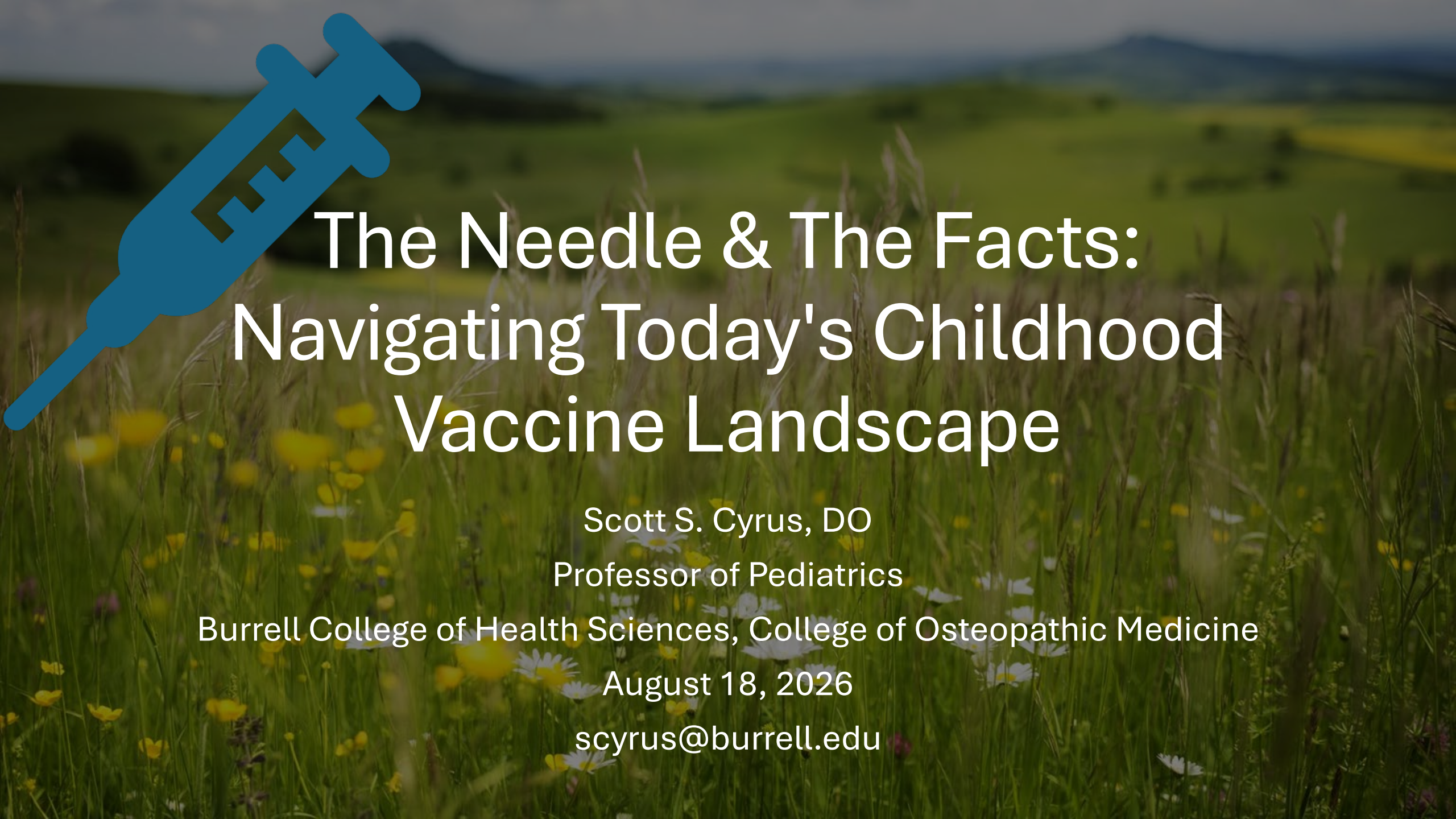


# The Needle & The Facts: Navigating Today's Childhood Vaccine Landscape

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August 18, 2026

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# Disclosures

- I am an employee of Burrell College of Health Sciences, School of Osteopathic Medicine, Las Cruces, NM
- I am a proud past member and Chair of the OFF Board of Trustees
- I have no financial disclosures
- I am compensated for my time
- I am not discussing off-label uses of medications or medical devices

# Objectives

01

Identify recent changes in childhood vaccination schedules

02

Examine the operational and financial challenges for practitioners

03

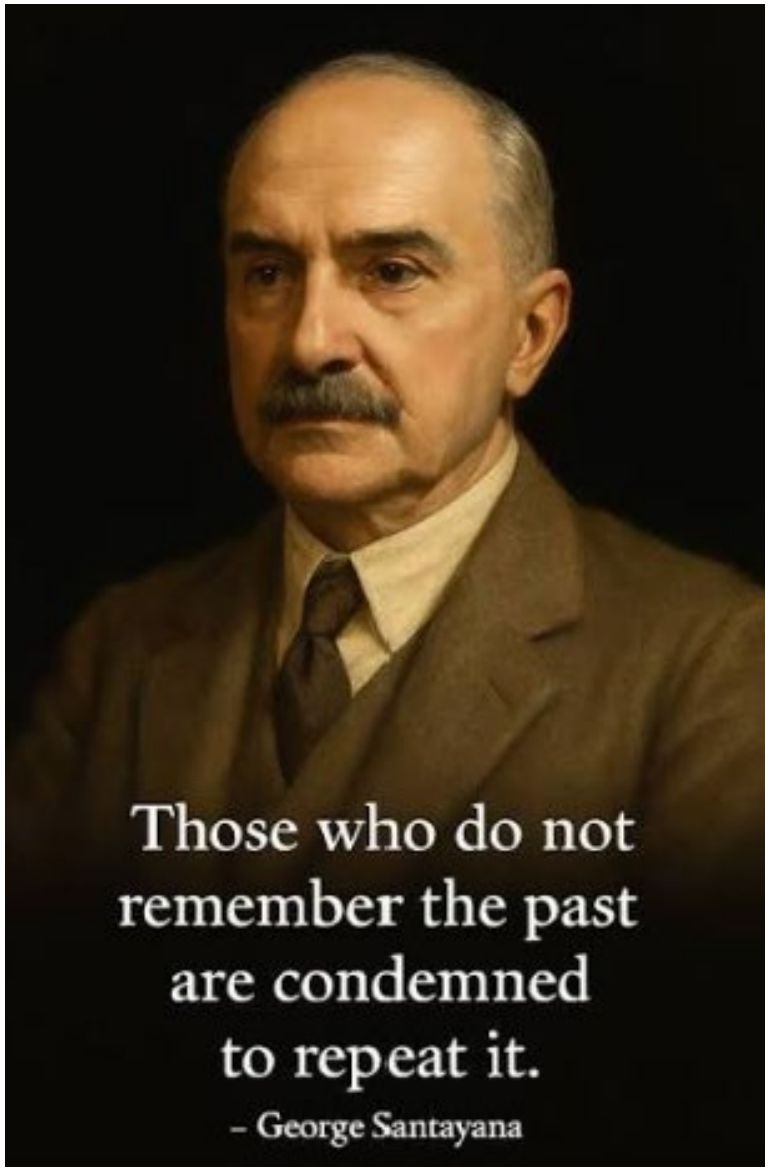
Develop strategies to counter parental confusion caused by inconsistent messaging

04

Outline actionable methods to maintain high immunization rates and prevent needless morbidity and mortality

# Doomed to Repeat History

- Written by the philosopher George Santayana in 1905
- *The Life of Reason*: From the series Great Ideas of Western Man
- **“Those who cannot remember the past are condemned to repeat it.”**
- Forgetting past errors leads people and societies to make the same bad choices again.



# U.S. Historical Aspects of Childhood Vaccines

- 1853: First school requirement for vaccination  in Massachusetts
- 1900: Most New England states had vaccine requirements
- Edward Jenner in 1796 developed the smallpox vaccine from cowpox blisters
- Smallpox was the main disease of the time, and prevention was through **Variolation** (giving the child a small dose)
- **Risks:** Natural smallpox had a high death rate of about 30%; variolation had a much lower death rate of 1% to 2%.





# Historical Context of Child Mortality

- **High overall death rates:** Around 1900, roughly 1 in 5 (20%) children died before reaching their fifth birthday. (Nearly **500,000** children)
- **Leading causes:** Respiratory infections like pneumonia and influenza were top killers of young children before modern hygiene, antibiotics, and vaccines.
- **Lack of tracking:** Individual viral strains and specific pediatric flu death tolls were not systematically logged or studied the way the Centers for Disease Control and Prevention tracks them today.

# Osteopathic Historical Context

- **1874:** A.T. Still formulated the foundational concepts of osteopathy after losing his children to spinal meningitis.
- Emphasizing holistic, whole-person care over heavy drug use.
- **1892:** He established the American School of Osteopathy (now known as part of A.T. Still University (ATSU)) in Kirksville, Missouri.
- **1894:** The first class graduated, which included three of his own children alongside other pioneering students.



**HAPPY BIRTHDAY** A.T. Still, August 6, 1828



## 2024-25 Child Mortality from Influenza and Pneumonia

- Influenza and pneumonia remain among the recognized categorical causes of childhood mortality.
- **Influenza Season:** 3.8 per 1 million children (totaling 280 deaths)
- Multi-year high
- Pneumonia acts as a major secondary complication in roughly 38% of those fatal flu cases
- Approximately 56% of children who died had an underlying medical condition, and 89% were not fully vaccinated.



# Navigating the Facts

- **2024–2025 Influenza Season:** Classified as high severity, resulting in an estimated 51 million illnesses, 710,000 hospitalizations, and 45,000 deaths
- **2025** COVID-19 deaths: 20,685 – 2026: 5,623
- 2025 Car accident deaths: 36,640
- Before the rotavirus vaccine was introduced in the United States in 2006, rotavirus was the leading cause of severe, dehydrating diarrhea and acute gastroenteritis in infants and young children, causing 2.7 million cases in 2005
- Currently, there are 7,660 annual rotavirus hospitalizations among children under age five.
- Respiratory syncytial virus (RSV) was associated with 190,000 to 350,000 hospitalizations from July 1, 2024, to June 30, 2025, as well as 10,000 to 23,000 deaths

# Diphtheria Vaccine (*Corynebacterium diphtheriae*)

Greek word for “leather” or “hide,” which describes the coating that appears in the throat: the pseudomembrane.

1890: A vaccine was not possible, but they used guinea pig antitoxin, then horse antitoxin.

1921: 206,000 cases with15,520 deaths.  Higher in children (exceeded 20%). Cause: Suffocation

Children given toxin-antitoxin (TAT) mixture

1923: French Veterinarian Gaston Ramon developed a toxoid vaccine.

1943: War breaks out in Europe, and there were 1 million cases in Europe, with 50,000 deaths



French physician Pierre Bretonneau (1778-1862) gave the disease diphtheria its name.

# *Tetanus Vaccine (Clostridium tetani)*



1884: Isolated from the soil by Arthur Nicolaier



1890s: Short-acting antitoxin developed from horse serum used in WWI



1923- 24: Formaldehyde was used to deactivate the toxic proteins. Created a “toxoid” that stimulated human antibody production.



1930s: Active immunization made possible for the general public & military



1938: Alum-precipitated toxoid vaccine providing longer immunity



World War II: Routine vaccination reduced battlefield tetanus rates by 95%

# Evolution of DTP

**Pertussis (Whooping Cough):** First licensed in the U.S. in 1914 and refined in the 1930s.

**Diphtheria:** The toxoid vaccine was developed in the 1920s and registered in 1926.

**Tetanus:** The passive horse-serum antitoxin discovered in the 1890s was widely used during World War I. A formalin-inactivated toxoid vaccine was developed in 1924 (inactive toxin). Alum-precipitated/absorbed toxoid was put on the market in 1937 and 1938.

**DTP** (diphtheria, tetanus, and whole-cell pertussis) vaccine was developed in 1942 by Pearl Kendrick and her colleagues, and it was officially licensed for use in the United States in 1948

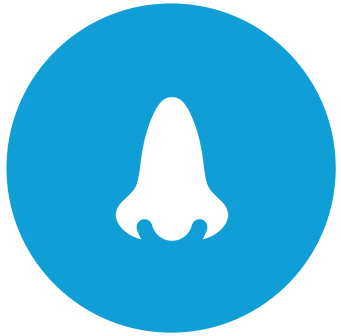
# DTP Common Adverse Effects



Redness, swelling, and pain at the injection site



Mild to moderate fever (around 101°F or higher)



Drowsiness, fussiness, and loss of appetite



Usually treated with acetaminophen

# DTP Adverse Effects

- **Severe or Rare Adverse Events**
- **Persistent crying:** Inconsolable screaming lasting three hours or longer
- **Hypotonic-hyporesponsive episodes (HHE):** Sudden limpness, paleness, and unresponsiveness
- **High fever:** Temperatures spiking to 105°F (40.5°C) or higher
- **Seizures:** Usually, febrile convulsions linked to high body temperature
- **Acute encephalopathy:** Rare, acute brain dysfunction temporally linked to the vaccine, which prompted the transition to purified acellular pertussis vaccines (DTaP) in the 1990s



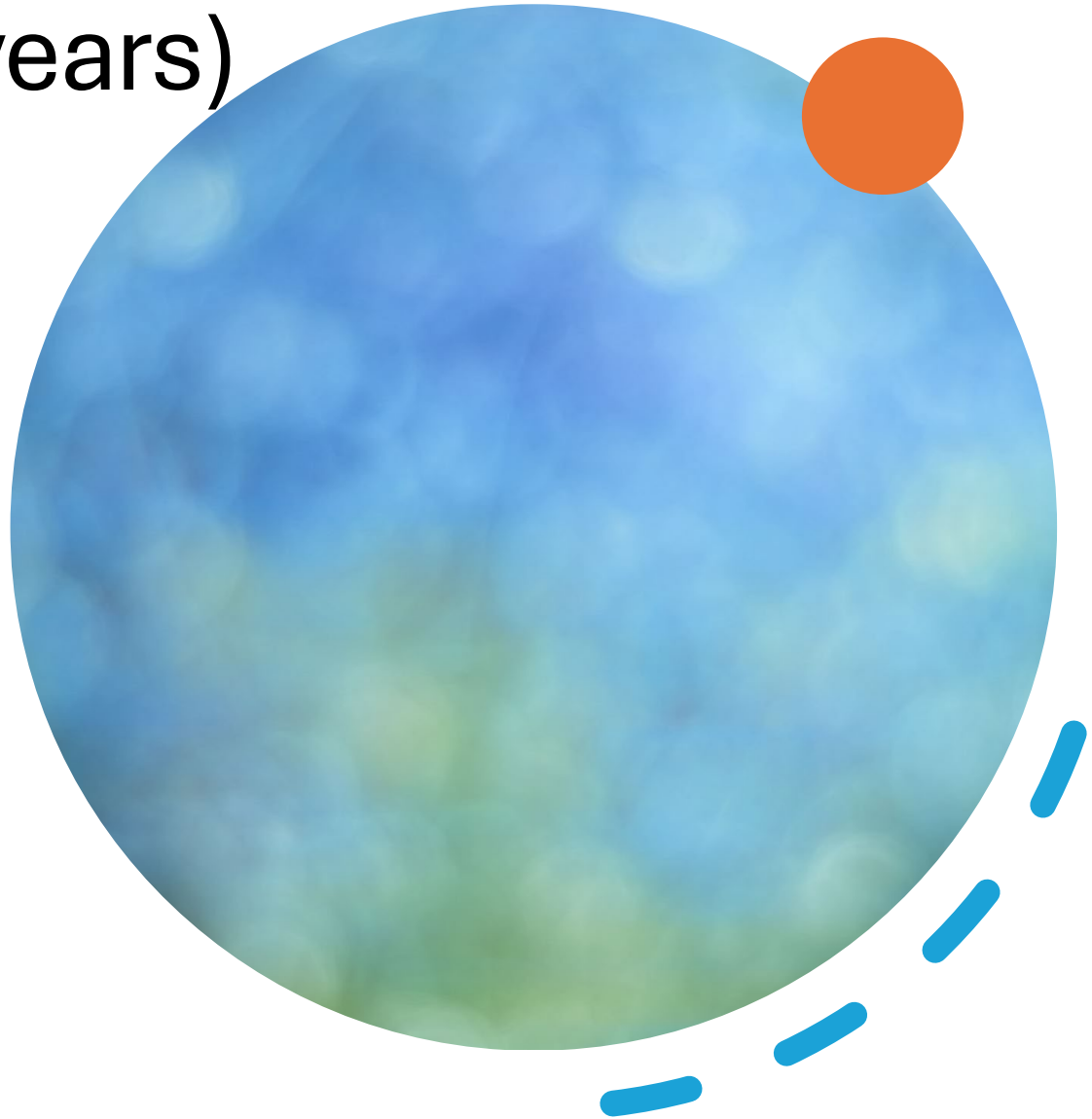
# DTwP refined to DTaP (40+ years)

DTwP was officially licensed in the United States

DTaP completely replaced older whole-cell DTP formulations for routine childhood immunization schedules.

1948 1991 1997

The safer acellular pertussis combination (DTaP) was officially licensed in the U.S.



# U.S. Historical Aspects of Childhood Vaccines

- July 1, 1946: The Centers for Disease Control and Prevention (CDC) was founded as the Communicable Disease Center
- 1954: Salk Polio vaccine recommended
- 1955: Congress funded local entities to purchase the vaccine.
- 1962: CDC directed to work with states to deliver necessary vaccines to children
- 1964: Advisory Committee on Immunization Practices (ACIP) was created under the US Public Health Service.



# 1960s-1970s



1963

MEASLES VACCINE SINGLE DOSE



1971

MMR VACCINE DEVELOPED



1989

2-DOSE STANDARD SERIES APPROVED BECAUSE OF A SIGNIFICANT OUTBREAK



1979:

ERADICATION OF SMALLPOX WORLDWIDE

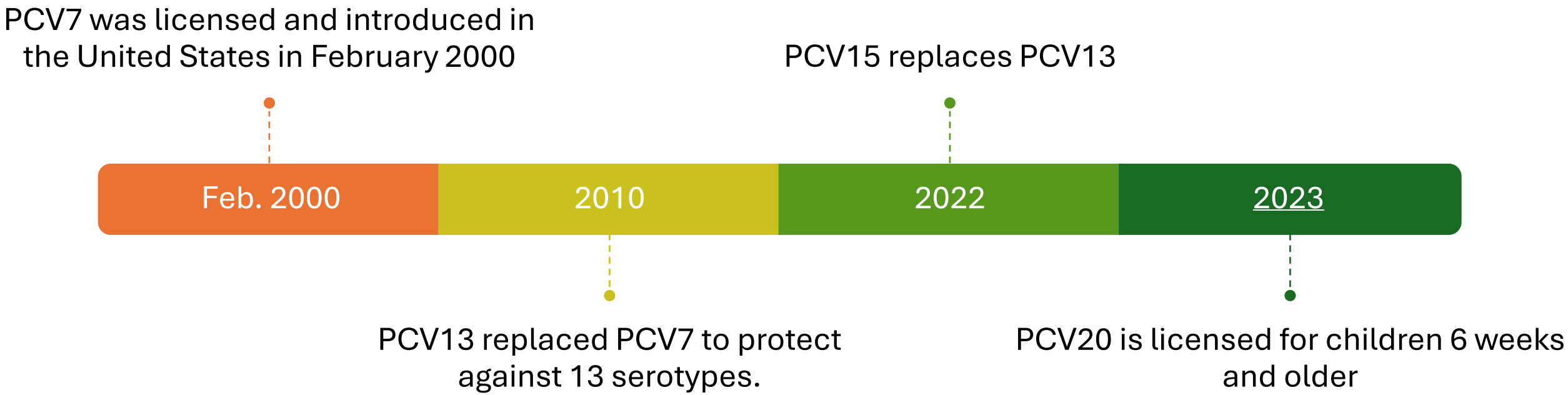
FIRST IN HUMAN HISTORY

# 1980s-1990s Vaccine Development

- Haemophilus Influenza type B 1985
- Hepatitis B (1st Anti-cancer vaccine) 1981
- Pneumococcal Polysaccharide 1983 for 2 years and older
- Varicella vaccine 1995 single dose
  - 2-dose series in 2006 because of breakthrough cases



# Pneumococcal conjugate vaccine

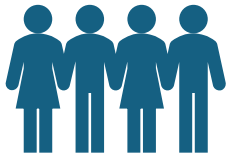


# Human papillomavirus 9-valent vaccine, recombinant 2006 - 2014

- Protects against nine types of HPV: 6, 11, 16, 18, 31, 33, 45, 52, and 58
- Strains 16 and 18 alone cause roughly 70% of cervical cancers. The additional five strains account for another 20%.
- Protect against cancers of the cervix, anus, vulva, vagina, and throat
- Types **6 and 11**strains do not cause cancer but are responsible for about 90% of all genital warts
- Recommended for males and females with varied dosing schedules

# Respiratory Syncytial Virus (2023)

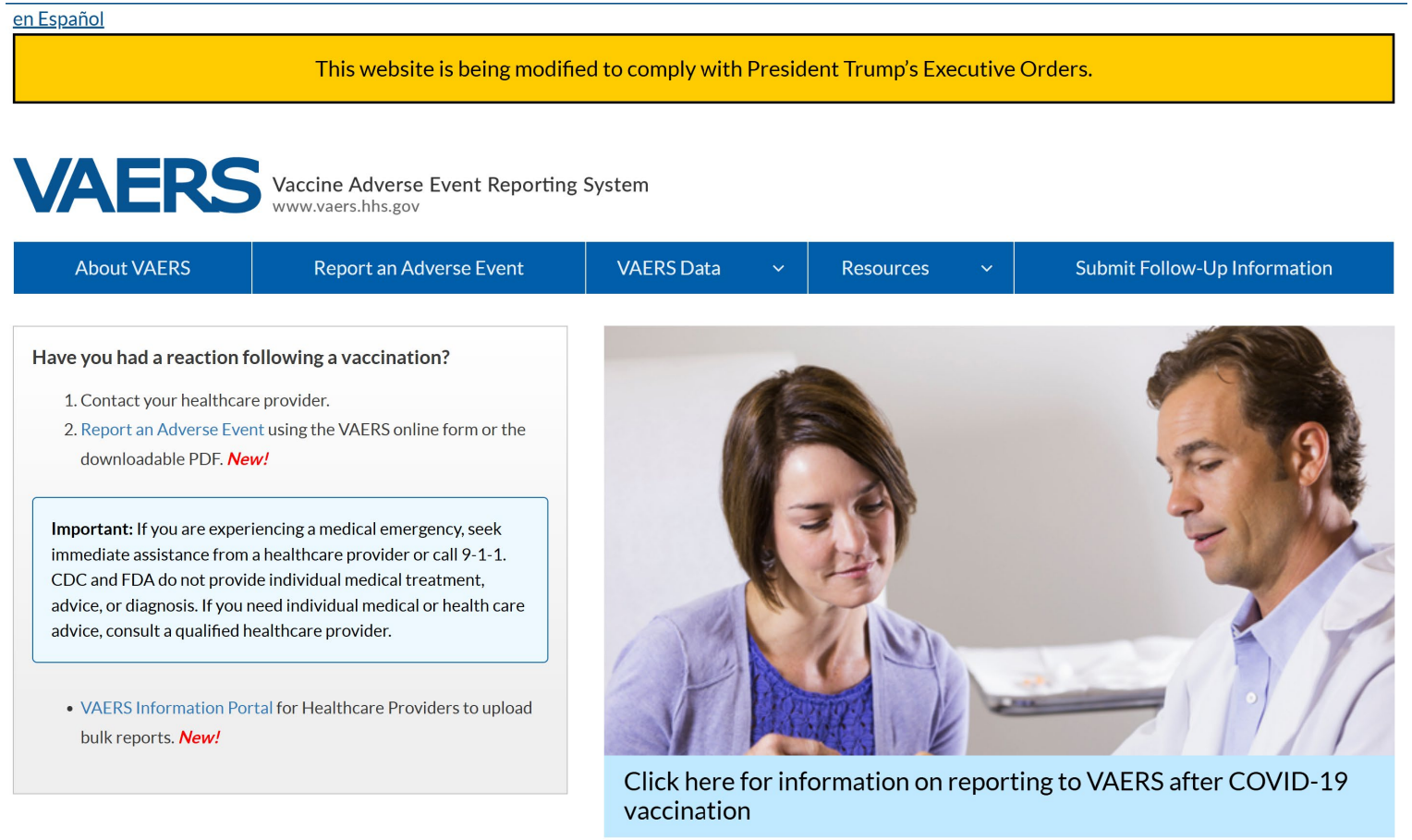
- **Who Should Get Vaccinated**



- **Adults 75+**: Universal single dose recommended.
- **Adults 50–74**: Recommended if at high risk for severe illness (e.g., chronic heart, lung, or kidney conditions, or residents in nursing homes).
- **Pregnant Individuals**: One dose of *RSVpreFa/preFb-recombinant* given during weeks 32–36 of pregnancy (typically September through January) to protect the newborn.
- **Infants**: Can be protected via maternal vaccination or through infant monoclonal antibody immunizations like nirsevimab.

# National Childhood Vaccine Injury Act

- 1986
- Developed to prevent a public health crisis
- Stabilized the U.S. vaccine supply
- Protected the vaccine manufacturers from a wave of liability lawsuits.
- Established a fair, no-fault system to compensate individuals injured by certain childhood vaccines.

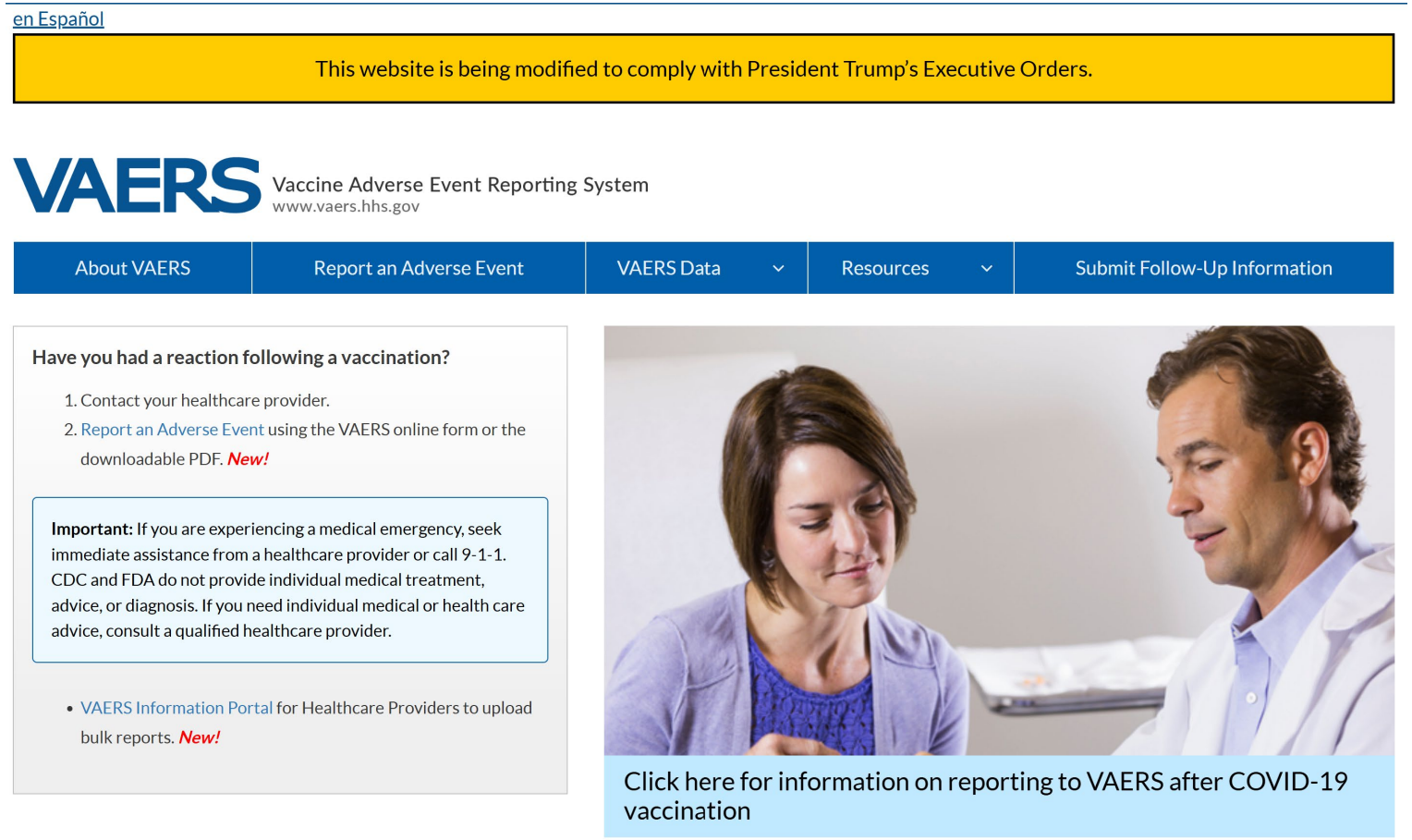


# National Childhood Vaccine Injury Act

- Created a system of passive and active surveillance for adverse reactions to vaccines

- Vaccine Adverse Event Reporting System (VAERS)

  - https://vaers.hhs.gov/



# National Childhood Vaccine Injury Act



**Purpose:**
Handles claims for severe adverse reactions from standard routine childhood and adult vaccines (such as flu, MMR, Tdap).



**Total Payouts:**
Has awarded over $4.9 billion to petitioners since the program began in 1986.



**Award Types:**
Covers documented out-of-pocket medical expenses, lost wages, legal/attorney fees, and up to $250,000 for pain, suffering, or death.



**Success Rate:**
Approximately 60% of compensation awards are settled through negotiated agreements rather than formal rulings of direct fault

# Countermeasures Injury Compensation Program (CICP)

Health Resources and Services Administration (HRSA)

Established by the Public Readiness and Emergency Preparedness (PREP) Act in **2005**

Provides a federal safety net for individuals who suffer serious injury or death from emergency medical countermeasures (such as pandemic vaccines or anthrax treatments)

Protects manufacturers from liability to encourage rapid product development.

The first claims under the program were filed in October 2010 for vaccine-related expenses from the 2009 H1N1 Influenza vaccine for $182.20

# First Universal School Vaccine Schedule

1995

Approved by the ACIP, AAP, and American Academy of Family Practice (AAFP)

Schedule included:

Diphtheria, tetanus, pertussis (whole-cell) (DTP)

Measles, mumps, rubella (MMR)

Hepatitis B

Polio (oral)

Haemophilus influenzae type b

# Historical Precedent  (Vaccine Removal)

**Live, oral rhesus-human reassortant rotavirus vaccine**: Less than one year it was pulled from the market 9 months after its 1998 approval due to a rare bowel obstruction (Intussusception) risk flagged by surveillance data.

- Re-marketed as RV-1 and RV-5 with strict age guidelines

**Lyme disease Vaccine**: Approved for children 5 years and older in 1998. Removed in **2002** due to dropping sales and public fears regarding side effects (autoimmune arthritis)

**Intranasal Influenza**: Approved for children 2 years and older in September 2007. Pulled from the U.S. market ahead of the 2016–2017 flu season due to poor effectiveness.  Failed to protect children from the H1N1 strain the previous year. Restored in the 2018-2019 season



# *Haemophilus influenzae* type b (Hib) conjugate

- **Recall Date:** December 12, 2007.
- **Product:** Pediatric Hib conjugate vaccine batches distributed starting in April 2007 in two forms
- **Reason:** Plant equipment testing identified *Bacillus cereus* in the production suite, prompting a precautionary recall.
- **Volume:** Approximately 1.2 million doses
- To conserve shrinking national supplies, health agencies temporarily deferred the routine 12-to-15-month toddler booster dose, while the primary three-dose series was maintained
- Deferral lasted until mid-2009

# Bivalent human papillomavirus (HPV)

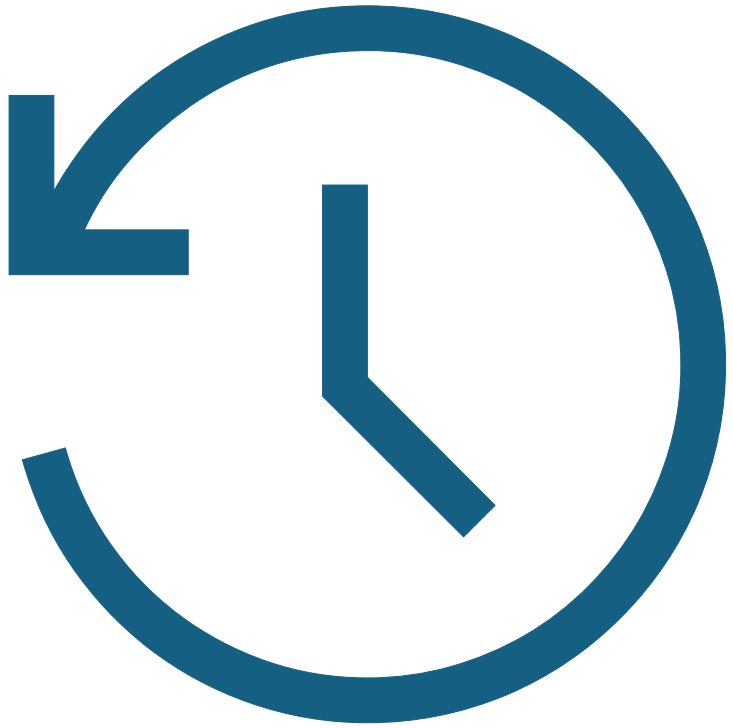




# Vaccine Regulation Process

- **Pre-clinical testing:** Scientists test new vaccines in the laboratory and on animals first.
- **Clinical trials:** Human testing occurs in three distinct phases across thousands of volunteers to measure safety and effectiveness.
- **FDA license review:** The FDA's Center for Biologics Evaluation and Research evaluates all trial data and inspects manufacturing facilities before approval.
- **Post-market monitoring:** Systems like VAERS track ongoing safety after public distribution to detect rare side effects

# Quiz Question ??



What is the typical time for vaccines to make it from research to the market?

# Answer

**10-15 years**

The lengthy process involves extensive laboratory research, multi-phase human clinical trials, and regulatory authorization managed through guidance from the FDA, CDC, and ACIP

# Standard Development Stages



**Exploratory & Preclinical (1–2 years):** Basic laboratory research and animal testing to check if the vaccine triggers an immune response.



**Clinical Trials (6–7 years):** Human testing divided into three sequential phases (Phase I for small safety groups, Phase II for dosage/side effects, and Phase III for large-scale efficacy and safety).



**Regulatory Review (1–2 years):** Government evaluation of trial data and manufacturing facility inspections before approval.



**Manufacturing & Distribution (2+ years):** Scaling up industrial production, quality control validation, and commercial launch

# Quiz Question ??



What was the timeframe for the COVID vaccines to prevent the SARS-CoV-2 virus to make it from research to the market?

# Answer

**Less than 1 year**

# Operation Warp Speed Timeline

**Prior Research:** Scientists built on years of prior study regarding related coronaviruses like SARS and MERS.

**New Technology:** Messenger RNA (mRNA) platforms allowed rapid design without needing to grow physical virus cultures.

**Overlapping Trials:** Phase 1, 2, and 3 clinical trials ran concurrently rather than sequentially.

**Financial Backing:** Governments provided billions of dollars upfront, removing financial risks for early manufacturing scale-ups.

# Vaccine Recall  versus other Products

- A vaccine can be pulled from the market in **hours or days**
- When a severe, urgent safety hazard or major manufacturing defect is identified.
- **Vaccines:** Frequently recalled out of an abundance of caution due to minor temperature excursions, slightly reduced potency during storage, or a compromised sterile vial seal—often *before* any adverse event occurs.
- **Other Products:** Typically recalled only after consumer complaints, injuries, or failures have already manifested in the field (e.g., car brakes failing or food contaminated with bacteria)



# Similarly, Highly Regulated Fields



**Commercial Nuclear Energy:** Nuclear Regulatory Commission (NRC)



**Commercial Aviation:** Federal Aviation Administration (FAA) 9-11



**Gene and Cellular Therapies:** FDA



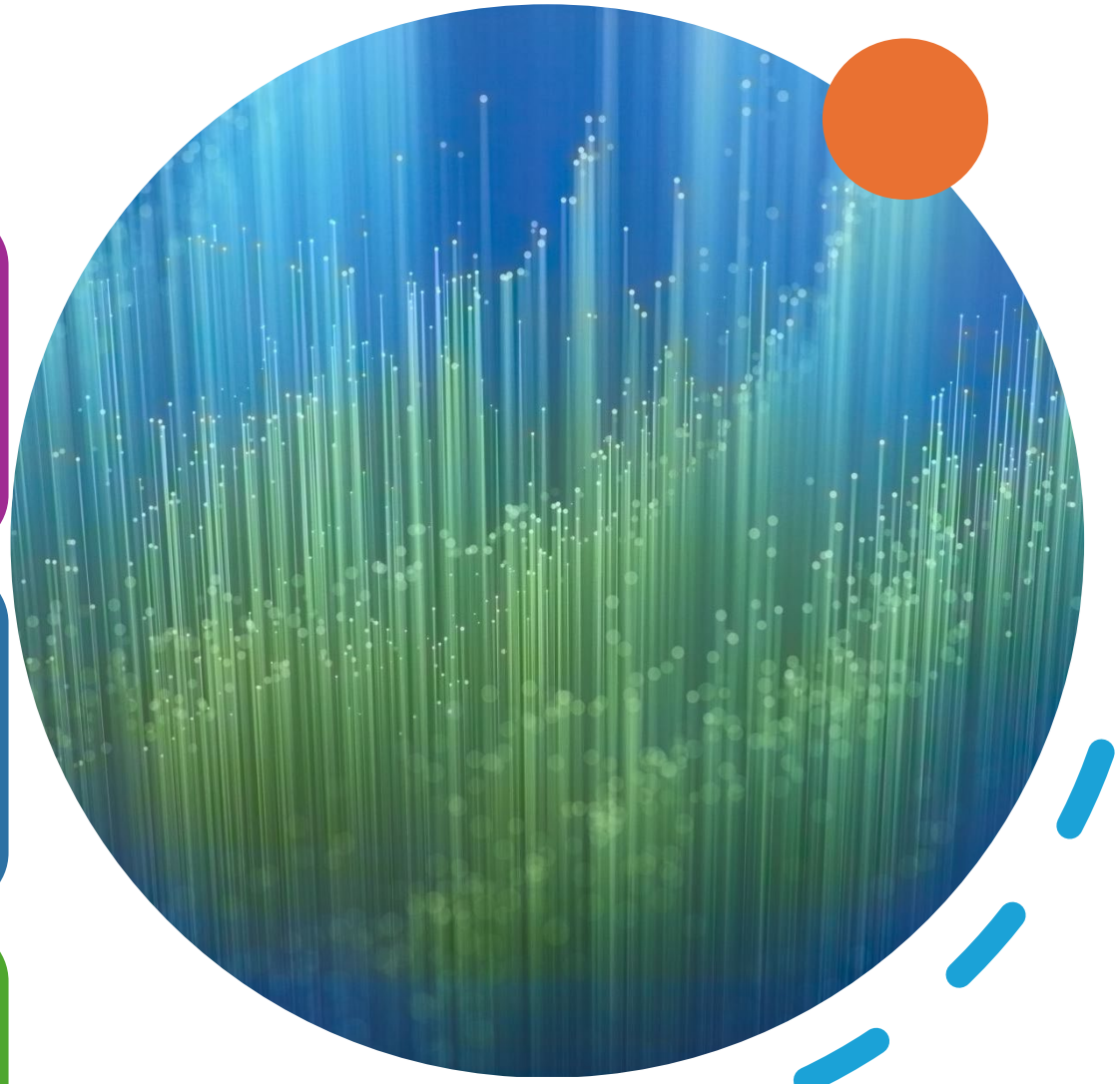
**New Chemical/Biological Drugs:** FDA

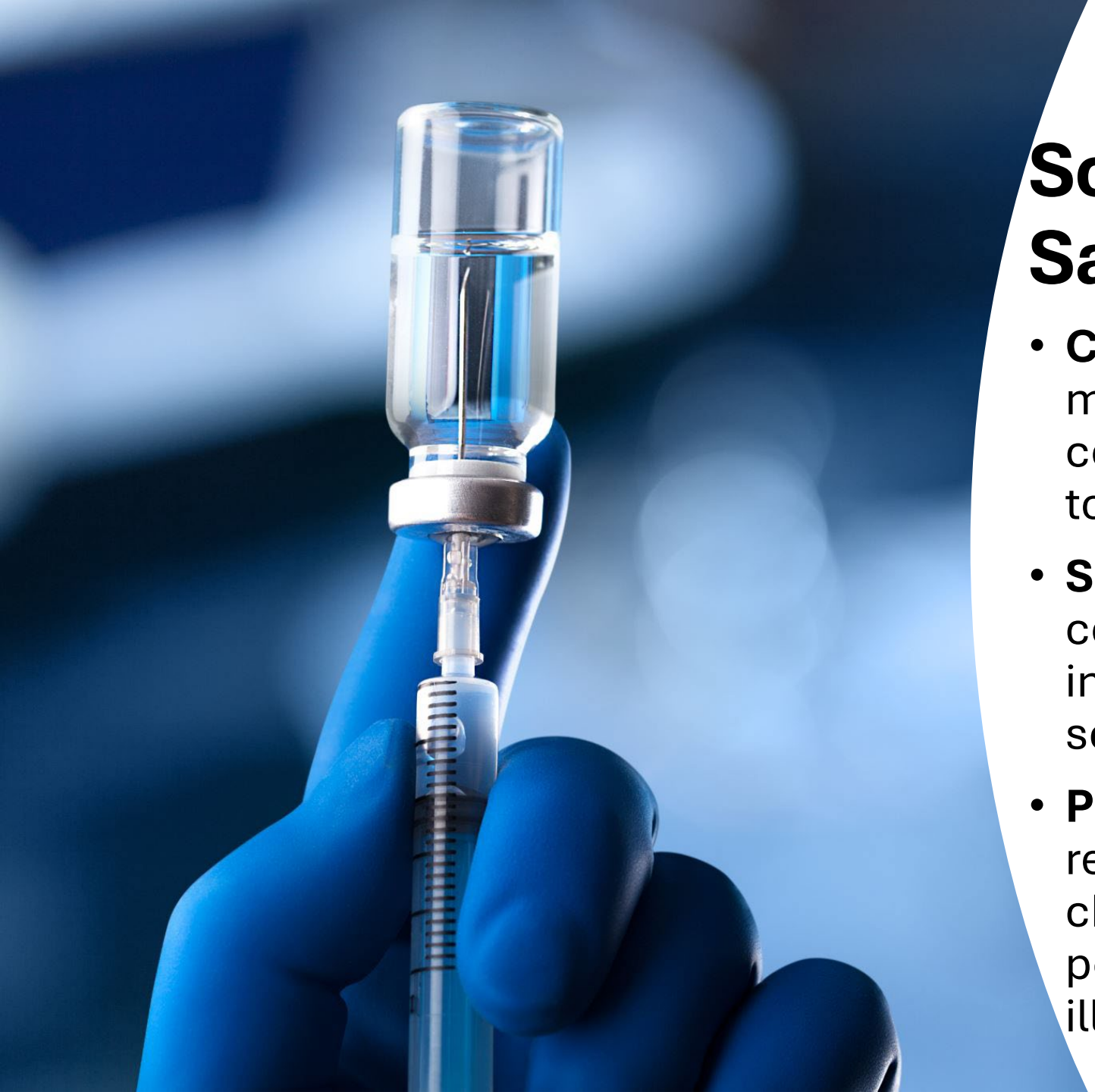
# Immune System Capacity

**Natural exposure:** Babies face thousands of environmental germs every day. Routine vaccines represent a tiny fraction of that daily exposure.

**No overload:** Multiple shots given together do not weaken or confuse the immune system.

**Independent response:** Each vaccine prompts a targeted antibody response specific to that distinct disease.





# Schedule Structure and Safety

- **Combination efficiency:** Shots like the measles, mumps, and rubella vaccine combine antigens into a single injection to reduce the total number of pokes.
- **Separate visits lack benefit:** Spreading combination vaccines into separate individual visits provides no medical or scientific advantage.
- **Practical protection:** Grouping recommended vaccines ensures children receive timely protection before potential exposure to dangerous illnesses.

# Breakdown of Immunogens

- Routinely recommended childhood vaccines contain about 160 to 170 total immunologic components
- While modern schedules protect against more diseases than in the past, advances in biotechnology mean vaccines use purified, refined pieces of microbes rather than whole cells, substantially lowering the overall immunogen load.
- **Historical shift**: The old whole-cell pertussis vaccine exposed the immune system to roughly 3,000 antigens from a single shot, whereas modern acellular pertussis components use far fewer.
- **Current totals**: The entire standard pediatric series exposes a child's immune system to roughly 165 total antigens across all recommended shots combined.
- **Daily comparison**: Infants encounter thousands of environmental antigens (from food, dust, and bacteria) every single day

# ACIP Regular Meeting Schedule

- The last fully convened meeting took place on **December 4–5, 2025**.
- March 18–19: Canceled due to federal court litigation.
- June 24-26: Due to ongoing litigation, this meeting was canceled.
- October 21-23: We will see what happens
- Interrupts the approval process and updates to the official U.S. child, adolescent, and adult immunization schedules
- Unable to provide national public health policy and decisions that allow health insurers and state programs to make regarding vaccine coverage



# January 2026
# U. S. Department of Health & Human Services

Directed the **Centers for Disease Control and Prevention (CDC)** to enact an unprecedented overhaul of the federal childhood immunization schedule.

The federal changes are currently stalled by a federal court order

This led to a split where many states and national medical groups continue to follow the traditional, more comprehensive (evidence-based) guidelines



# Targeted Diseases

- The overhaul reduced the number of diseases targeted by universally recommended childhood vaccines **from 17 down to 11**.
- Under this policy, six major immunizations were stripped of their "universal routine" status and moved to more restricted categories
- Confusion from the public and parents puts the children at risk



# Shared Clinical Decision-Making or High-Risk Only

Vaccines protecting against **Influenza (flu), COVID-19, Rotavirus, Hepatitis A, Hepatitis B, and Meningococcal meningitis**.

**No Newborn Shots:** Under new federal guidelines, routine vaccinations (such as Hepatitis B) are no longer recommended before age 2 months for infants not in high-risk categories. RSV seasonal vaccine

**HPV Dose Reduction:** The recommended doses for the Human Papillomavirus (HPV) vaccine were reduced from two or three doses to just a single dose.

Without evidence that this schedule is valid

Learn the lesson of MMR and Varicella

# Denmark's Childhood Vaccine Schedule

**3 Months:** First dose of DTaP-IPV-Hib (diphtheria, tetanus, pertussis, polio, and *Haemophilus influenzae* type b) and first dose of the pneumococcal conjugate vaccine (PCV).

**5 Months:** Second dose of DTaP-IPV-Hib and second dose of PCV.

**12 Months:** Third dose of DTaP-IPV-Hib and third dose of PCV.

**15 Months:** First dose of the MMR (measles, mumps, and rubella) vaccine.

**4 Years:** Second dose of the MMR vaccine.

**5 Years:** DTaP-IPV revaccination (booster shot).

**12 Years:** HPV vaccination (two doses). [1, 2, 3]

# Altering the Vaccine Schedule

**Extended vulnerability:** Spacing out shots leaves children unprotected for longer periods.

**Untested safety:** Custom or delayed timelines lack scientific proof that they work or reduce side effects.

**Extra visits:** Spreading out injections requires more frequent doctor appointments and extra costs.

**Incomplete series:** More visits make it harder to finish the full set of shots

At the end of the day, one given vaccine is a win




# Trump issues landmark childhood vaccine order focused on parental rights, reducing shots

# Core Changes in the Executive Order



**Fewer Universal Disease Recommendations**: The order cuts the CDC's previously recommended target diseases down to **11 core vaccinations**. Vaccines for diseases like influenza, hepatitis B, COVID-19, rotavirus, and hepatitis A will switch to "shared clinical decision-making," meaning they require individual doctor sign-offs.



**Splitting Up the MMR Vaccine**: The directive calls for breaking up the combined measles, mumps, and rubella (MMR) vaccine into **three** separate injections given across different medical visits.



**Spreading Out Doctor Appointments**: The administration recommends that children have **five separate vaccine appointments during their first year** rather than receiving multiple injections at once.

# Child vaccine schedule reduced as Trump moves to dramatically shift medical power to parents

The order urges spreading immunizations across five doctor visits and ending COVID jab recommendations for children

August 10, 2026

The memo recommends that parents should have five separate vaccine appointments, instead of children taking all of the vaccines at once.

"I **think** you're going to see some amazing results [by] breaking it up," Trump said in the Oval Office while announcing the order on Monday.

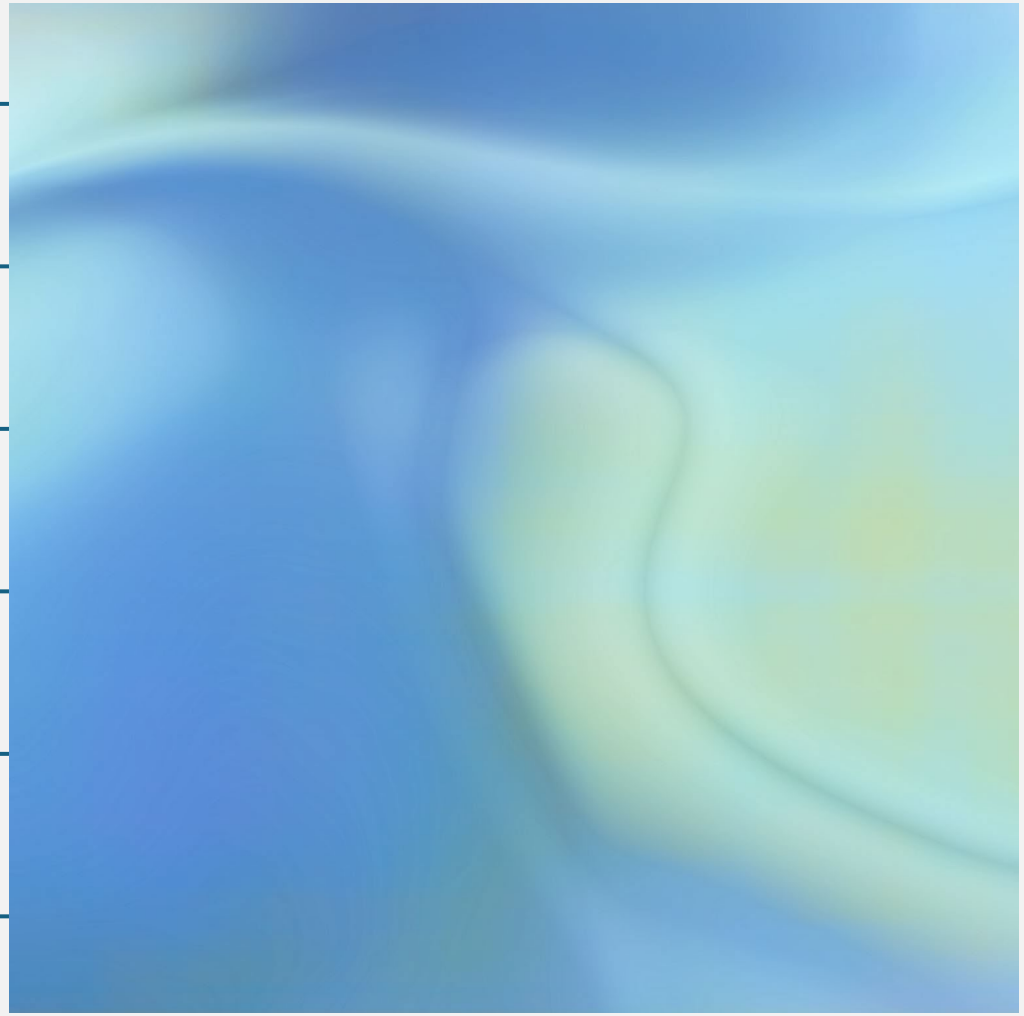
"It's not just that you're doing fewer vaccines or jabs, as they say, but you're doing them in a series of visits to the doctor. Much smaller amounts.

What's the evidence-based information that supports this move, or is this just "Abyss"

Will the amazing results be disastrous? Increased mortality and morbidity for our children

Currently, the vaccine schedule is delivered over 7 visits

Continue to work with parents as we have over decades



# ACOP and APP Statements

In an August 11, 2026 statement, the American College of Osteopathic Pediatricians (ACOP) Executive Committee reaffirmed its commitment to evidence-based science. ACOP stated that it will continue to provide unbiased, medically sound recommendations—such as the standard American Academy of Pediatrics (AAP) vaccination schedule—to protect children despite political changes.

The AAP strongly condemned the executive order on childhood vaccines as unscientific and dangerous. AAP President Dr. Andrew D. Racine stated that no new evidence justifies changing current guidelines and that the order aims to sow confusion and promote a disproven idea

# Remember the Science, Don’t repeat History

**No Evidence:** Stated there is no scientific basis to reduce recommended shots from 18 down to 11.

**Safety Risks:** Warned that delaying or skipping shots increases infection risks, especially with measles spreading.

**Reiterating Guidance:** Maintained that its own schedule supporting all 18 vaccines remains the standard for children.

**Parent Advice:** Urged parents to talk directly with pediatricians instead of following the executive order




# Questions??

Many Thanks to "You"

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