer-lasting than routine soreness that can follow injections. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions to a vaccine are estimated at about 1 in a million doses, and would happen within *a few minutes to a few* hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety/**

5 What if there is a serious problem?

What should I look for?

- Look for anything that concerns you, such as signs of 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?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement

MMR Vaccine

Office use only

2/12/2018 | 42 U.S.C. § 300aa-26

M-M-R® II
(MEASLES, MUMPS, and RUBELLA VIRUS VACCINE LIVE)

DESCRIPTION

M-M-R® II (Measles, Mumps, and Rubella Virus Vaccine Live) is a live virus vaccine for vaccination against measles (rubeola), mumps, and rubella (German measles).

M-M-R II is a sterile lyophilized preparation of (1) ATTENUVAX® (Measles Virus Vaccine Live), a more attenuated line of measles virus, derived from Enders' attenuated Edmonston strain and propagated in chick embryo cell culture; (2) MUMPSVAX® (Mumps Virus Vaccine Live), the Jeryl Lynn™ (B level) strain of mumps virus propagated in chick embryo cell culture; and (3) MERUVAX® II (Rubella Virus Vaccine Live), the Wistar RA 27/3 strain of live attenuated rubella virus propagated in WI-38 human diploid lung fibroblasts.{1,2}

The 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.

The growth medium for rubella is Minimum Essential Medium (MEM) [a buffered salt solution containing vitamins and amino acids and supplemented with fetal bovine serum] containing recombinant human albumin and neomycin. Sorbitol and hydrolyzed gelatin stabilizer are added to the individual virus harvests.

The cells, virus pools, and fetal bovine serum are all screened for the absence of adventitious agents.

The reconstituted vaccine is for subcutaneous administration. Each 0.5 mL dose contains not less than 1,000 $TCID_{50}$ (tissue culture infectious doses) of measles virus; 12,500 $TCID_{50}$ of mumps virus; and 1,000 $TCID_{50}$ of rubella virus. Each dose of the vaccine is calculated to contain sorbitol (14.5 mg), sodium phosphate, sucrose (1.9 mg), sodium chloride, hydrolyzed gelatin (14.5 mg), recombinant human albumin (≤0.3 mg), fetal bovine serum (<1 ppm), other buffer and media ingredients and approximately 25 mcg of neomycin. The product contains no preservative.

Before reconstitution, the lyophilized vaccine is a light yellow compact crystalline plug. M-M-R II, when reconstituted as directed, is clear yellow.

CLINICAL PHARMACOLOGY

Measles, mumps, and rubella are three common childhood diseases, caused by measles virus, mumps virus (paramyxoviruses), and rubella virus (togavirus), respectively, that may be associated with serious complications and/or death. For example, pneumonia and encephalitis are caused by measles. Mumps is associated with aseptic meningitis, deafness and orchitis; and rubella during pregnancy may cause congenital rubella syndrome in the infants of infected mothers.

The impact of measles, mumps, and rubella vaccination on the natural history of each disease in the United States can be quantified by comparing the maximum number of measles, mumps, and rubella cases reported in a given year prior to vaccine use to the number of cases of each disease reported in 1995. For measles, 894,134 cases reported in 1941 compared to 288 cases reported in 1995 resulted in a 99.97% decrease in reported cases; for mumps, 152,209 cases reported in 1968 compared to 840 cases reported in 1995 resulted in a 99.45% decrease in reported cases; and for rubella, 57,686 cases reported in 1969 compared to 200 cases reported in 1995 resulted in a 99.65% decrease.{3}

Clinical studies of 284 triple seronegative children, 11 months to 7 years of age, demonstrated that M-M-R II is highly immunogenic and generally well tolerated. In these studies, a single injection of the vaccine induced measles hemagglutination-inhibition (HI) antibodies in 95%, mumps neutralizing antibodies in 96%, and rubella HI antibodies in 99% of susceptible persons. However, a small percentage (1-5%) of vaccinees may fail to seroconvert after the primary dose (see also INDICATIONS AND USAGE, *Recommended Vaccination Schedule*).

A study{4} of 6-month-old and 15-month-old infants born to vaccine-immunized mothers demonstrated that, following vaccination with ATTENUVAX, 74% of the 6-month-old infants developed detectable neutralizing antibody (NT), titers while 100% of the 15-month-old infants developed NT. This rate of seroconversion is higher than that previously reported for 6-month-old infants born to naturally immune mothers tested by HI assay. When the 6-month-old infants of immunized mothers were revaccinated at 15

months, they developed antibody titers equivalent to the 15-month-old vaccinees. The lower seroconversion rate in 6-month-olds has two possible explanations: 1) Due to the limit of the detection level of the assays (NT and enzyme immunoassay [EIA]), the presence of trace amounts of undetectable maternal antibody might interfere with the seroconversion of infants; or 2) The immune system of 6-month-olds is not always capable of mounting a response to measles vaccine as measured by the two antibody assays.

There is some evidence to suggest that infants who are born to mothers who had wild-type measles and who are vaccinated at less than one year of age may not develop sustained antibody levels when later revaccinated. The advantage of early protection must be weighed against the chance for failure to respond adequately or reimmunization.{5,6}

Efficacy of measles, mumps, and rubella vaccines was established in a series of double-blind controlled field trials which demonstrated a high degree of protective efficacy afforded by the individual vaccine components.{7-12} These studies also established that seroconversion in response to vaccination against measles, mumps, and rubella paralleled protection from these diseases.{1,3-1,5}

Following vaccination, antibodies associated with protection can be measured by neutralization assays, HI, or ELISA (enzyme linked immunosorbent assay) tests. Neutralizing and ELISA antibodies to measles, mumps, and rubella viruses are still detectable in most individuals 11 to 13 years after primary vaccination.{16-18} See INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females*, for Rubella Susceptibility Testing.

The RA 27/3 rubella strain in M-M-R II elicits higher immediate post-vaccination HI, complement-fixing and neutralizing antibody levels than other strains of rubella vaccine{19-25} and has been shown to induce a broader profile of circulating antibodies including anti-theta and anti-iota precipitating antibodies.{26,27} The RA 27/3 rubella strain immunologically simulates natural infection more closely than other rubella vaccine viruses.{27-29} The increased levels and broader profile of antibodies produced by RA 27/3 strain rubella virus vaccine appear to correlate with greater resistance to subclinical reinfection with the wild virus,{27,29-31} and provide greater confidence for lasting immunity.

INDICATIONS AND USAGE

Recommended Vaccination Schedule

M-M-R II is indicated for simultaneous vaccination against measles, mumps, and rubella in individuals 12 months of age or older.

Individuals first vaccinated at 12 months of age or older should be revaccinated prior to elementary school entry. Revaccination is intended to seroconvert those who do not respond to the first dose. The Advisory Committee on Immunization Practices (ACIP) recommends administration of the first dose of M-M-R II at 12 to 15 months of age and administration of the second dose of M-M-R II at 4 to 6 years of age.{32} In addition, some public health jurisdictions mandate the age for revaccination. Consult the complete text of applicable guidelines regarding routine revaccination including that of high-risk adult populations.

Measles Outbreak Schedule

Infants Between 6 to 12 Months of Age

Local health authorities may recommend measles vaccination of infants between 6 to 12 months of age in outbreak situations. This population may fail to respond to the components of the vaccine. Safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established. The younger the infant, the lower the likelihood of seroconversion (see CLINICAL PHARMACOLOGY). Such infants should receive a second dose of M-M-R II between 12 to 15 months of age followed by revaccination at elementary school entry.{32}

Unnecessary doses of a vaccine are best avoided by ensuring that written documentation of vaccination is preserved and a copy given to each vaccinee's parent or guardian.

Other Vaccination Considerations

Non-Pregnant Adolescent and Adult Females

Immunization of susceptible non-pregnant adolescent and adult females of childbearing age with live attenuated rubella virus vaccine is indicated if certain precautions are observed (see below and PRECAUTIONS). Vaccinating susceptible postpubertal females confers individual protection against subsequently acquiring rubella infection during pregnancy, which in turn prevents infection of the fetus and consequent congenital rubella injury.{33}

Women of childbearing age should be advised not to become pregnant for 3 months after vaccination and should be informed of the reasons for this precaution.

The ACIP has stated "If it is practical and if reliable laboratory services are available, women of childbearing age who are potential candidates for vaccination can have serologic tests to determine susceptibility to rubella. However, with the exception of premarital and prenatal screening, routinely performing serologic tests for all women of childbearing age to determine susceptibility (so that vaccine is given only to proven susceptible women) can be effective but is expensive. Also, 2 visits to the health-care provider would be necessary — one for screening and one for vaccination. Accordingly, rubella vaccination of a woman who is not known to be pregnant and has no history of vaccination is justifiable without serologic testing — and may be preferable, particularly when costs of serology are high and follow-up of identified susceptible women for vaccination is not assured."{33}

Postpubertal females should be informed of the frequent occurrence of generally self-limited arthralgia and/or arthritis beginning 2 to 4 weeks after vaccination (see ADVERSE REACTIONS).

Postpartum Women

It has been found convenient in many instances to vaccinate rubella-susceptible women in the immediate postpartum period (see PRECAUTIONS, *Nursing Mothers*).

Other Populations

Previously unvaccinated children older than 12 months who are in contact with susceptible pregnant women should receive live attenuated rubella vaccine (such as that contained in monovalent rubella vaccine or in M-M-R II) to reduce the risk of exposure of the pregnant woman.

Individuals planning travel outside the United States, if not immune, can acquire measles, mumps, or rubella and import these diseases into the United States. Therefore, prior to international travel, individuals known to be susceptible to one or more of these diseases can either receive the indicated monovalent vaccine (measles, mumps, or rubella), or a combination vaccine as appropriate. However, M-M-R II is preferred for persons likely to be susceptible to mumps and rubella; and if monovalent measles vaccine is not readily available, travelers should receive M-M-R II regardless of their immune status to mumps or rubella.{34-36}

Vaccination is recommended for susceptible individuals in high-risk groups such as college students, health-care workers, and military personnel.{33,34,37}

According to ACIP recommendations, most persons born in 1956 or earlier are likely to have been infected with measles naturally and generally need not be considered susceptible. All children, adolescents, and adults born after 1956 are considered susceptible and should be vaccinated, if there are no contraindications. This includes persons who may be immune to measles but who lack adequate documentation of immunity such as: (1) physician-diagnosed measles, (2) laboratory evidence of measles immunity, or (3) adequate immunization with live measles vaccine on or after the first birthday.{34}

The ACIP recommends that "Persons vaccinated with inactivated vaccine followed within 3 months by live vaccine should be revaccinated with two doses of live vaccine. Revaccination is particularly important when the risk of exposure to wild-type measles virus is increased, as may occur during international travel."{34}

Post-Exposure Vaccination

Vaccination of individuals exposed to wild-type measles may provide some protection if the vaccine can be administered within 72 hours of exposure. If, however, vaccine is given a few days before exposure, substantial protection may be afforded.{34,38,39} There is no conclusive evidence that vaccination of individuals recently exposed to wild-type mumps or wild-type rubella will provide protection.{33,37}

Use With Other Vaccines

See DOSAGE AND ADMINISTRATION, *Use With Other Vaccines*.

CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine, including gelatin.{40}

Do not give M-M-R II to pregnant females; the possible effects of the vaccine on fetal development are unknown at this time. If vaccination of postpubertal females is undertaken, pregnancy should be avoided for three months following vaccination (see INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females* and PRECAUTIONS, *Pregnancy*).

Anaphylactic or anaphylactoid reactions to neomycin (each dose of reconstituted vaccine contains approximately 25 mcg of neomycin).

Febrile respiratory illness or other active febrile infection. However, the ACIP has recommended that all vaccines can be administered to persons with minor illnesses such as diarrhea, mild upper respiratory infection with or without low-grade fever, or other low-grade febrile illness.{41}

Patients receiving immunosuppressive therapy. This contraindication does not apply to patients who are receiving corticosteroids as replacement therapy, e.g., for Addison's disease.

Individuals with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.

Primary and acquired immunodeficiency states, including patients who are immunosuppressed in association with AIDS or other clinical manifestations of infection with human immunodeficiency viruses;{41-43} cellular immune deficiencies; and hypogammaglobulinemic and dysgammaglobulinemic states. Measles inclusion body encephalitis{44} (MIBE), pneumonitis{45} and death as a direct consequence of disseminated measles vaccine virus infection have been reported in immunocompromised individuals inadvertently vaccinated with measles-containing vaccine.

Individuals with a family history of congenital or hereditary immunodeficiency, until the immune competence of the potential vaccine recipient is demonstrated.

WARNINGS

Due caution should be employed in administration of M-M-R II to persons with a history of cerebral injury, individual or family histories of convulsions, or any other condition in which stress due to fever should be avoided. The physician should be alert to the temperature elevation which may occur following vaccination (see ADVERSE REACTIONS).

Hypersensitivity to Eggs

Live measles vaccine and live mumps vaccine are produced in chick embryo cell culture. Persons with a history of anaphylactic, anaphylactoid, or other immediate reactions (e.g., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) subsequent to egg ingestion may be at an enhanced risk of immediate-type hypersensitivity reactions after receiving vaccines containing traces of chick embryo antigen. The potential risk to benefit ratio should be carefully evaluated before considering vaccination in such cases. Such individuals may be vaccinated with extreme caution, having adequate treatment on hand should a reaction occur (see PRECAUTIONS).{46}

However, the AAP has stated, "Most children with a history of anaphylactic reactions to eggs have no untoward reactions to measles or MMR vaccine. Persons are not at increased risk if they have egg allergies that are not anaphylactic, and they should be vaccinated in the usual manner. In addition, skin testing of egg-allergic children with vaccine has not been predictive of which children will have an immediate hypersensitivity reaction...Persons with allergies to chickens or chicken feathers are not at increased risk of reaction to the vaccine."{47}

Hypersensitivity to Neomycin

The AAP states, "Persons who have experienced anaphylactic reactions to topically or systemically administered neomycin should not receive measles vaccine. Most often, however, neomycin allergy manifests as a contact dermatitis, which is a delayed-type (cell-mediated) immune response rather than anaphylaxis. In such persons, an adverse reaction to neomycin in the vaccine would be an erythematous, pruritic nodule or papule, 48 to 96 hours after vaccination. A history of contact dermatitis to neomycin is not a contraindication to receiving measles vaccine."{47}

Thrombocytopenia

Individuals with current thrombocytopenia may develop more severe thrombocytopenia following vaccination. In addition, individuals who experienced thrombocytopenia with the first dose of M-M-R II (or its component vaccines) may develop thrombocytopenia with repeat doses. Serologic status may be evaluated to determine whether or not additional doses of vaccine are needed. The potential risk to benefit ratio should be carefully evaluated before considering vaccination in such cases (see ADVERSE REACTIONS).

PRECAUTIONS

General

Adequate treatment provisions, including epinephrine injection (1:1000), should be available for immediate use should an anaphylactic or anaphylactoid reaction occur.

Special care should be taken to ensure that the injection does not enter a blood vessel.

Children and young adults who are known to be infected with human immunodeficiency viruses and are not immunosuppressed may be vaccinated. However, vaccinees who are infected with HIV should be monitored closely for vaccine-preventable diseases because immunization may be less effective than for uninfected persons (see CONTRAINDICATIONS).{42,43}

Vaccination should be deferred for 3 months or longer following blood or plasma transfusions, or administration of immune globulin (human).{47}

Excretion of small amounts of the live attenuated rubella virus from the nose or throat has occurred in the majority of susceptible individuals 7 to 28 days after vaccination. There is no confirmed evidence to indicate that such virus is transmitted to susceptible persons who are in contact with the vaccinated individuals. Consequently, transmission through close personal contact, while accepted as a theoretical possibility, is not regarded as a significant risk.{33} However, transmission of the rubella vaccine virus to infants via breast milk has been documented (see *Nursing Mothers*).

There are no reports of transmission of live attenuated measles or mumps viruses from vaccinees to susceptible contacts.

It has been reported that live attenuated measles, mumps and rubella virus vaccines given individually may result in a temporary depression of tuberculin skin sensitivity. Therefore, if a tuberculin test is to be done, it should be administered either before or simultaneously with M-M-R II.

Children under treatment for tuberculosis have not experienced exacerbation of the disease when immunized with live measles virus vaccine;{48} no studies have been reported to date of the effect of measles virus vaccines on untreated tuberculous children. However, individuals with active untreated tuberculosis should not be vaccinated.

As for any vaccine, vaccination with M-M-R II may not result in protection in 100% of vaccinees.

The health-care provider should determine the current health status and previous vaccination history of the vaccinee.

The health-care provider should question the patient, parent, or guardian about reactions to a previous dose of M-M-R II or other measles-, mumps-, or rubella-containing vaccines.

Information for Patients

The health-care provider should provide the vaccine information required to be given with each vaccination to the patient, parent, or guardian.

The health-care provider should inform the patient, parent, or guardian of the benefits and risks associated with vaccination. For risks associated with vaccination see WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

Patients, parents, or guardians should be instructed to report any serious adverse reactions to their health-care provider who in turn should report such events to the U.S. Department of Health and Human Services through the Vaccine Adverse Event Reporting System (VAERS), 1-800-822-7967.{49}

Pregnancy should be avoided for 3 months following vaccination, and patients should be informed of the reasons for this precaution (see INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females*, CONTRAINDICATIONS, and PRECAUTIONS, *Pregnancy*).

Laboratory Tests

See INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females*, for Rubella Susceptibility Testing, and CLINICAL PHARMACOLOGY.

Drug Interactions

See DOSAGE AND ADMINISTRATION, *Use With Other Vaccines.*

Immunosuppressive Therapy

The immune status of patients about to undergo immunosuppressive therapy should be evaluated so that the physician can consider whether vaccination prior to the initiation of treatment is indicated (see CONTRAINDICATIONS and PRECAUTIONS).

The ACIP has stated that "patients with leukemia in remission who have not received chemotherapy for at least 3 months may receive live virus vaccines. Short-term (<2 weeks), low- to moderate-dose systemic corticosteroid therapy, topical steroid therapy (e.g. nasal, skin), long-term alternate-day treatment with low to moderate doses of short-acting systemic steroid, and intra-articular, bursal, or tendon injection of corticosteroids are not immunosuppressive in their usual doses and do not contraindicate the administration of [measles, mumps, or rubella vaccine]."{33,34,37}

Immune Globulin

Administration of immune globulins concurrently with M-M-R II may interfere with the expected immune response.{33,34,47}

See also PRECAUTIONS, *General*.

Carcinogenesis, Mutagenesis, Impairment of Fertility

M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.

Pregnancy

Animal reproduction studies have not been conducted with M-M-R II. It is also not known whether M-M-R II can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, the vaccine should not be administered to pregnant females; furthermore, pregnancy should be avoided for 3 months following vaccination (see INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females* and CONTRAINDICATIONS).

In counseling women who are inadvertently vaccinated when pregnant or who become pregnant within 3 months of vaccination, the physician should be aware of the following: (1) In a 10-year survey involving over 700 pregnant women who received rubella vaccine within 3 months before or after conception (of whom 189 received the Wistar RA 27/3 strain), none of the newborns had abnormalities compatible with congenital rubella syndrome;{50} (2) Mumps infection during the first trimester of pregnancy may increase the rate of spontaneous abortion. Although mumps vaccine virus has been shown to infect the placenta and fetus, there is no evidence that it causes congenital malformations in humans;{37} and (3) Reports have indicated that contracting wild-type measles during pregnancy enhances fetal risk. Increased rates of spontaneous abortion, stillbirth, congenital defects and prematurity have been observed subsequent to infection with wild-type measles during pregnancy.{51,52} There are no adequate studies of the attenuated (vaccine) strain of measles virus in pregnancy. However, it would be prudent to assume that the vaccine strain of virus is also capable of inducing adverse fetal effects.

Nursing Mothers

It is not known whether measles or mumps vaccine virus is secreted in human milk. Recent studies have shown that lactating postpartum women immunized with live attenuated rubella vaccine may secrete the virus in breast milk and transmit it to breast-fed infants.{53} In the infants with serological evidence of rubella infection, none exhibited severe disease; however, one exhibited mild clinical illness typical of acquired rubella.{54,55} Caution should be exercised when M-M-R II is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of measles vaccine in infants below the age of 6 months have not been established (see also CLINICAL PHARMACOLOGY). Safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established.

Geriatric Use

Clinical studies of M-M-R II did not include sufficient numbers of seronegative subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger subjects.

ADVERSE REACTIONS

The following adverse reactions are listed in decreasing order of severity, without regard to causality, within each body system category and have been reported during clinical trials, with use of the marketed vaccine, or with use of monovalent or bivalent vaccine containing measles, mumps, or rubella:

Body as a Whole

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

Cardiovascular System

Vasculitis.

Digestive System

Pancreatitis; diarrhea; vomiting; parotitis; nausea.

Endocrine System

Diabetes mellitus.

Hemic and Lymphatic System

Thrombocytopenia (see WARNINGS, *Thrombocytopenia*); purpura; regional lymphadenopathy; leukocytosis.

Immune System

Anaphylaxis and anaphylactoid reactions have been reported as well as related phenomena such as angioneurotic edema (including peripheral or facial edema) and bronchial spasm in individuals with or without an allergic history.

Musculoskeletal System

Arthritis; arthralgia; myalgia.

Arthralgia and/or arthritis (usually transient and rarely chronic), and polyneuritis are features of infection with wild-type rubella and vary in frequency and severity with age and sex, being greatest in adult females and least in prepubertal children. This type of involvement as well as myalgia and paresthesia, have also been reported following administration of MERUVAX II.

Chronic arthritis has been associated with wild-type rubella infection and has been related to persistent virus and/or viral antigen isolated from body tissues. Only rarely have vaccine recipients developed chronic joint symptoms.

Following vaccination in children, reactions in joints are uncommon and generally of brief duration. In women, incidence rates for arthritis and arthralgia are generally higher than those seen in children (children: 0-3%; women: 12-26%),{17,56,57} and the reactions tend to be more marked and of longer duration. Symptoms may persist for a matter of months or on rare occasions for years. In adolescent girls, the reactions appear to be intermediate in incidence between those seen in children and in adult women. Even in women older than 35 years, these reactions are generally well tolerated and rarely interfere with normal activities.

Nervous System

Encephalitis; encephalopathy; measles inclusion body encephalitis (MIBE) (see CONTRAINDICATIONS); 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.

Encephalitis and encephalopathy have been reported approximately once for every 3 million doses of M-M-R II or measles-, mumps-, and rubella-containing vaccine administered since licensure of these vaccines.

The risk of serious neurological disorders following live measles virus vaccine administration remains less than the risk of encephalitis and encephalopathy following infection with wild-type measles (1 per 1000 reported cases).{58,59}

In severely immunocompromised individuals who have been inadvertently vaccinated with measles-containing vaccine; measles inclusion body encephalitis, pneumonitis, and fatal outcome as a direct consequence of disseminated measles vaccine virus infection have been reported (see CONTRAINDICATIONS). In this population, disseminated mumps and rubella vaccine virus infection have also been reported.

There have been reports of subacute sclerosing panencephalitis (SSPE) in children who did not have a history of infection with wild-type measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccine distribution, the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. This is far less than the association with infection with wild-type measles, 6-22 cases of SSPE per million cases of measles. The results of a retrospective case-controlled study conducted by the Centers for Disease Control and Prevention suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with its inherent higher risk of SSPE.{60}

Cases of aseptic meningitis have been reported to VAERS following measles, mumps, and rubella vaccination. Although a causal relationship between the Urabe strain of mumps vaccine and aseptic meningitis has been shown, there is no evidence to link Jeryl Lynn™ mumps vaccine to aseptic meningitis.

Respiratory System

Pneumonia; pneumonitis (see CONTRAINDICATIONS); sore throat; cough; rhinitis.

Skin

Stevens-Johnson syndrome; erythema multiforme; urticaria; rash; measles-like rash; pruritis.

Local reactions including burning/stinging at injection site; wheal and flare; redness (erythema); swelling; induration; tenderness; vesiculation at injection site; Henoch-Schönlein purpura; acute hemorrhagic edema of infancy.

Special Senses — Ear

Nerve deafness; otitis media.

Special Senses — Eye

Retinitis; optic neuritis; papillitis; retrobulbar neuritis; conjunctivitis.

Urogenital System

Epididymitis; orchitis.

Other

Death from various, and in some cases unknown, causes has been reported rarely following vaccination with measles, mumps, and rubella vaccines; however, a causal relationship has not been established in healthy individuals (see CONTRAINDICATIONS). No deaths or permanent sequelae were reported in a published post-marketing surveillance study in Finland involving 1.5 million children and adults who were vaccinated with M-M-R II during 1982 to 1993.{61}

Under the National Childhood Vaccine Injury Act of 1986, health-care providers and manufacturers are required to record and report certain suspected adverse events occurring within specific time periods after vaccination. However, the U.S. Department of Health and Human Services (DHHS) has established a Vaccine Adverse Event Reporting System (VAERS) which will accept all reports of suspected events.{49} A VAERS report form as well as information regarding reporting requirements can be obtained by calling VAERS 1-800-822-7967.

DOSAGE AND ADMINISTRATION

FOR SUBCUTANEOUS ADMINISTRATION

Do not inject intravascularly.

The dose for any age is 0.5 mL administered subcutaneously, preferably into the outer aspect of the upper arm.

The recommended age for primary vaccination is 12 to 15 months.

Revaccination with M-M-R II is recommended prior to elementary school entry. See also INDICATIONS AND USAGE, *Recommended Vaccination Schedule.*

Children first vaccinated when younger than 12 months of age should receive another dose between 12 to 15 months of age followed by revaccination prior to elementary school entry.{32} See also INDICATIONS AND USAGE, *Measles Outbreak Schedule.*

Immune Globulin (IG) is not to be given concurrently with M-M-R II (see PRECAUTIONS, *General* and PRECAUTIONS, *Drug Interactions*).

CAUTION: A sterile syringe free of preservatives, antiseptics, and detergents should be used for each injection and/or reconstitution of the vaccine because these substances may inactivate the live virus vaccine. A 25 gauge, 5/8" needle is recommended.

To reconstitute, use only the diluent supplied, since it is free of preservatives or other antiviral substances which might inactivate the vaccine.

Single Dose Vial — First withdraw the entire volume of diluent into the syringe to be used for reconstitution. Inject all the diluent in the syringe into the vial of lyophilized vaccine, and agitate to mix thoroughly. If the lyophilized vaccine cannot be dissolved, discard. Withdraw the entire contents into a syringe and inject the total volume of restored vaccine subcutaneously.

It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of hepatitis B and other infectious agents from one person to another.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. M-M-R II, when reconstituted, is clear yellow.

Use With Other Vaccines

M-M-R II should be given one month before or after administration of other live viral vaccines.

M-M-R II has been administered concurrently with VARIVAX® [Varicella Virus Vaccine Live (Oka/Merck)], and PedvaxHIB® [*Haemophilus b* Conjugate Vaccine (Meningococcal Protein Conjugate)] using separate injection sites and syringes. No impairment of immune response to individually tested vaccine antigens was demonstrated. The type, frequency, and severity of adverse experiences observed with M-M-R II were similar to those seen when each vaccine was given alone.

Routine administration of DTP (diphtheria, tetanus, pertussis) and/or OPV (oral poliovirus vaccine) concurrently with measles, mumps and rubella vaccines is not recommended because there are limited data relating to the simultaneous administration of these antigens.

However, other schedules have been used. The ACIP has stated "Although data are limited concerning the simultaneous administration of the entire recommended vaccine series (i.e., DTaP [or DTwP], IPV [or OPV], Hib with or without Hepatitis B vaccine, and varicella vaccine), data from numerous studies have

indicated no interference between routinely recommended childhood vaccines (either live, attenuated, or killed). These findings support the simultaneous use of all vaccines as recommended."{62}

HOW SUPPLIED

No. 4681 — M-M -R II is supplied as follows: (1) a box of 10 single-dose vials of lyophilized vaccine (package A), **NDC** 0006-4681-00; and (2) a box of 10 vials of diluent (package B). To conserve refrigerator space, the diluent may be stored separately at room temperature.

Storage

To maintain potency, M-M-R II must be stored between -58°F and +46°F (-50°C to +8°C). Use of dry ice may subject M-M-R II to temperatures colder than -58°F (-50°C).

Protect the vaccine from light at all times, since such exposure may inactivate the viruses.

Before reconstitution, store the lyophilized vaccine at 36°F to 46°F (2°C to 8°C). The diluent may be stored in the refrigerator with the lyophilized vaccine or separately at room temperature. **Do not freeze the diluent.**

It is recommended that the vaccine be used as soon as possible after reconstitution. Store reconstituted vaccine in the vaccine vial in a dark place at 36°F to 46°F (2°C to 8°C) and discard if not used within 8 hours.

For information regarding stability under conditions other than those recommended, call 1-800-MERCK-90.

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REVIEW

Autoimmune/Inflammatory Syndrome Induced by Adjuvants and Thyroid Autoimmunity

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The autoimmune/inflammatory syndrome induced by adjuvants (ASIA), presented by Shoenfeld and Agmon-Levin in 2011, is an entity that incorporates diverse autoimmune conditions induced by the exposure to various adjuvants. Adjuvants are agents that entail the capability to induce immune reactions. Adjuvants are found in many vaccines and used mainly to increase the response to vaccination in the general population. Silicone has also been reported to be able to induce diverse immune reactions. Clinical cases and series of heterogeneous autoimmune conditions including systemic sclerosis, systemic lupus erythematosus, and rheumatoid arthritis have been reported to be induced by several adjuvants. However, only a small number of cases of autoimmune thyroid disorder have been included under the umbrella of ASIA syndrome. Indeed, clinical cases of Hashimoto's thyroiditis and/or subacute thyroiditis were observed after the exposure to vaccines as well as silicone implantation. In our review, we aimed to summarize the current knowledge on ASIA syndrome presented as endocrinopathies, focusing on autoimmune thyroid disorders associated with the various adjuvants.

Keywords: autoimmune/inflammatory syndrome induced by adjuvants, thyroid, endocrinopathy, adjuvants, vaccines, silicone, Hashimoto's thyroiditis, Graves disease

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INTRODUCTION

Adjuvants are substances that are able to trigger autoimmunity *via* a variety of mechanisms, such as alteration of the host's immune system, polyclonal activation of B cells, effects on cellular immunity, immunoregulatory cells, viral-induced antibodies, and acceleration of molecular mimicry (1). Exposure to adjuvants can occur in a variety of methods due to their wide range of uses in vaccines, mineral oils, silicone implants, and many other products and devices. The association between adjuvant exposure and autoimmunity manifests itself in five autoimmune conditions sharing similar autoimmunity manifestations (2, 3), such as the postvaccination phenomena, the macrophagic myofasciitis syndrome (MMF), the Gulf war syndrome (GWS), siliconosis, and the sick building syndrome (SBS) (4, 5). The autoimmune/inflammatory syndrome induced by adjuvants (ASIA), presented by Shoenfeld and Agmon-Levin (6) in 2011, is a single entity that incorporates all five conditions. Extensive research has identified the genetic background, contributing to the development of ASIA syndrome in predisposed individuals following adjuvant exposure. A large number of autoimmune diseases share several alleles of the HLA class II such as DRB1 locus. The development

of specific autoantibodies is determined by DRB1 alleles leading to an abnormal response and development of full-blown autoimmune diseases (7, 8).

When used in vaccines, adjuvants are purposely used as immunogenicity enhancing agents that are essential for directing the adaptive immunorespon se (9). However, they might also trigger undesired autoimmune reactions that question the use of adjuvants and their safety in the context of DRB1*01 genetic background (10).

A systematic review by Jara et al. (4) reported that 4479 ASIA cases have been identified since its presentation in 2011. Among them, 305 were considered severe, with the majority of these cases being developed following vaccines mainly directed to HPV, HBV, and seasonal influenza. Despite vaccines' proven record of safety and efficiency, aluminum hydroxide was used in these vaccines along with the viral antigens as an adjuvant. Due to aluminum's capability to enhance the immunoresponse, it enables the usage of smaller amount of antigens. However, enhanced immunogenicity might lead to enhanced reactogenicity in a process not always benign involving pathological stimulation (11).

The other adjuvants containing products yielding severe clinical manifestations are silicone implants and mineral oil fillers (4, 12).

Silicone has been considered as an inert material, which is unable to induce immune reactions in the human body. Therefore, it has been used in many medical devices for the last 60 years, including both silicone and saline breast implants. However, a possible association between silicone exposure and autoimmune diseases has been reported in many studies demonstrating the development of autoimmune diseases and autoantibodies in patients following exposure to silicone implants (13, 14). Improved clinical manifestations after the extraction of implants (15) support the relationship between silicone and autoimmunity.

Mineral oil injections, which are prevalent in Mexico and Latin America for cosmetic uses, have been identified as a leading cause of ASIA syndrome as well *via* the proposed mechanism of chronic inflammation induction leading to granuloma formation and thickening of the dermis (4, 10).

The risk for autoimmune diseases, determined by the patient's genetic background, is increased in patients with autoimmune diseases history such as type 1 diabetes mellitus (T1DM). Thyroid antibodies can be identified in approximately 20–25% of patients with type 1 diabetes, and up to 50% of them progress to clinical autoimmune thyroid disease (AITD) (16). Thyroid autoimmune diseases have been described in many case reports and case series, presenting thyroid autoimmune manifestations along with other autoimmune conditions.

In genetically predisposed individuals, under particular conditions, molecular mimicry between microbial and human antigens has been shown to be able to turn a defensive immunoresponse into autoimmune response. This mechanism has yet to be explored in the field of thyroid autoimmune diseases (17). In our review, we aimed to summarize the current knowledge about ASIA syndrome and the relationship between adjuvants and autoimmune diseases, focusing on its association with autoimmune endocrinopathies and thyroid autoimmunity.

ENDOCRINOPATHY AND ASIA SYNDROME

Pathological processes of the endocrine glands result in abnormal levels of circulating hormones, which lead to endocrinopathies. Some endocrine disorders are immune mediated, such as Hashimoto's thyroiditis (HT), Graves' disease, and T1DM (18–20). Thus, it is possible that endocrine autoimmune diseases can be triggered by adjuvants, configuring cases of ASIA syndrome. Case reports, cohort and case–control studies on ASIA syndrome, and the majority of the endocrinopathies are still scarce. Lately, primary ovarian failure (POF) has been linked to ASIA, especially after vaccination (21–23).

Primary ovarian failure or premature ovarian insufficiency is defined as a combination of amenorrhea, for a minimum of 4 months, decline in sex steroids, and follicle-stimulating hormone (FSH) above 40 IU/l at two measurements with an interval of at least 1 month in women younger than 40 years (26). POF is a disorder with multiple etiologic mechanisms. The presence of lymphocytic invasion in the oophorus and the identification of autoantibodies against ovarium antigens on the theca, granulose, corpus luteum, and zona pellucida (27–29) support the idea that part of its etiology, estimated in 20–30% (30), is immune mediated. Furthermore, POF is commonly associated with other autoimmune diseases, including Addison's disease, thyroiditis, autoimmune polyglandular syndrome, systemic lupus erythematosus (SLE), hemolytic anemia, idiopathic thrombocytopenic purpura (ITP), and Sjogren's syndrome (31). The pathogenesis of POF also involves genetic mutations, metabolic disorders, and environmental factors, such as virus infection, chemo and radiotherapy, and surgeries (30).

HPV vaccine has been reported as an important issue in ASIA syndrome, already being related, for instance, to Guillain-Barré syndrome and other neuropathies, such as SLE, vasculitis, ITP, and autoimmune hepatitis (32–36). Developing autoimmune diseases as an adverse effect of the vaccine can be both due to its HPV virus-like particles, which have potent immuno-stimulatory properties (and can induce autoimmunity by molecular mimicry, epitope spreading, bystander activation, and polyclonal activation) (37), and due to the presence of aluminum as an adjuvant in the vaccine (38). Adjuvants are capable of increasing, intensifying, and prolonging antigen-specific immunoresponse of the vaccines without holding its own specific antigenic effect (38). Autoimmune well-defined diseases, as well as the non-specific immune disorders, following vaccination can present as a subacute vaccination side effect or appear months or years after the boosters (39–43). Genetically predisposed patients are more likely to exhibit late manifestations and are in a higher risk of developing ASIA syndrome (36, 44).

Colafrancesco et al. (21) recently reported three cases of POF following immunization with HPV vaccine. The three patients fulfilled the criteria for ASIA syndrome suggested by Shoenfeld and Agmon-Levin (6). They described three young women, previously healthy and with normal sexual development, who received three administrations of the quadrivalent HPV vaccine. The patients experienced general symptoms, including nausea, stomachaches, heavy and burning sensations in the injected arm.

headaches, insomnia, arthralgia, depression, anxiety; and difficulty in concentrating, and then presented amenorrhea within approximately 10 months, 2 years, and 10 years after the first dose. Two of them were positive for previously negative antibodies (anti-TPO and antiovarian). Hormonal screening was performed, showing increased FSH and luteinizing hormone (LH) plus extremely low levels of estradiol. Pregnancy was excluded, as well as no abnormalities were revealed in the transvaginal and pelvic ultrasound. After a karyotype evaluation and search for Fragile X syndrome with no aberrations, they were diagnosed with POF. Moreover, two of the three patients were siblings leading to the hypothesis that may exist as a rare risk factor for this adverse effect.

Little and Ward (22) also reported a case of POF succeeding HPV vaccination, in a 16-year-old patient, who presented irregular menses after taking the quadrivalent vaccine, followed by oligomenorrhea and amenorrhea. Her hormone profile also showed high levels of FSH and LH and low levels of estradiol and anti-mullerian hormone (AMH), and after excluding pregnancy and genetic, endocrinal, and other causes, she was diagnosed with POF.

Problems of quadrivalent HPV vaccine introduction in the market were wisely pointed by Little and Ward (23). They reported three other cases of young women who develop POF after having quadrivalent HPV vaccine and questioned some issues about its safety. First, despite the fact that the vaccine protocol suggests three doses, in the preclinical studies for toxicity, only two boosters were given to the rats. Still, the animals' reproductive system was not analyzed in a long-term period. Moreover, the phase II and III clinical studies on safety of the vaccine regarding the fertility were not complete: half of the subjects studied were lost to follow-up at 1 year; some of the subjects were on hormone contraception methods, which could mask the ovarian insufficiency; they have not considered medical conditions that flourished more than 7 months after the vaccination as associated with the vaccine; and adverse effects were only reported 2 weeks after the boosters. Furthermore, the placebo used as control in the phase III safety studies of the quadrivalent HPV vaccine was aluminum, also present in the vaccine solution, which was already shown to play as an adjuvant in ASIA syndrome.

Thus, HPV vaccine is likely to be an important trigger in ASIA syndrome, including immuno-mediated endocrine disorders, such as POF. Due to long periods of intervals between the vaccine injections and the development of the ovarian insufficiency, it is questionable if there is indeed a causal relationship between them. However, as previously mentioned, the safety preclinical and clinical studies of HPV vaccine are lacking some information regarding fertility safety, and the side effects were shown to be able to appear even after months or years.

Other vaccines and adjuvants may also trigger POF, as well as other immuno-mediated endocrinopathies, like for instance, type 1-diabetes may be induced by the same adjuvants. Indeed, in a cohort study with 211 young female patients with autoimmune diseases and 857 matched controls, they showed that patients exposed to quadrivalent HPV vaccine were in a higher risk of developing type 1-diabetes mellitus (OR = 1.2) (13). Additionally, it was shown in a prospective cohort study (46) that some vaccines are related to increased levels of diabetes autoantibodies, such as antibody against glutamic acid decarboxylase (GADA) and tyrosine phosphatase (IA-2A). These autoantibodies, which are considered reliable markers for the disease process (47, 48), were more frequently found in the subjects who received hemophilus influenza B (HIB) vaccination (OR = 5.9 and 3.4 in IA-2A and GADA, respectively). Especially, the IA-2A serum concentrations were significantly higher in patients exposed to HIB. Also, BCG was correlated to an enhanced prevalence of IA-2A ($p < 0.01$). The previously mentioned studies suggest that ASIA syndrome, particularly post vaccination, and endocrinopathies might be linked.

AUTOIMMUNE THYROID DISEASE AND ASIA SYNDROME

During the last years, abundant case reports and series were published supporting that various autoimmune disorders may be induced by adjuvants and be enclosed under ASIA syndrome (4, 12). Despite the fact of being the most common autoimmune disorder, unexpectedly, we have revealed very few articles and case reports in the literature describing the induction of AITD by various adjuvants. In this section, we report that the relevant case descriptions of AITD were reported to be correlated to immunization and silicone implants.

Hernàn Martinez et al. (49) described a case of a 55-year-old man with a family history of autoimmune diseases and medical history of diabetes and psoriasis, who developed subacute thyroiditis shortly after the administration of an influenza vaccine. Subacute thyroiditis is a very rare disease, and the authors of the mentioned case concluded that the induction of the disease was a result of an interaction between the genetic predisposition and vaccination. Another similar case of subacute thyroiditis was reported in a 25-year-old female (50). The patient was admitted due to fever, swelling, and tender mass in the neck. Two days before her presentation, she received influenza vaccine (Vaxigrip). Biopsy of the thyroid has revealed multinuclear giant cell granulomas.

A previously healthy 36-year-old female presented with clinical symptoms of thyrotoxicosis including tachycardia, anxiety, and tenderness in her neck (51). One month before her presentation, she received H1N1 vaccine. Thyroid function tests confirmed remarkable thyrotoxicosis. Thyroid scintigraphy was performed and showed significant diffuse reduction in the technetium uptake. Therefore, a diagnosis of subacute thyroiditis was made. Moving to another type of adjuvant, cases of granulomatous inflammation of the thyroid have been reported with silicone breast implants (52). Vayssairat et al. (53) described two cases of HT after receiving a silicone gel-filled breast implants. Both cases were induced after a long period of incubation, the first case is a 45-year-old women who had bilateral silicone implant of the breast in 1976 and developed HT in 1991. In addition, the patient complained of other non-specific symptoms including fatigue, morning stiffness, and sicca syndrome. Thyroid ultrasonography

showed an enlarged thyroid gland with a diffusely hypoechogenic pattern. The implants were painful and removed, showing extremely dense connective tissue with fibrosis. The second case of HT presented with hyperthyroidism clinical manifestation, 10 years after the silicon implantation, reporting positive anti-TPO. The implants were again painful, and the patient developed positive antinuclear antibodies (ANA). An animal experiment aimed to evaluate the immunological adjuvancy potential of silicone gel taken from breast implants (54). The study has found that silicone gel is able to stimulate the production of autoantibodies to rat thyroglobulin and bovine collagen II. However, this immune reaction was not associated with any histological evidence of thyroiditis or arthritis.

A cohort study was performed to assess the risk of new onset autoimmune disease in young women exposed to human papillomavirus-16/18 AS04-adjuvanted vaccine in the United Kingdom (55). The study reported an incidence rate ratio (95% CI) of 3.75 (1.25–11.31) for autoimmune thyroiditis among females.

An animal study has reported that immunization of BALB/c mice with the extracellular domain of the human TSH receptor led to the production of TSH binding-inhibiting and thyroid-blocking antibodies accompanied by lymphocytic infiltration of the thyroid (56).

In summary, ASIA syndrome is being more recognized by physicians, and therefore, more studies and cases have reported the correlation of the exposure to various adjuvants with diverse autoimmune diseases. Still, very few clinical reports and animal models studies were published to show the relationship between endocrinopathies in general and AITD in particular with adjuvants. However, the clinical cases of HT and/or subacute thyroiditis were observed after the exposure to vaccines as well as silicone implantation. Therefore, we believe that the minority of cases is not owing to rarity of association between adjuvants and AITD rather than the lack of awareness among physicians of such association. Consequently, physicians must be mindful that thyroiditis and other thyroid disorders can be induced by diverse adjuvants and therefore to reconsider non-essential vaccination in genetically predisposed individuals for autoimmune diseases.

AUTHOR CONTRIBUTIONS

AW, PD, SB, and YS designed the study and reviewed the literature on ASIA syndrome and thyroid autoimmunity. AW, PD, and SB wrote the manuscript. AW and YS edited the manuscript. All the authors have revised the paper and approved the final edition.

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DOSES of VACCINES for U.S. CHILDREN from BIRTH-18 YEARS (CDC)

1983

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)
Td (15 years)

*1986:
Pharmaceutical manufacturers producing vaccines were freed from ALL liability resulting from vaccine injury or death by the Childhood Vaccine Injury Act.

From Jennifer Peery

(SOURCE: www.CDC.gov)

DTP- Diphtheria, Tetanus, Pertussis (whole cell)
OPV- Oral Polio Virus
MMR- Measles, Mumps, Rubella
Hep B- Hepatitis B
DTaP- Diphtheria, Tenatus, Pertussis (acellular)
HIB- Haemophilus influenzae Type B
PCV- Pneumococcal
IPV- Inactivated Polio Virus
Varicella- Chicken Pox
Td- Tetanus, Diphtheria
Tdap- Tetanus, Diphtheria, and Pertussis
HPV- Human papillomavirus (Gardasil)

2019

Influenza (Pregnancy)
TdaP (Pregnancy)
Hep B (birth)
Hep B (2 months)
Rotavirus (2 months)
DTaP (2 months)
HIB (2 months)
PCV (2 months)
IPV (2 months)
Rotavirus (4 months)
DTaP (4 months)
HIB (4 months)
PCV (4 months)
IPV (4 months)
Hep B (6 months)
Rotavirus (6 months)
DTaP (6 months)
HIB (6 months)
PCV (6 months)
IPV (6 months)
Influenza (6 months)
Influenza (7 months)
HIB (12 months)
PCV (12 months)
MMR (12 months)
Varicella (12 months)
Hep A (12 months)
DTaP (18 months)
Influenza (18 months)
Hep A (18 months)
Influenza (30 months)
Influenza (42 months)
DTaP (4 years)
IPV (4 years)
MMR (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)
HPV (11 years)

Influenza (11 years)
TdaP (12 years)
Influenza (12 years)
Meningococcal (12 yrs)
Influenza (13 years)
Influenza (14 years)
Influenza (15 years)
Influenza (16 years)
Meningococcal (16 yrs)
Influenza (17 years)
Influenza (18 years)

TOTAL DOSES: 69
Injections: **50**
(3 Doses of Rotavirus are liquid)
Total Doses without the Flu shot

1983
TOTAL DOSES: 24
Injections: 7
(4 Doses of Polio were liquid)

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Vaccine Safety Project

VIDEO TRANSCRIPT

ROBERT F. KENNEDY, JR.

Children's Health Defense

Introduction

Hi, I'm Robert F. Kennedy, Jr. and I'm the Chairman of the Children's Health Defense and I made this video primer because in a dozen states across America today, state legislatures and governors are considering passing vaccine mandates and the facts in this video are facts that every political leader who's trying to decide whether to vote for or against those mandates ought to understand.

I want to start by saying that I am fiercely pro-vaccine. I had all six of my children vaccinated. I believe that vaccines have saved millions of lives.

But I want vaccines that are as safe as possible, I want science that is robust and I want to make sure that we have a regulatory agency that has unquestioned integrity and freedom of conflicts of interest and we don't have those things today.

The vaccine ingredient that got me involved in this controversy was thimerosal, which of course is a mercury-based preservative that is still in 48 million flu shots annually.

One of the characteristics of mercury is that it tends to injure boys instead of girls or over girls. Science indicates the reason for that is because testosterone tends to amplify the neurotoxic impacts of the mercury molecule and estrogen tends to wrap that molecule and protect the female brain.

This video indicates some of the human impacts of the continued use of thimerosal in American flu shots.

Trace Amounts Excerpt

I was six and a half months pregnant with twins, a boy and a girl. I went in for a routine exam and at the end of the exam, as I was about to leave, my doctor said, "You know, I really would like you to stop "by the nurse's station and get a flu shot." Against my better judgment, I went ahead and let them give me the shot.

Within five to six hours after the shot, I started getting severe cramps and bleeding. I immediately went back to the hospital where my doctor was and he said, "You are having a miscarriage."

I lost my son and my daughter ended up, at 18 months, diagnosed with severe autism. She regressed in my womb. I had her baby teeth analyzed and baby teeth form in the womb, her baby teeth had tons of mercury in them.

My doctor was so horrified by what happened, he said, "I'm not giving any more flu shots "to pregnant women."

- Any toxicologist will tell you that if you inject mercury or aluminum into a little baby, or a child, or a pregnant woman, there's going to be bad consequences including neurodevelopmental damages.

I. Who is Responsible?

But my question was, how did those neurotoxic elements get into our vaccine supply? What kind of testing was done? The answers to that investigation were shocking to me and I believe that they will be shocking to any pediatrician, any public health regulator, and any politician who is now considering vaccine I'm going to start by talking about this study that was published in February of 2017, of this year.

One of the leaders of the team is Dr. Peter Aaby.

Dr. Aaby is one of the world's foremost authorities on vaccines, particularly vaccines in Africa.

This study was a study of the DTP vaccine, diphtheria, tetanus, and pertussis, the most popular vaccine in the world and a vaccine that's given to virtually every vaccinated child in Africa.

Because of a quirk in the way that the vaccines were administered in the nation of Guinea-Bissau, it allowed Dr. Aaby and his team to do the kind of study vaccine safety advocates in this country have advocated for many, many years.

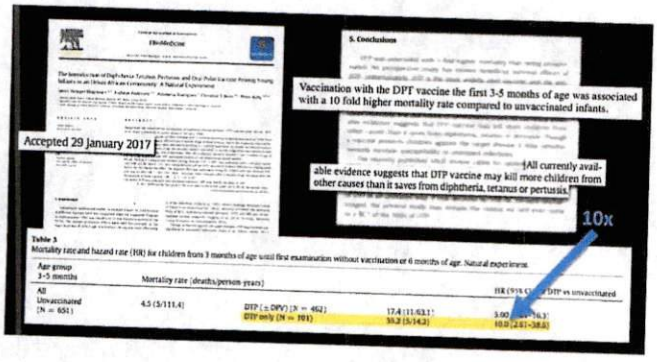
It is a vaccinated versus unvaccinated study and what they found was the vaccinated children had 10 times the death rate of unvaccinated children.

But the things that the vaccinated children were dying of, were things you would never associate with vaccines.

What the scientists concluded was that the vaccine, while it was protecting children from diphtheria, tetanus, and pertussis, had wrecked their immune system so that they were dying of these unrelated illnesses.

And here's what they concluded,

"All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis."



This is rather shocking. The interesting thing and the frightening thing about this study is that this was data that was 30 years old. Nobody noticed that this vaccine had been killing times the amount of kids.

And the relevant question for us, this study begs, is there a surveillance system in this country that would send off an alarm if the same thing was happening here from our current vaccine program? Or is there a safety testing program that would assure that this can't happen? And the answer, I'm about to show you, is no.

I'm going to start with this slide, and this slide shows a short list of vaccine adverse events. In other words, these are injuries that are acknowledged by the government and by the manufacturer to be caused by vaccines.

How do we know that? Well, this first list are injuries that have been compensated by the Vaccine Court. So the courts have decided yes, your injury was caused by the vaccine and we are going to pay you money for that.

Short list of Vaccine Adverse Events
(Compensated in Vaccine Court or Listed on Vaccine Inserts)

- Guillain-Barre Syndrome (GBS)
- Transverse Myelitis
- Encephalopathy
- Seizure Disorder
- Death
- Brachial Neuritis
- Acute Disseminated Encephalomyelitis
- Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)
- Bell's Palsy
- Idiopathic Thrombocytopenic Purpura (ITP)
- Rheumatoid Arthritis
- Multiple Sclerosis (MS)
- Fibromyalgia
- Infantile Spasms
- Anaphylaxis
- Ocular Myasthenia Gravis
- Hypoxic Seizure

(Listed on Vaccine Inserts)

- Autoimmune Diseases
- Food Allergies
- Asthma
- Eczema
- Juvenile Diabetes
- Rheumatoid Arthritis
- Tics
- ADD
- ADHD
- Speech Delay
- Neurodevelopmental Disorder
- Autism
- SIDS
- Narcolepsy
- Seizure Disorder
- Epilepsy
- Multiple Sclerosis
- Tourette's

These include autoimmune diseases, encephalopathy, that is brain damage, seizure disorder, death. Below is another list that really overlaps with the top list.

These are the injuries that the manufacturer is saying, "These could be caused by our vaccine." And they include autoimmune diseases, asthma, eczema, juvenile diabetes.

Now look at this, according to CDC one in six children now has a developmental disorder. The same injuries associated with vaccines.

According to the CDC
1 in 6 children has a developmental disability*

- ADHD
- Autism
- Intellectual Disabilities
- Learning Disabilities
- Hearing Loss
- Developmental Delays

*Source: cdc.gov/ncbddd/developmentaldisabilities/specificconditions.html

According to HHS Funded Publication
54% of children have chronic illnesses†

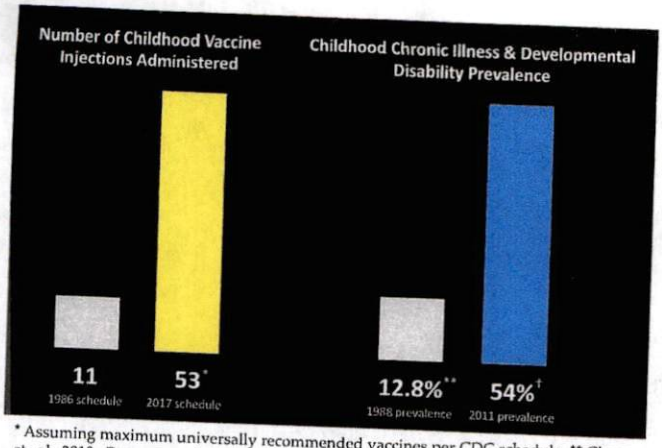
- Obesity
- Risk of Developmental Delay
- Environmental Allergies
- Learning Disability
- Asthma
- ADD/ADHD
- Chronic Ear Infections
- Behavior Problems
- Migraines
- Speech Problems
- Hearing Loss
- 12 others not listed

†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.

This is an epidemic. And according to HHS, it gets worse. 54% of children have some kind of chronic illness.

In 1986, Congress passed the Vaccine Act and gave blanket immunity to vaccine companies for injuries caused by vaccines. And for some of these new vac-

cines, they can make up to a billion dollars a year in profits or even more.



* Assuming maximum universally recommended vaccines per CDC schedule. ** 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.

This is what happened, in 1986 there were 11 vaccines on the schedule, but today there are 53 jabs.

Look what happened at the same time, in 1988 only 12.8% of kids had chronic disease, today 54%. So the rise was coterminous with the expansion of the vaccine schedule.

Question one, who is responsible then for vaccine safety? In every other sector in this country, it's the manufacturer and distributor of the product who is responsible for safety.

With an automobile, it would be the automobile manufacturer, with a drug like Phen-fen or Vioxx, when those drugs were found to be unsafe, the company was responsible.

And, of course, that responsibility and that liability keeps the company concerned and focused on safety.

> By 1986: "The litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine research and development programs as well as to stop producing already licensed vaccines."
>
> (Source: IOM)

So this is the language of the Vaccine Act, "No person may bring a civil action against any vaccine "administrator or manufacturer in a State or Federal court "for damages arising from a "vaccine-related injury and death." So no matter ols, no matter how dange grievous the inju manufacturer fo

Rise in Chronic Childhood Illnesses

> "No person may bring a c ccine administrator or manufacturer i court for damages arising from a vaccine jury or death."
>
> (42 U.S.C. § 300aa-11)

So what are the consequences to having the only consumer product in America that's completely liability-free? First of all, there's no incentive among manufacturers to conduct safety studies.

In fact, there's a disincentive because there's a provision in the Vaccine Act that says essentially that the only way that a manufacturer can be liable is if they know of a side effect from that vaccine and they fail to warn. So their incentive is to do everything that they can to not learn of any side effects.

That's one consequence. The second is that there's a liability-free market of 74 million American children.

1986	2017	
11 Vaccines	53 Vaccines (plus 2 prenatal)	
DTP (2 months)	Hepatitis B (one day)	Influenza (2 years)
Polio (2 months)	Hepatitis B (one month)	Influenza (3 years)
DTP (4 months)	DTaP (2 months)	Influenza (4 years)
Polio (4 months)	Polio (2 months)	DTaP (4 years)
DTP (6 months)	Hib (2 months)	MMR (4 years)
MMR (15 months)	PCV (2 months)	IPV (4 years)
DTP (18 months)	Rotavirus (2 months)	Varicella (4 years)
Polio (18 months)	DTaP (4 months)	Influenza (5 years)
DTP (4 years)	Polio (4 months)	Influenza (6 years)
Polio (4 years)	Hib (4 months)	Influenza (7 years)
Tetanus (14 years)	PCV (4 months)	Influenza (8 years)
	Rotavirus (4 months)	Influenza (9 years)
	DTaP (6 months)	Influenza (10 years)
	Polio (6 months)	HPV (11 years)
	Hepatitis B (6 months)	MenACWY (11 years)
	Hib (6 months)	Influenza (11 years)
	PCV (6 months)	TDaP (11 years)
	Rotavirus (6 months)	HPV (11 ½ years)
	Influenza (6 months)	Influenza (12 years)
	MMR (12 months)	Influenza (13 years)
	Varicella (12 months)	Influenza (14 years)
	Hib (12 months)	Influenza (15 years)
	Hepatitis A (12 months)	MenACWY (16 years)
	PCV (12 months)	Influenza (16 years)
	DTaP (15 months)	Influenza (17 years)
	Hepatitis A (18 months)	Influenza (18 years)
	Influenza (18 months)	

The third is that there is a very strong incentive to develop more and more and more vaccines because the profits are so enormous and the costs are almost nothing.

Here are the results in detail, 11 vaccines in 1986. Fifty-three vaccines that our children are being given today under the schedule, and here's the future: 270 vaccines that are already in the pipeline.

Thousands of clinical trials that are developing new vaccines for the industry and a vaccine industry that is projecting vaccines as a $90 billion profit center over the next few years.

So, if the manufacturers have been lifted of any responsibility for vaccine safety, well, who's responsible?

Well, the Vaccine Act did not want to leave a vacuum. So it said that HHS is responsible, Health and Human Services Department and that specifically FDA, CDC, NIH and HRSA would be the agencies responsible. There's two stages before a vaccine comes to market.

First, the FDA has to license the vaccine. Then CDC has to add it to the schedule. The FDA is the agency that is in charge of the initial step of licensing the vaccine, and here's what FDA says that it does.

It says, "Vaccines undergo rigorous and extensive testing "to determine their safety." Is that true? Let's see. Let's first look at what FDA requires for regular drugs.

Now, for most other drugs, the safety testing is, indeed, rigorous and that kind of testing takes several thousand people who are given the drug and then the same number of people who, usually similarly situated people, who are given a pill that looks exactly like that drug but it's inert and neither the researchers nor the patients know which ones got the saline drug and which ones got the real drug, so it's double blind.

Then the researchers look at both of those groups for typically five years and they look at health outcomes and that's how they figure out whether or not the drug is safe.

For example, with Lipitor the safety review period was 4.8 years and the placebo group received a sugar pill that looked exactly like a Lipitor pill.

With Enbrel, which is another prescription drug, the safety review period was 6.6 years, and the placebo group was a saline injection.

National Childhood Vaccine Injury Act

42 USC § 300aa-2. Program responsibilities

(1) Vaccine research. ...**research carried out in or through [NIH, CDC, FDA]... to prevent adverse reactions to vaccines.**

(2) Vaccine development. The Director... shall ...coordinate and provide direction for activities carried out in or through [NIH, FDA] **to develop the techniques needed to produce safe and effective vaccines.**

(3) Safety and efficacy testing of vaccines. ...**safety and efficacy testing of vaccines carried out in or through [NIH, CDC, FDA].**

Evaluating the need for and the effectiveness and adverse effects of vaccines and immunization activities. The Director... shall ... coordinate and provide direction to [NIH, CDC, FDA, and other agencies]... in **monitoring... adverse effects of vaccines and immunization activities.**

42 USC § 300aa-27. Mandate for safer childhood vaccines

(a) General rule. ... the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions..., and

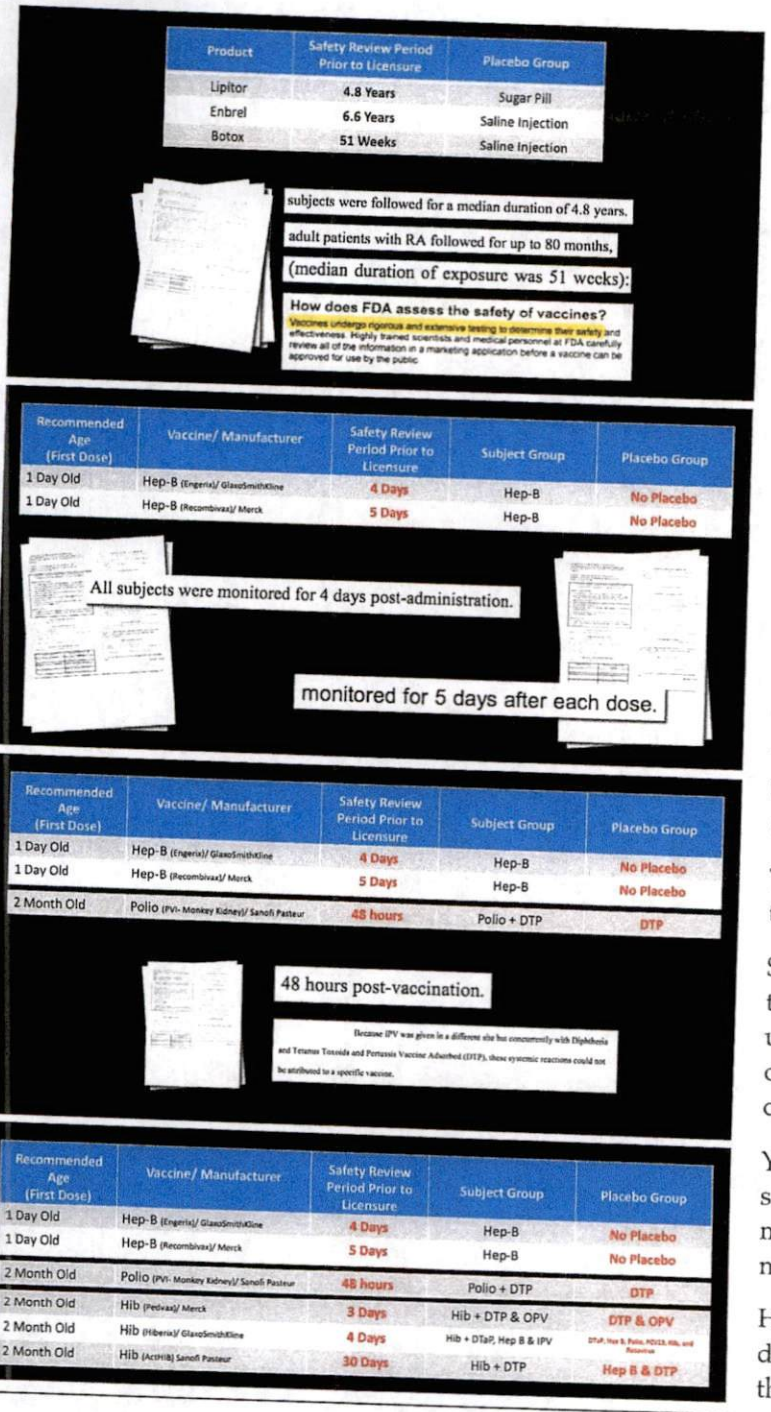
(2) make or assure improvements in... the licensing, manufacturing, processing, testing, ...field surveillance, adverse reaction reporting... and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force.

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of [NIH, FDA, and CDC].

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

(3) ...the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).



1986 Act: Vaccine Adverse Events Reporting System (VAERS)

In 2016, VAERS received 59,117 reports including:

43,200 ~~432~~ deaths,

109,100 ~~1,091~~ permanent disabilities,

413,200 ~~4,132~~ hospitalizations, and

1,028,400 ~~10,284~~ emergency room visits

"fewer than 1% of adverse events are reported"

(Source: healthit.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system

But look what they do with vaccines.

Vaccines are characterized by FDA not as drugs, but as biologics, and that gives FDA the capacity to fast track them without all of that rigorous and bothersome testing.

These are the two hepatitis B vaccines that are the only two that are approved for one day old children. So these vaccines are given to virtually every child that's born in this country in a hospital today.

Here was the safety review period, four days. That means if baby had a seizure and died on the fifth day, it never happened, it wouldn't ever be reported, no one will ever know because they only look at them for four days.

This one got five days. And then, look at this, there was no placebo.

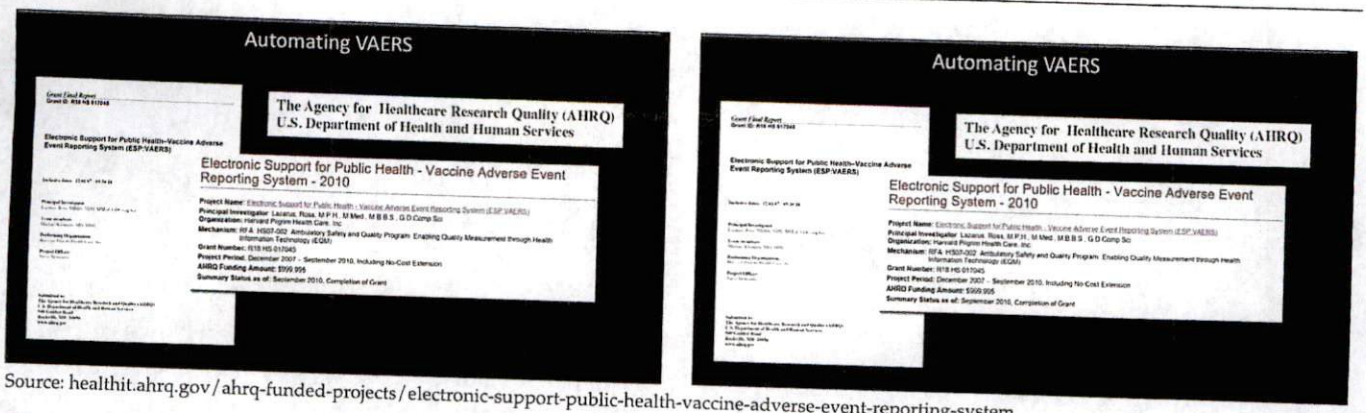
So what are they measuring it against? How do they even tell whether the test group had an unusual number of illnesses unless there's a placebo group to test them against? Of course they can't, it's not real safety science.

Yet, this is the only testing these vaccines received, so whoever approved these vaccines was not making an evidence-based decision. They were making a decision based upon something else.

Here's the polio vaccine for two-month-old children, the safety review was 48 hours. Look at the placebo group, they tested against the DTP vaccine.

This is the vaccine that was causing so many injuries that it caused Congress to pass the Vaccine Act because manufacturers were saying, "We're getting sued so much that we're going to "go out of business." That's not real science. That's not a placebo, that's what we call a spiked placebo. A placebo where you're using something toxic.

Here's some more examples, these are the Hib vaccines. And here are the safety review periods.



Source: healthit.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system

This got the longest one, the Sanofi Pasteur version got 30 days, the others got four days and three days respectively. But look what they were tested against, not a placebo. This one was tested against six vaccines at the same time.

That's not going to tell you anything about the safety of this vaccine prior to licensing, which means that the only thing that we're left with to determine whether vaccines are safe or not are post-licensing surveillance studies.

And what I'm going to show you is that the post-licensing surveillance is next to worthless.

The central mechanism for post-licensing vaccine safety surveillance is called the VAERS system, the Vaccine Adverse Events Reporting System.

VAERS last year alone said that 59,117 Americans were injured by vaccines and that doesn't tell the whole story. According to HHS, this number represents fewer than 1% of adverse events which are reported.

What would it look like if we were actually capturing all vaccine injuries? According to HHS's own calculations, it would be close to six million Americans injured by vaccines every year. And in 2010, the HHS actually commissioned a study that confirmed these astronomical levels of vaccine injury.

The HHS wanted to determine whether or not it was feasible to automate the VAERS system, so they hired an outside consulting group who came in and automated a system for one of the HMOs.

What they found, when they looked at how many people were actually getting injured, a true number, not reported by volunteers, but taken from medical records, of 376,452 individuals who were vaccinated, 35,000 of them had some kind of adverse reaction. That's one in ten.

That's very, very far from the one in a million number that the industry commonly uses when it talks about vaccine injury.

And it's a number that most public health officials and most Americans would consider completely unacceptable.

What happened to this system? Did HHS and CDC say, "This is science "that the public needs to know about, "so that we can ensure the safety of the vaccine supply?" No, they did the opposite. They literally stopped answering the phone calls for those consultants.

The consultant says, "Unfortunately, there was never 'an opportunity to perform system performance assessments' because the necessary CDC 'contacts were no longer available.'" So, instead of expanding the system nationwide, they shut it down.

They simply stopped answering the phone. These consultants had bad news and they didn't want to hear it.

Understandably there's going to be a lot of people out there who are going to want to dismiss what Robert F. Kennedy, Jr. says about the adequacy or inadequacy of vaccine safety science at HHS.

But it's not just me saying that, this is what the Institute of Medicine says about vaccine safety science at HHS. The Institute of Medicine, IOM, top scientists in the country, who are brought together to review the vaccine safety science at HHS.

This is their job, these are very prestigious individuals and they're paid for by the Federal government.

Here's what IOM says, in 1991, IOM reviewed a single vaccine, the DTP vaccine They found that there were 22 injuries or diseases that had been reported to be caused by that vaccine.

Of those 22, the existing literature, the scientific literature, supported causation in six of them. Existing literature acknowledged that six of those diseases were, in fact, caused by the DTP.

With four of those diseases, the literature rejected causation. But look at this number, with 12 of those diseases, there was no literature. It had never been studied.

And what kind of disease are we talking about? Meningitis, neurological damage, learning disabilities, and autoimmune diseases.

Because of the lack of science, they were handicapped in being able to make any kind of assessment about whether this vaccine was dangerous or safe.

So that was 1991, but look what happened three years later.

In 1994, IOM came back and looked at four other vaccines, they found that there were 54 illnesses that had been reported to be associated with those vaccines.

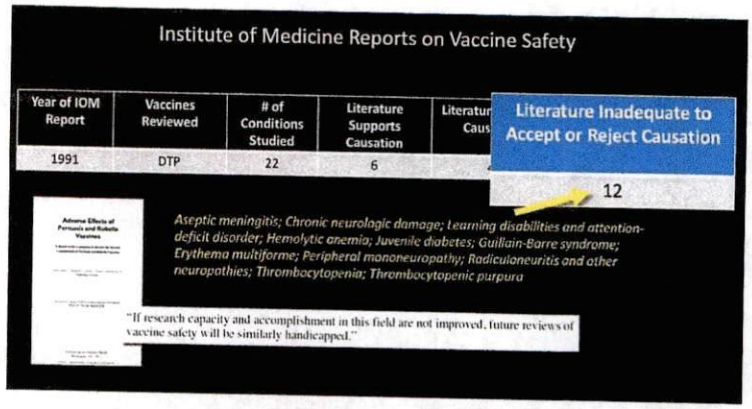
But for 38, there was no literature. It simply had never been studied.

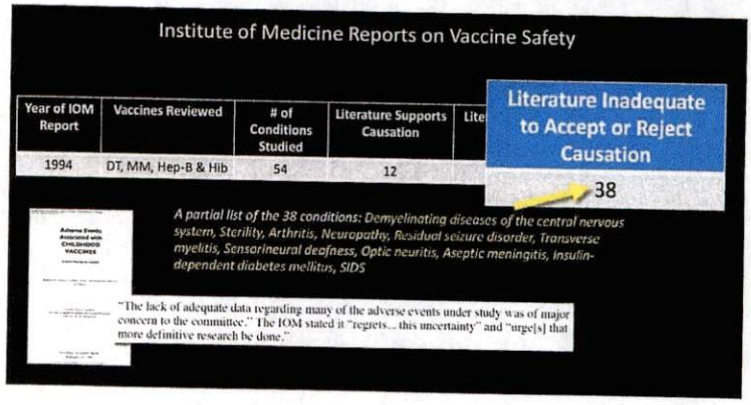
So, the IOM here is saying, "We don't have "the ability to assess the safety of vaccines "because the science simply doesn't exist." 17 years later, in 2011, IOM came back again. This time they reviewed four other vaccines, 155 conditions were reported.

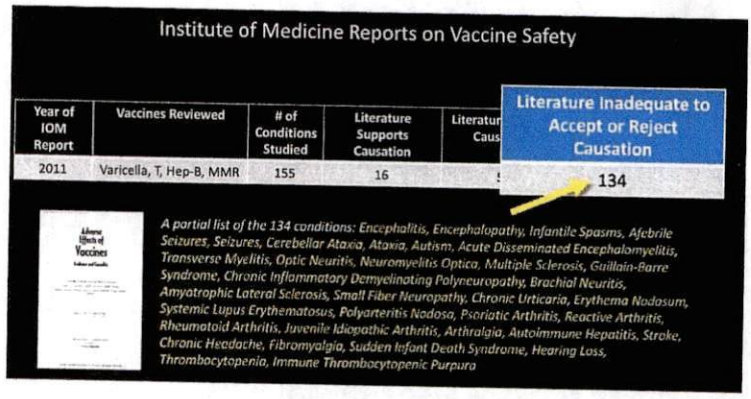
For 134 we don't know, and nobody knows, if the vaccines are causing that epidemic because we don't have the science to reject that hypothesis.

IOM's report was extensive and it was a 700-page report and I selected this because this deals with an injury that we've all heard about and that there's a lot of controversy about, which is autism.

This page was looking at whether the DTP vaccine can cause autism.







And what they found at the end of that is that, the evidence is inadequate to accept or reject a causal relationship between DTP and autism.

So what they're saying here is that they couldn't find any study of the relationship between DTP and autism, but in fact, they acknowledge in the first paragraph, they did find that there was one study out there, but that study found that DTP does cause autism.

But IOM decided to reject that study because it provided data from a passive surveillance system and lacked an unvaccinated comparison population.

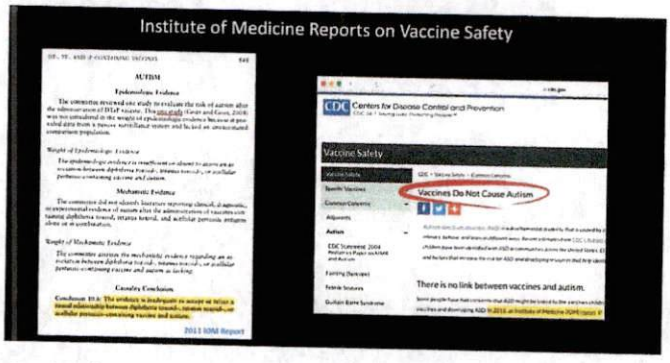
Well, that system that it relied on, was the VAERS system. It's HHS's own system.

What IOM is saying here is HHS is so slovenly and reckless at gathering data on vaccine safety that we cannot use the one system that they have because it's so unreliable.

So what does CDC do with this information? Do they come clean with the American public? Does it say to the American public, "We need to do our job.

"We need to go out and commission these studies "and find out whether there are any associations "between DTaP vaccine and autism?" No, this is what they do.

This is CDC's website: Vaccines do not cause autism.



And what does it cite? A 2011 Institute of Medicine study, this study.

CDC is counting on the fact that nobody is going to go out and read the 700-page report that it's citing there and find out that's not what the report says at all.

This is a lie. Now I want you to watch a 2008 interview with Dr. Bernadine Healy who was the former head of NIH.

- This is the time when we do have the opportunity to understand whether or not there are susceptible children, perhaps genetically, perhaps they have a metabolic issue, mitochondrial disorder, immunological issue, that makes them more susceptible to vaccines plural, or to one particular vaccine, or to a component of vaccine like mercury.

So we now, in these times, have to I think take another look at that hypothesis, not deny it.And I think we have the tools today that we didn't have 10 years ago, that we didn't have 20 years ago, to try and tease that out, and find out if, indeed, there is that susceptible group.

Why is this important? A susceptible group does not mean that vaccines aren't good.

Vaccine Ingredients (Partial List)

α-tocopheryl hydrogen succinate
β-propiolactone
2-phenoxyethanol
aluminum hydroxide
aluminum phosphate
aluminum salts
amino acids
aminoglycoside
ammonium sulfate
amorphous aluminum hydroxyphosphate sulfate
baculovirus and cellular DNA
beta-propiolactone
bovine serum albumin
calcium carbonate
calcium chloride
calf bovine serum
Canine Kidney (MDCK) cell protein
casamino acids
cetyltrimethlyammonium bromide
chick embryo cell culture
CMRL 1969 medium with calf serum
complex fermentation media
CRM197 carrier protein
dibasic sodium phosphate
dimethyl-beta-cyclodextrin
disodium phosphate dihydrate
DNA
Dulbecco's Modified Eagle Medium
EDTA (Ethylenediaminetetraacetic acid)
egg protein
ferric (III) nitrate
fetal bovine serum
formaldehyde
formalin
Frozen human embryonic lung cell cultures
glutamate
glutaraldehyde
guinea pig cell cultures
human diploid cell cultures (MRC-5) & (WI-38)
hydrolyzed gelatin
L-250 glutamine
L-histidine
L-tyrosine
lactalbumin hydrolysate
lactose
lipids
M-199 without calf bovine serum
magnesium sulfate
MDCK cell DNA
Medium 199 without calf serum
modified Latham medium derived from bovine casein
modified Mueller and Miller medium
modified Mueller-Miller casamino acid medium
monkey kidney cells
monobasic potassium phosphate
monobasic sodium phosphate
monosodium L-glutamate
MRC-5 cells (a line of normal human diploid cells)
MRC-5 diploid fibroblasts
neomycin sulfate
non-viral protein
nonylphenol ethoxylate
octylphenol ethoxylate (Triton X-100)
ovalbumin
phenol
phenoxyethanol
phosphate buffer
phosphate-buffered saline solution
polymyxin B sulfate
polysorbate 20
polysorbate 80
Porcine circovirus type 1
potassium aluminum sulfate
potassium chloride
potassium phosphate monobasic
potassium phosphate potassium chloride
recombinant human albumin
sodium bicarbonate
sodium borate
sodium chloride
sodium citrate
sodium deoxycholate
sodium dihydrogen phosphate dihydrate
sodium hydrogenocarbonate
sodium hydroxide
sodium phosphate
sodium phosphate dibasic
sodium phosphate monobasic monohydrate
sodium phosphate buffered isotonic sodium chloride solution
sodium pyruvate
sodium taurodeoxycholate
sorbitol
soy peptone
Spodoptera frugiperda cell proteins
Stainer-Scholte medium
streptomycin
succinate buffer
synthetic medium
thimerosal
Triton X-100
urea
VERO cells
vero cells (a continuous line of monkey kidney cells)
WI-38 human diploid lung fibroblasts
xanthan
yeast extract-based medium
yeast protein

What a susceptible group will tell us is that maybe there is a group of individuals, or a group of children, that shouldn't have a particular vaccine or shouldn't have vaccine on the same schedule.

I do not believe that, if we identified a susceptibility group, if we identified a particular risk factor for vaccines, or if we found out that maybe they should be spread out a little longer, I do not believe that the public would lose faith in vaccines.

It is the job of the public health community, and of physicians to be out there and to say, "Yes, we can make it safer.

Because we are able to say this is a subset, "we're going to deliver it in a way that we think is safer." So I think the public

would respect that. I think the government, or certain public health officials in the government, have been too quick to dismiss the concerns of these families without studying the population that got sick.

I haven't seen major studies that focus on 300 kids who got autistic symptoms within a period of a few weeks of a vaccine.

I think that the public health officials have been too quick to dismiss the hypothesis as irrational without sufficient studies of causation.

The reason why they didn't want to look for those susceptibility groups was because they're afraid that if they found them, however big or small they were, that would scare the public away.

Reporter: It sounds like you don't think the hypothesis of a link between vaccines and autism is completely irrational.

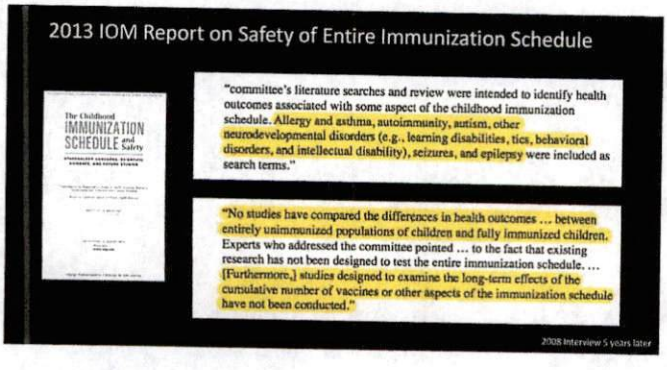
Healy: So when I first heard about it, I thought that doesn't make sense to me.

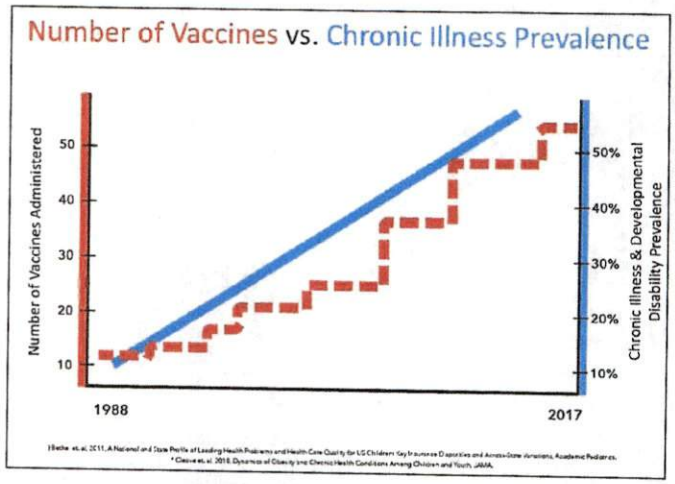
The more you delve into it, if you look at the basic science, if you look at the research that's been done on animals, if you also look at some of these individual cases and if you look at the evidence that there is no link, what I come away with is the question has not been answered.

So as you just heard, Dr. Healy's central point is that, if we really want to know the safety profile of individual vaccines and the vaccine schedule, there's one study that we need in order to do that.

That is a vaccinated versus unvaccinated study.

But despite Dr. Healy's call for that in 2008, by 2013 the Institute of Medicine found that studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have never been conducted.





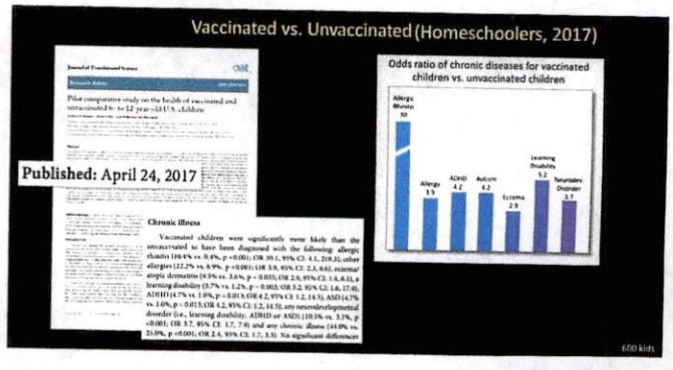
The good news is that CDC has the database with a capacity to do that study.

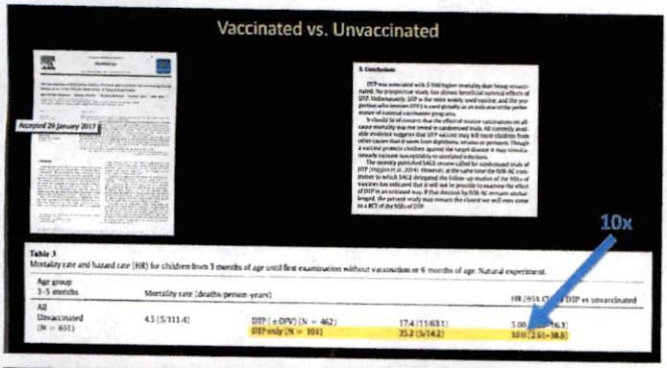
The CDC's Vaccine Safety Datalink has the health records and the vaccination records of 10 million people including hundreds of thousands of children.

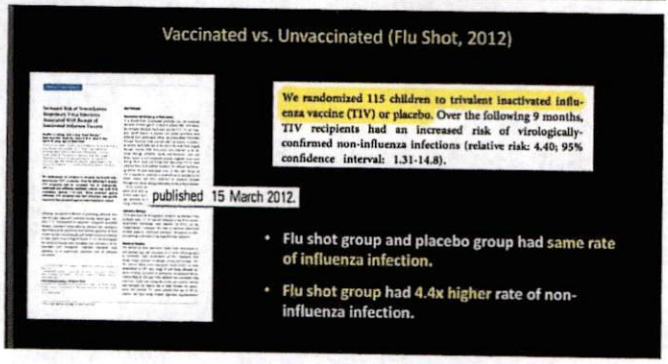
In 2011, IOM said, "It is possible to make this comparison "through analysis of patient information contained "in large databases such as the VSD." And why is the CDC not conducting these obvious kind of studies? Well, maybe it's because they don't like the results when those kind of studies are conducted.

For example, in the African study that I opened this presentation with, where vaccinated kids had 10 times the death rate of unvaccinated kids, or this study that was done in April of this year, and it's a study of about 700 homeschool kids ages 6 to 12.

The study found that the vaccinated children had less chicken pox and less pertussis, but that they had 30 times the levels of allergic rhinitis as unvaccinated children. 3.9 times the allergies. ADD 4.2 times. Autism 4.2 times.







This study that was published in 2012, which was a randomized study that compared children who received placebo to those who received a flu shot. What they found was that the flu shot group and the placebo group, had the same rate of flu infections.

But again, the flu shot group had 4.4 times higher rate of non-influenza infection So the flu shot was not giving the children protection against the flu, but it was influencing in a bad way, their immune systems to make them much more vulnerable to other illnesses.

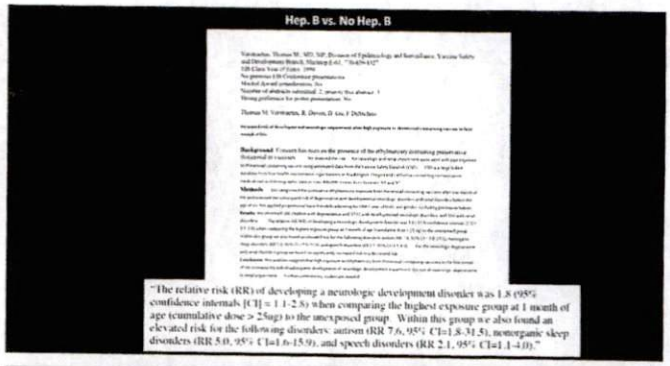
This is a CDC study done in 1999 secretly of its own vaccine safety database. What they found was astonishing.

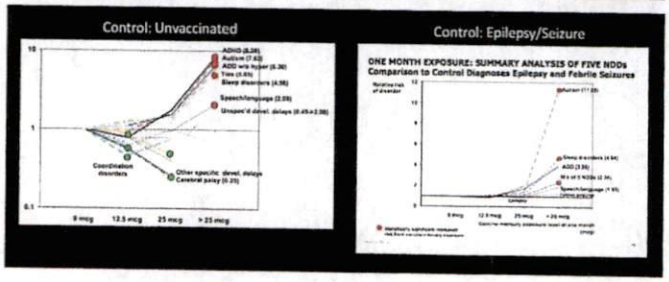
It looked at children who had received thimerosal vaccines and compared those to children who had not and what they found was that kids who had received the thimerosal vaccine had 1100% greater risk of receiving an autism diagnosis.

For comparison, smoking one pack of cigarettes a day for 20 years will create a relative risk of for lung cancer. This was 11.35.

CDC never published this version of the study, never let the public know about these risks and effectively closed the vaccine safety database to almost any independent researcher.

Now that study was known as the Verstraeten study and after that study came out, CDC panicked and began producing numerous studies in-house.





Those studies are almost all epidemiological studies and in my line of business, which is environmental law, epidemiological studies are regarded as the weakest form of studies.

We have an old saying that says, "Statistics don't lie, "but statisticians do." You could make an epidemiological study that proves, for example, that sex doesn't make you pregnant. How do you do that? You get rid of all the pregnant people before you study the population.

And then you can have a population where a lot of people are having sex and none is getting pregnant and you can prove that sex doesn't make you pregnant.

That's one of the gimmicks that CDC used in creating this new wave of epidemiological studies.

So we knew there was tremendous corruption inside of that department, but in 2014, we had a senior scientist in the CDC come forward and acknowledge that corruption.

Dr. William Thompson is a current employee at CDC.

He's a 17-year veteran of vaccine safety programs, he is the lead author, or a leading co-author on virtually all of the landmark studies that CDC has performed to exonerate vaccines from an association with autism.

Here's what he had to say.

- Here's the deal, is that the CDC is ... they're paralyzed.

So there's less and less and less being done as the place just comes to a grinding halt.

- [Interviewer] Mm-hmm-- [William] So really, what we need is for Congress just to come in and say give us the data and we're going to have an independent contractor do it and bring in the autism advocates and have them intimately involved in the study.

When I talk to you, you have a son with autism.

I have great shame now when I meet families with kids with autism because I have been part of the problem.

I shoulder that the CDC has put the research 10 years behind, alright? - [Interviewer] Mm-hmm-- [William] Because the CDC has not been transparent, we've missed 10 years of research because the CDC is so paralyzed right now by anything related to autism.

- [Interviewer] Right.

- [William] They're not doing what they should be doing- - [Interviewer] Right.

- [William] because they're afraid to look for things that might be associated.

So anyway, I ...

There's still a lot of shame with that.

So when I talk to a person like you who has to live this day in and day out, I say, well, so I have to deal with, you know, a few months of hell if this all becomes public, no big deal.

I'm not having to deal with a child who's suffering day in and day out.

So that's, you know, that's the way I view all this.

I am completely ashamed of what I did.

So that's that.

In the summer of 2014, Dr. William Thompson handed tens of thousands of pages of incriminating documents over to Congressman Bill Posey and he told Congressman Posey that he wanted to be subpoenaed to testify in front of Congress about the corruption in CDC's vaccine safety division.

In addition, he gave a private deposition to Congressman Posey and here's Congressman Posey's account of what Dr. Thompson told him during that deposition.

Congressman Posey:
In August 2014, Dr. William Thompson, a senior scientist at the Centers for Disease Control and Prevention, worked with a whistleblower attorney to provide my office with documents related to a 2004 CDC study that examined the possibility of a relationship between mumps, measles, rubella vaccines and autism.

In a statement released in August 2014, Dr. Thompson stated, "I regret that my co-authors and I omitted "statistically significant information in our 2004 article published in the Journal of Pediatrics.

The co-authors scheduled a meeting to destroy documents related to the study.

The remaining four co-authors all met and brought a big garbage can into the meeting room and reviewed and went through all the hard copy documents that we had thought we should discard and put them in a huge garbage can.

However, because I assumed it was illegal and would violate both FOIA and DOJ requests, I kept hard copies of all documents in my office and I retained all associated computer files.

Kennedy: So now we're going to show you that the governmental groups that are assigned with the responsibility of licensing the vaccines and adding them to the schedules are bedeviled by massive conflicts of interest that incentivize them to overlook that lack of scientific safety data.

So FDA is charged with the initial licensing phase of the vaccines, and the specific committee charged with that responsibility is called the Vaccine and Related Biological Products Advisory Committee, it's a mouthful.

The acronym is also a mouthful, VRBPAC.

There was an investigation of VRBPAC in 2013 by the US Government Reform Committee of Congress and here's what they found: "The overwhelming majority of members, 'both voting members and consultants, have substantial ties to the pharmaceutical industries,'" which is making huge profits on those vaccines.

Here are the specific conflicts that Congress found at FDA:

Three of the five FDA advisory committee members who voted to approve the rotavirus vaccine in December had financial ties to the pharmaceutical companies that were developing different versions of the vaccine.

One of the five voting members had a $9 million contract for a rotavirus vaccine. One of the five voting members was the principal investigator for a Merck grant to develop a rotavirus vaccine.

One of the five voting members received approximately

HHS Licenses, Recommends, Promotes and Defends Vaccines

FDA's Vaccine and Related Biological Products Advisory Committee ("VRBPAC")

2000 Investigation by U.S. House Government Reform Committee into VRBPAC :

- "The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry."
- "conflict of interest rules employed by the FDA... have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have given waivers to participate in committee proceedings... In many cases, significant conflicts of interest are not deemed to be conflicts at all."

Example of Conflicts of Interest

- For instance, "3 out of 5 FDA advisory committee [VRBPAC] members who voted to approve the rotavirus vaccine in December 1997 had financial ties to pharmaceutical companies that were developing different versions of the vaccine."
- 1 of the 5 voting members' employer had a $9,586,000 contract for a rotavirus vaccine.
- 1 of the 5 voting members was the principal investigator for a Merck grant to develop a rotavirus vaccine.
- 1 of the 5 voting members received approx. $1,000,000 from vaccine manufacturers toward vaccine development.

An ACIP vote to recommend a vaccine results in:

- Mandating the vaccine to millions of children.
- Immunity from liability for the manufacturer.
- Inclusion in the Vaccine for Children program.

Liability free captive market of 74 million American children with guaranteed payment

one million dollars from vaccine manufacturers toward vaccine development.

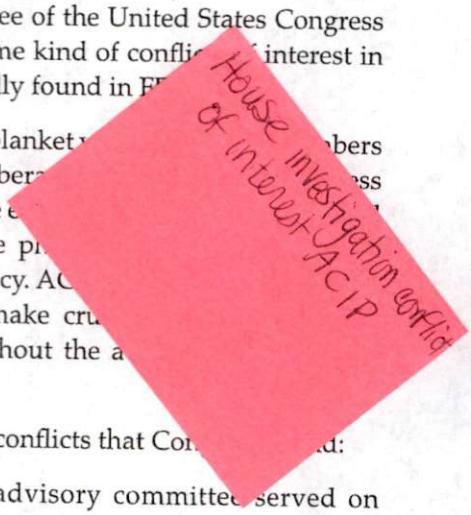
These are not independent arbiters of science who are looking out for our children. These are people who are looking out for themselves.

Once FDA licensed the vaccine, then it goes over to the CDC and CDC needs to decide whether or not to add that vaccine to the schedule.

This committee has really the frightening power to create a liability-free captive market of 74 million American children with guaranteed payment to the manufacturers. This committee has the power to create billions of dollars in profit for the pharmaceutical industry.

Of all the committees in the country, of all the committees in the world, this is the one committee that should be absolutely free of financial conflicts of interest with the pharmaceutical industry and yet the opposite is true.

This was a year 2000 investigation by the US Government Reform Committee of the United States Congress and they found the same kind of conflic interest in CDC as they had initially found in F



They said CDC grants blanket bers that allow them to deliber ss of their conflicts, for the e working groups where pr tively craft vaccine policy. AC government officials make cru American children without the a the governed.

Here are some specific conflicts that Co d:

The chairman of the advisory committe served on Merck's immunization advisory board.

Another member shares the patent on a vaccine under development for the very same disease that he voted on and he had a $350,000 grant from Merck to develop this vaccine and was a consultant for Merck.

So you start out with having no good science, and handing that no-good science to this group of pharmaceutical industry insiders.

Until 2011, they acknowledged they weren't using evidence based guidelines.

That means most of the vaccines, almost all the vaccines, that are currently on the schedule, that your children are taking were added to that schedule not because of evidence, not because of science, but some other reason.

ACIP recommendations have transformed the vaccine market from a $1 billion industry in 1 to a $44 billion industry in 2017. And $44 billion buys a lot of corruption.

In 2009, the HHS Inspector General conducted a new investigation and here's what they found, CDC had a systematic lack of oversight. There were no changes.

97% of committee members' conflict disclosures had omissions. 58% had at least one unidentified potential conflict.

CDC has an $11.5 billion budget and look, almost $5 billion of that is allocated to purchase and promote vaccines and only $20 million to study vaccine safety. That pays for a couple of studies. CDC effectively is a vaccine company. It owns 56 vaccine patents.

The scientists who work for FDA and the CDC can receive royalties of $150,000 a year on vaccines that they develop, so this is the last agency that ought to be regulating vaccines. And yet we are trusting this agency with the health of our children.

Here's an example of the revolving door at CDC.

The former CDC Director from 2002 to 2009, when many of these vaccines were approved and many of these studies, these phony studies were being formulated, was Julie Gerberding. She oversaw numerous vaccine studies, many of which were recently deemed unreliable by IOM.

And in 2010, she became, a year after leaving the CDC, she was rewarded, let's say, with the Presidency of Merck's vaccines division with an estimated 2.5 million in annual salary and lucrative stock options.

Here's another unspoken conflict within HHS. After HHS licenses, recommends, and promotes vaccines with virtually no safety data, HHS is then statutorily required and vigorously defends against any claim that vaccines cause harm.

The Vaccine Act says, "In all proceedings brought "by filing a petition in Vaccine Court "the Secretary of HHS is named as the defendant." So the HHS, because it's defending vaccine injury cases, has a built-in incentive, rather than studying vaccines for safety, to kill any studies that may show that a vaccine is unsafe. This isn't just theoretical, this actually happens in real life and I'll show you an example.

In 2009, the Interagency Autism Coordinating Committee, which was a committee that was made up of scientists, public health officials, was looking at the wave of autism and thousands of parent complaints that said,

HHS Licenses, Recommends, Promotes and Defends Vaccines

2000 - Investigation Into ACIP by U.S. Government Reform Committee:

- "The CDC grants blanket waivers to the ACIP members each year that allow them to deliberate on any subject, regardless of their conflicts, for the entire year."
- ACIP routinely used working groups where pharma insiders would effectively craft vaccine policy.
- ACIP reflects "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed."

2000 - Investigation Into ACIP by U.S. House Government Reform Committee:

Majority of the eight ACIP members were conflicted in their most recent vote:

[1] the chairman served on Merck's Immunization Advisory Board,

[2] another member shares the patent on a vaccine under development for the very same disease, had a $350,000 grant from Merck to develop this vaccine, and was a consultant for Merck,

[3] another member was under contract with the Merck Vaccine Division, received funds from various vaccine manufacturers including Pasteur, and was under contract as a principal investigator for SmithKline,

[4] another member received a salary from Merck as well as other payments from Merck,

[5] another member was participating in vaccine studies with Merck, Wyeth, and SmithKline, and

[6] another member received grants from Merck and SmithKline.

2009 – HHS Office of Inspector General Investigation

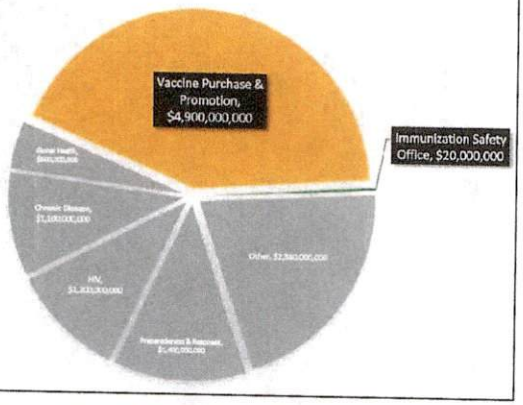
- "CDC had a systemic lack of oversight of the ethics program"
- 97 percent of committee members' conflict disclosures had omissions.
- 58 percent had at least one unidentified potential conflict.
- 32 percent had at least one conflict that remained unresolved.
- CDC continued to grant broad waivers to members with conflicts.

"Our child got autism from the vaccine." They recommended to HHS to study that relationship.

The Chairman of that committee, who was Dr. Tom Insel who was the head of the National Institute of Mental Health, came in and made the statement that, "I'm concerned about the optics."

If we say, "Yes, we think it's important to look at this "and to provide additional information, it implies "that

CDC's Budget: $11.5 Billion



HHS Licenses, Recommends, Promotes and Defends Vaccines

CDC's website claims over 130 times that:
"CDC does not accept commercial support."
British Medical Journal (May 15, 2015)

- "Despite the agency's disclaimer, the CDC does receive millions of dollars in industry gifts and funding, both directly and indirectly, and several recent CDC actions and recommendations have raised questions about the science it cites, the clinical guidelines it promotes, and the money it is taking."
- "classic stealth marketing, in which industry puts their message in the mouths of a trusted third party"
- Quoting UCLA Professor of Medicine: "Most of us were shocked to learn the CDC takes funding from industry … it is outrageous that industry apparently is allowed to punish the CDC if the agency conducts research that has the potential to cut into profits."
- 2002-2009: Former CDC Director, Julie Gerberding oversaw numerous vaccine studies, many of which were recently deemed unreliable by the IOM.
- 2010: Became President of Merck Vaccines with estimated $2.5 million annual salary and lucrative stock options.
- CDC or NIH Employees whose names appear on vaccine patents can receive up to $150k in licensing fees per year (in perpetuity).
- After HHS licenses, recommends, and promotes vaccines with virtually no safety data, HHS is then statutorily required and vigorously defends against any claim vaccines cause 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 ("1986 Act")

we believe that there is a relationship "between autism and vaccines, and in some ways "this runs opposite to what HHS may define "through the HRSA process."

So he killed the approved study in 2010 leaving us no answers to this question.

Interagency Autism Coordinating Committee ("IACC")

After the IACC voted to conducted more research regarding autism and vaccines it was withdrawn because of concern it could support claims that vaccines cause autism in the Vaccine Injury Compensation Program. As head of the IACC explained:

DR. INSEL: "One thing that didn't get discussed when we voted on this is a problem that didn't occur to me until after the meeting, which is that this is perhaps the only issue that we've dealt with that is now part of litigation that involves the department; that it's a HRSA issue, and I'm concerned about the optics." "If we say, yes, we think it's important to look at this and to provide additional information, it implies that we believe that there's a relationship between autism and vaccines, and it suggests that in some way this runs opposite to what HHS may define through the HRSA process."

Vaccine Injury Compensation Program ("VICP")

Americans Injured by a Vaccine Must File a Claim in the VICP where:

- All filings are submitted under seal.
- They must fight against HHS (the Respondent)
- They must fight without any discovery as-of-right
- They must almost always prove causation
- They must fight against the Department of Justice (HHS's attorneys)

Placing the burden on the vaccine injured child's family to conduct the very safety science which would have potentially prevented the child's injury in the first place is unconscionable, but, yet, how HHS operates.

I have to say this, that it's a misnomer to call the Vaccine Court a court. It's a government program. All filings are submitted under seal, in secret.

The plaintiffs, the people who are injured by a vaccine must fight against HHS, respondent, they have to fight without any discovery as-of-right.

The manufacturer is not part of this lawsuit and there's no depositions, there's no document searchers, so how is that plaintiff supposed to prove the connection between their injury and the vaccine? They must almost always prove causation.

How can you do that without documents? They must fight against the Department of Justice, which is HHS attorneys, so they have the full power of the United States government against them, trying to deny them compensation.

Of course this system places the burden on the vaccine-injured child's family to conduct the very same safe-

$4,060,857,713.42

Despite the high hurdle to obtain compensation, VICP has paid more than $4 billion for vaccine injuries and this is with cap of $250k for pain and suffering and death.

*Source: hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/monthly-stats-january-2019.pdf

Conflict of Interest Summary

- Industry incentivized to not conduct proper safety testing
- Regulatory agency incentivized to not conduct safety testing
- Regulatory function subsumed by promoting, distributing and defending vaccines

ty science that would have potentially prevented the child's injury in the first place.

Even in the face of all of these enormous hurdles against recovery, people who have been injured by vaccines have recovered more than $4s billion from HHS vaccine program in recent years. And that's despite a cap of $250,000 for pain and suffering and death.

I didn't get into this controversy because I wanted to. I was dragged, as I said at the beginning, kicking and screaming into this controversy. I've stayed in it because I don't know anything that's more important.

All of the environmental issues that I've worked on are absolutely critical, the future of our country and our planet, but we can't solve those environmental problems if we don't have kids with functioning brains and with good health. We need a generation of kids that's ready to grapple with big problems.

The things that I've shown you today are not my opinions, these are facts.

We want to make sure that the conflicts are removed from the regulators who are making decisions over our vaccines. And that the vaccines that our children get are as safe as they can possibly be. That the science is strong and robust. And none of that is possible unless we first do these things.

What's the Solution?

1. Subject vaccines to the same **rigorous approval process** as other drugs.
2. **Mandatory reporting** of vaccine adverse events and automate the VAERS* and VSD* databases.
3. Ensure everyone involved with Federal vaccine approvals and recommendations are free from **conflicts of interest.**
4. **Reevaluate all vaccines** recommended by the ACIP* prior to the adoption of evidence-based guidelines.
5. Study what makes some individuals **more susceptible to vaccine injury.**
6. Support **fully informed consent and individual rights** to refuse vaccination.

*VAERS: Vaccine Adverse Events Reporting System, *VSD: Vaccine Safety Datalink, *ACIP: Advisory Committee on Immunization Practices

First, we need to require that the vaccines go through the same rigorous approval process as other drugs.

We need to require mandatory reporting of vaccine adverse events and that means automating the VAERS and the VSD database. This is obvious.

We need to ensure that everyone involved with Federal vaccine approvals and recommendations are free from conflicts of interest.

We need to reevaluate all vaccine recommended by the ACIP prior to the adoption of evidence-based guidelines.

If they weren't making those decisions based upon science, those decisions ought to be invalidated. We need science-based policymaking.

We need to study what makes some individuals more susceptible to vaccine injury and we need to work to do the real science to identify the other subsets that have not yet been characterized.

And finally, we need to support fully informed consent and individual rights to refuse vaccination. We live in America, part of our tradition is informed consent.

We know that vaccines are a risky medical intervention and parents should not be removed from the debate over the rights of their children to receive or not receive a vaccine.

Thank you for your time.

You know, we all want the best for America's children and we need to start by having **good science and a clean regulatory process.** Thanks.

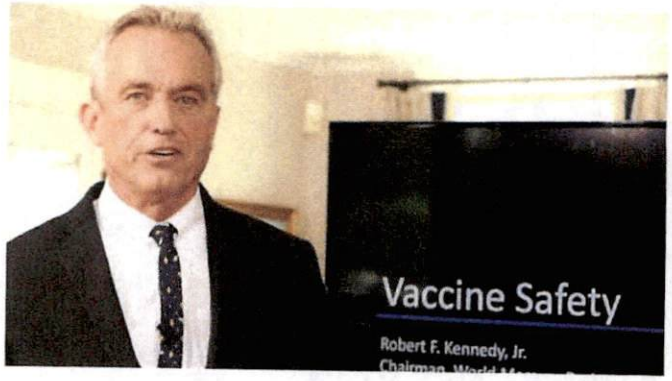
Robert F. Kennedy, Jr., Chairman
Children's Health Defense

Robert F. Kennedy, Jr.'s reputation as a resolute defender of the environment stems from a litany of successful legal actions. Mr. Kennedy was named one of *Time* magazine's "Heroes for the Planet" for his success helping Riverkeeper lead the fight to restore the Hudson River. The group's achievement helped spawn 300 Waterkeeper organizations across the globe.

Mr. Kennedy serves as President of Waterkeeper Alliance and of counsel to Morgan & Morgan, a nationwide personal injury practice. He was previously Chief Prosecuting Attorney for the Hudson Riverkeeper, Senior Attorney for the Natural Resources Defense Council, and a Clinical Professor and Supervising Attorney at Pace University School of Law's Environmental Litigation Clinic. He is co-host of Ring of Fire on Air America Radio. Earlier in his career he served as Assistant District Attorney in New York City.

He has worked on environmental issues across the Americas and has assisted several indigenous tribes in Latin America and Canada in successfully negotiating treaties protecting traditional homelands. He is credited with leading the fight to protect New York City's water supply. The New York City watershed agreement, which he negotiated on behalf of environmentalists and New York City watershed consumers, is regarded as an international model in stakeholder consensus negotiations and sustainable development.

Among Mr. Kennedy's published books are *American Values: Lessons I Learned From My Family, The New York Times'* bestseller *Crimes Against Nature* (2004), *The Riverkeepers* (1997), and *Judge Frank M. Johnson, Jr: A Biography* (1977) and two children's books *St. Francis of Assisi* (2005), *American Heroes: Joshua Chamberlain and the American Civil War* and *Robert Smalls: The Boat Thief* (2008).



His articles have appeared in *The New York Times, Washington Post, Los Angeles Times, The Wall Street Journal, Newsweek, Rolling Stone, Atlantic Monthly, Esquire, The Nation, Outside Magazine, The Village Voice,* and many other publications. His award-winning articles have been included in anthologies of *America's Best Crime Writing, Best Political Writing* and *Best Science Writing.*

Mr. Kennedy is a graduate of Harvard University. He studied at the London School of Economics and received his law degree from the University of Virginia Law School. Following graduation he attended Pace University School of Law, where he was awarded a Masters Degree in Environmental Law.

Updated 2/11/19