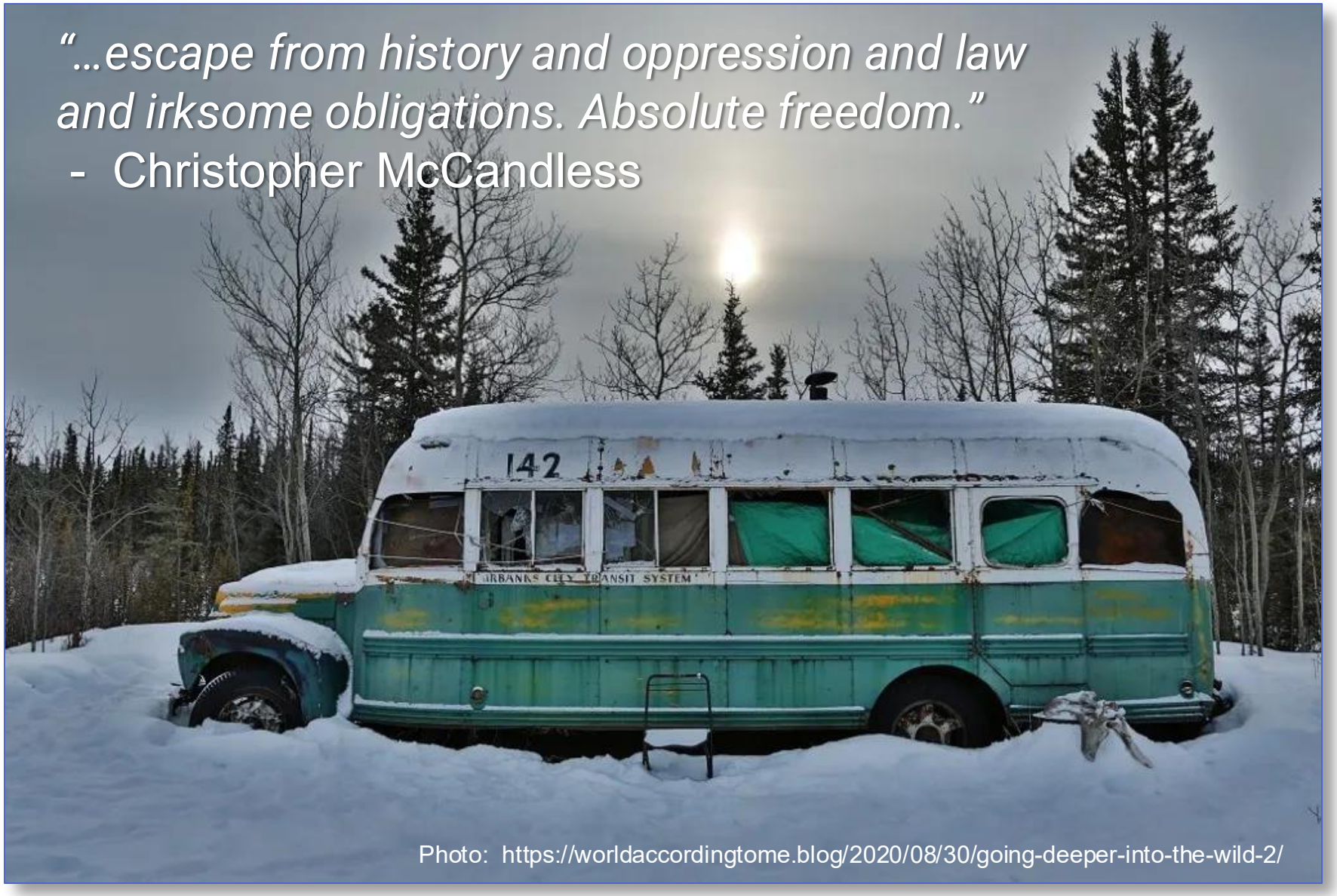
Into the Wild:

Vaccine Recommendations and Changes to the Advisory Committee on Immunization Practices

Jon Temte, MD/PhD
Professor of Family Medicine and Community Health
Associate Dean for Public Health and Community Engagement
UW School of Medicine and Public Health
Former ACIP Chair (2012-2015)

28 August 2025

Thanks to Dr. Jean Smith, CDC, for permission to adapt materials



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Into the Wild - Jon Krakauer, 1996

we are in a new era

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What We Know About the C.D.C. Shooting in Atlanta

A gunman who believed the Covid-19 vaccine had made him ill fired at the agency's Atlanta offices, killing a police officer and rattling the public health community.

Share full article

A shooting on Friday at the Atlanta headquarters of the Centers for Disease Control and Prevention killed a police officer. Elijah Nouvelage/Getty Images

https://www.nytimes.com/2025/08/10/us/cdc-shooting-atlanta.html

Childhood Vaccination Rates Have Dropped Again, C.D.C. Data Shows

The new report paints a sobering picture of immunizations as infectious diseases like measles surge across the United States.

Listen to this article · 6:08 min Learn more

Share full article 141

Mary Conlon/Associated Press

https://www.nytimes.com/2025/07/31/health/child-vaccinations-decline-cdc.html?smid=nytcore-ios-share&referringSource=articleShare

Exclusive: Medical journal rejects Kennedy's call for retraction of vaccine study

By **Michael Erman** and **Jennifer Rigby**

August 11, 2025 9:48 AM CDT · Updated 10 mins ago

U.S. Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr., speaks during a press conference at the Department of Health and Human Services in Washington, D.C., July 29, 2025. REUTERS/Jonathan Ernst/File Photo Purchase Licensing Rights

https://www.reuters.com/business/healthcare-pharmaceuticals/medical-journal-rejects-kennedys-call-for-retraction-vaccine-study-2025-08-11/

Objectives

- Understand the historical context of the ACIP: its responsibilities, structure, and function
- Identify components of immunization policy development in the U.S.
- Describe the interactions of ACIP with organizations and societies in the public and private sectors
- Appreciate the current challenges in immunization policy development and vaccine acceptance

Functional Anatomy of the
U.S. Advisory Committee on Immunization Practices

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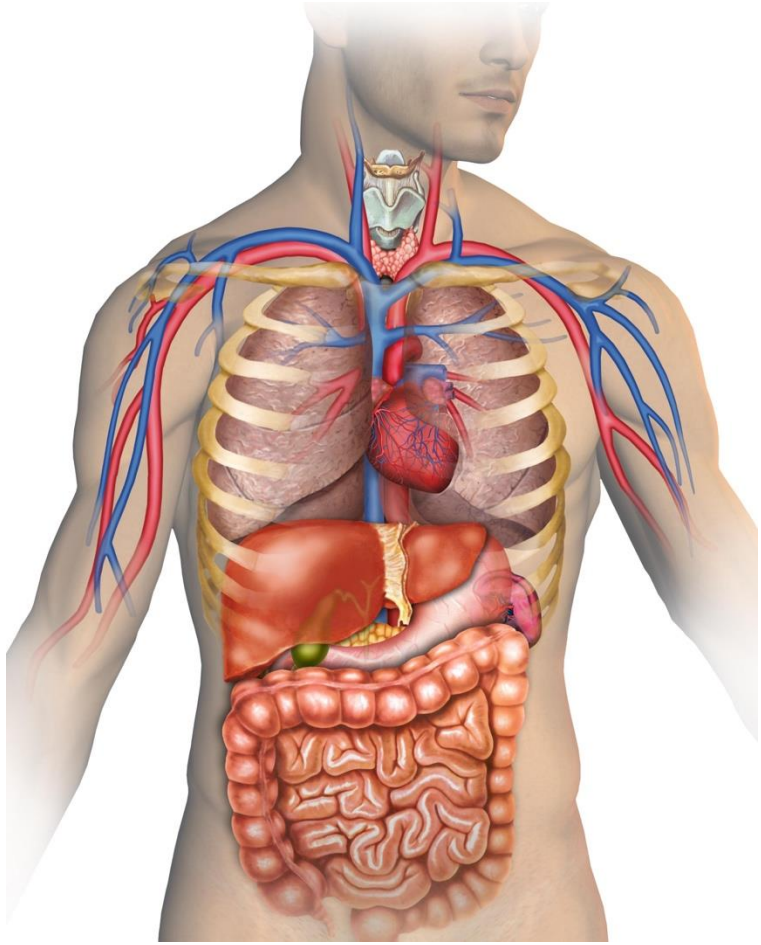

https://medlineplus.gov/anatomy.html

- Development
- Purpose
- Structure
- Function of ACIP
- Governmental authority
- Frequency of meetings
- Required reports
- Outcomes

Functional Anatomy of the
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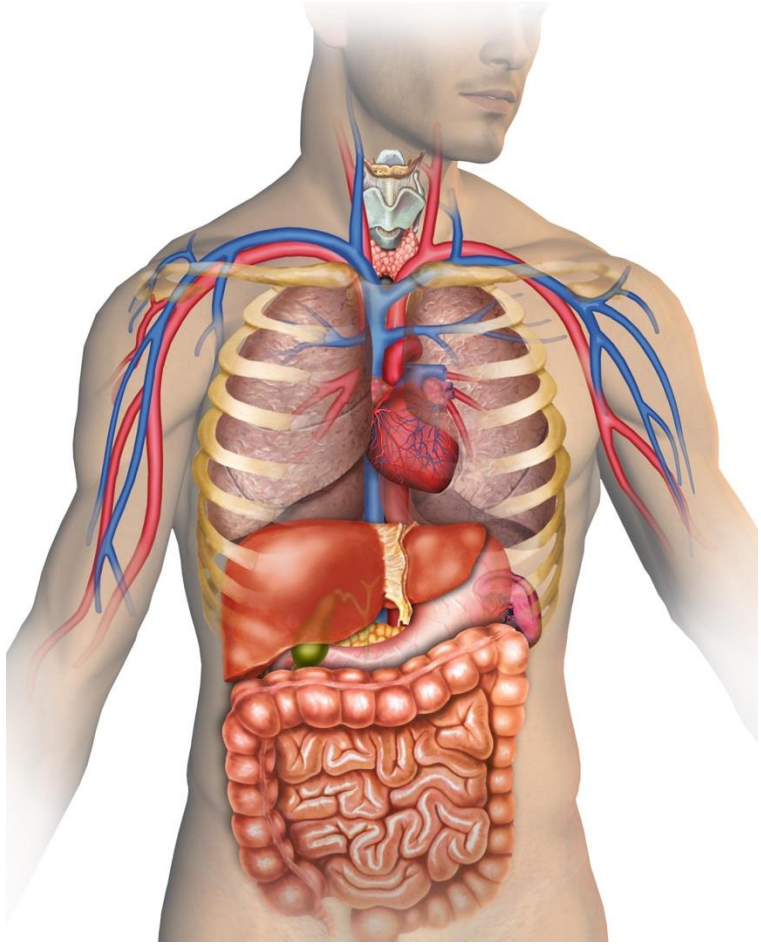

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- **Outcomes – Reduced for this audience**

Diseases Prevented by Vaccination

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1986	2010		2025	
Diphtheria	Diphtheria	Hepatitis A	Diphtheria	Influenza
Tetanus	Tetanus	Hepatitis B	Tetanus	Men ACWY
Pertussis	Pertussis	Human papilloma virus	Pertussis	Men B
Polio (OPV)	Polio (IPV)	Influenza	Polio	Rotavirus
Measles	Measles	Meningococcal disease	Measles	Varicella
Mumps	Mumps	Pneumococcal disease	Mumps	Zoster
Rubella	Rubella	Rotavirus	Rubella	COVID-19
Hib disease	Hib disease	Varicella	Hib Disease	RSV
		Zoster	Hepatitis A	Mpox
			Hepatitis B	Dengue
			HPV	

Functional Anatomy of the
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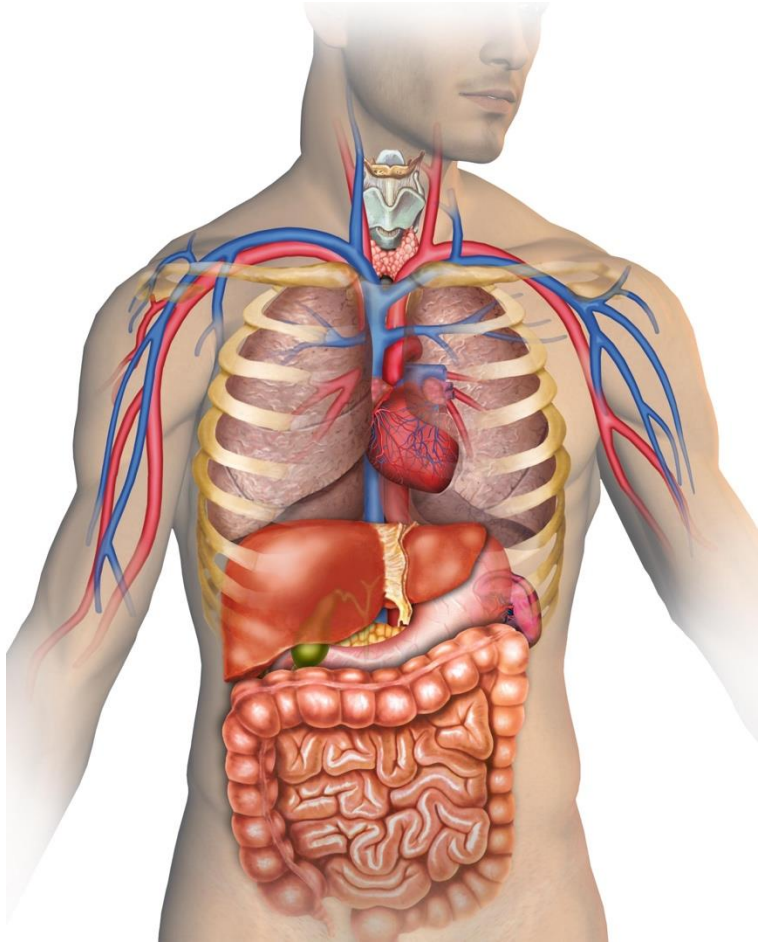

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Key Milestones in Federal Vaccine Policy (a bipartisan venture)

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- 1938: National Foundation for Infantile Paralysis
  - Became the “March of Dimes” (Roosevelt)
- 1955: Poliomyelitis Vaccination Assistance Act (Eisenhower)
  - start of Federal funding for vaccine purchase
- 1962: Vaccination Assistance Act (Kennedy)
  - Federal funds for purchase of polio, diphtheria, pertussis, tetanus vaccines (measles added in 1965)
- 1963: creation of National Immunization Program at CDC
- **1964: establishment of ACIP**
- 1972: Federal Advisory Committee Act (Nixon)
  - ACIP designated as a Federal Advisory Committee
- 1993: Childhood Immunization Initiative (Clinton)
  - Vaccines for Children (VFC) Program adopted

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Background – Origins of the ACIP

- Established in 1964 by Surgeon General of US Public Health Service
- Role: to provide advice and guidance to Office of Secretary, DHHS and Director, CDC on most effective means to prevent vaccine-preventable diseases in the civilian population
  - Vaccines and related agents (e.g., antisera, immune globulins, antiviral agents)
  - FDA-licensed vaccines (and unlicensed vaccines if warranted)

Agenda

Surgeon General's Advisory Committee on Immunization Practice
Room 207
Communicable Disease Center
May 25-26, 1964

Monday, May 25 - 9:30

1.	Introduction - Committee purpose and function	Dr. Goddard
2.	Previous Immunization Advisory Committees	Dr. Langmuir
3.	Definition of committee responsibility	Dr. Goddard
	a. Relationship to "Red Book" Committee	
	b. Relationship to other committees on immunization, e.g. APHA, AFEB, etc.	
4.	Simplification of Immunization Schedules	Dr. Bell
5.	Influenza	
	a. Influenza; 1963-1964, national and international	Dr. Silverman
	b. Influenza strains	Dr. Robinson
	c. Vaccine use - 1963	Dr. Henderson
	d. Field studies of vaccine efficacy - 1963-64	Dr. Henderson
	e. Vaccine composition	Dr. Murray
	f. Blood group antibodies induced by vaccine	Dr. Henderson
	g. Recommendations - 1964-65	

Room 207
Building 1
CDC

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Appendix I. Draft Statement Pertaining to Responsibilities of Surgeon General's Advisory Committee on Immunization Practice

(For subsequent discussion at next regular meeting)

Responsibility

The Advisory Committee on Immunization Practice was appointed by the Surgeon General in May, 1964. The Committee is charged with the responsibility of advising the Surgeon General regarding the most effective application in public health practice of specific preventive agents which may be applied in communicable disease control.

June 8, 1964

TO : For the Record

FROM : Secretary, Advisory Committee on Immunization Practice

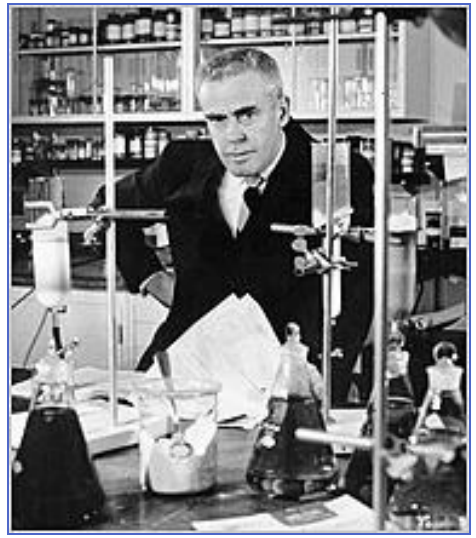
SUBJECT: Minutes - Meeting of Surgeon General's Advisory Committee on Immunization Practice - May 25-26, 1964

I. The Advisory Committee on Immunization Practice met at the Communicable Disease Center in Atlanta on May 25-26. Those in attendance were as follows:

a. Committee*

Dr. James L. Goddard, Chairman
Dr. Donald A. Henderson, Secretary
Dr. Ernest A. Ager
Dr. Gordon C. Brown
Dr. Alice D. Chenoweth
Dr. Geoffrey Edsall
Dr. Theodore A. Montgomery
Dr. Roderick Murray (May 26 only)
Dr. Paul F. Wehrle

*Because of illness, Dr. David Karzon could not attend.



The New York Times Magazine called Goddard “a wild-eyed crusader with a battle-ax flailing boldly.”

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Functional Anatomy of the
U.S. Advisory Committee on Immunization Practices

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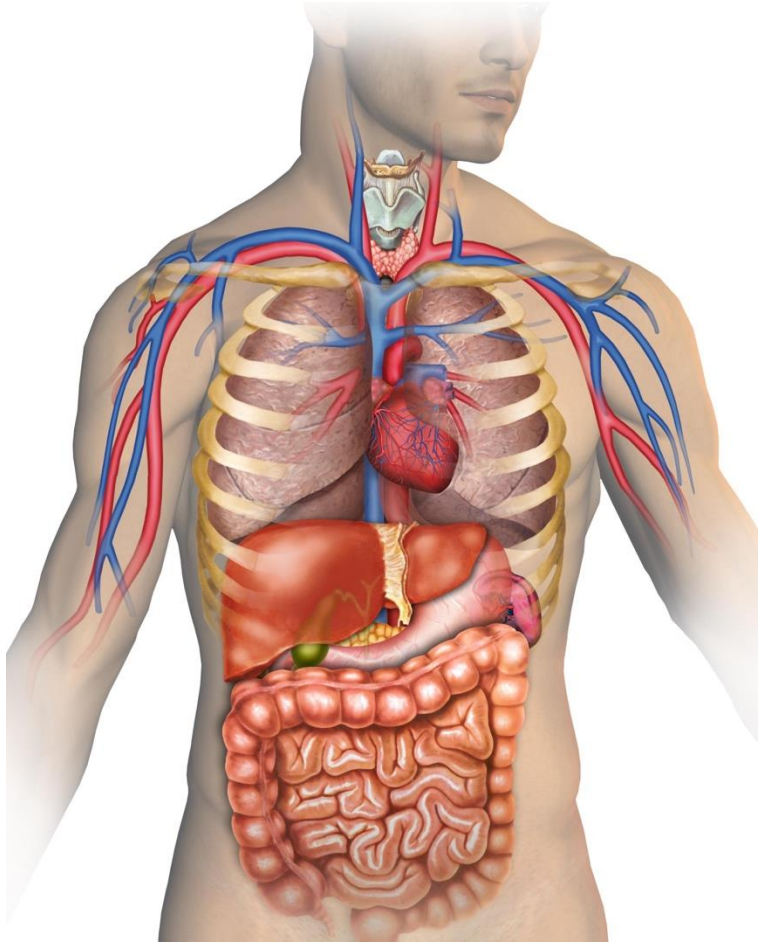

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Charge of the US Advisory Committee on Immunization Practices

ACIP charter

https://www.cdc.gov/acip/about/acip-charter.html

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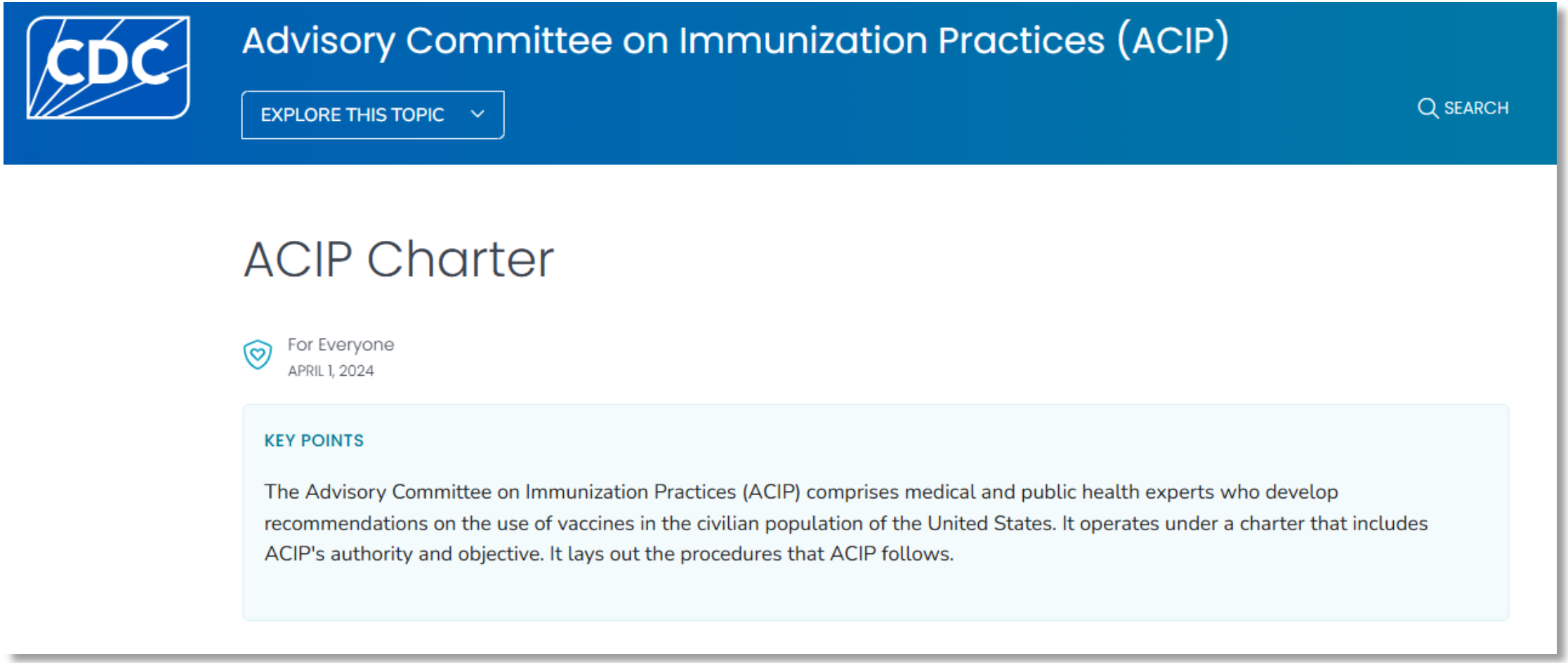

The Committee shall provide advice…

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for the control of diseases for which a vaccine is licensed in the U.S.

on population groups and/or circumstances in which a vaccine or related agent is recommended.

on contraindications and precautions for use of the vaccine and related agents and provides information on recognized adverse events.

the general use of vaccines and immune globulin preparations as a class of biologic agents… and special situations or populations that may warrant modification of the routine recommendations.

ACIP Charter – last updated April 1, 2024
www.cdc.gov/acip/about/acip-charter.html

Committee deliberations shall include …

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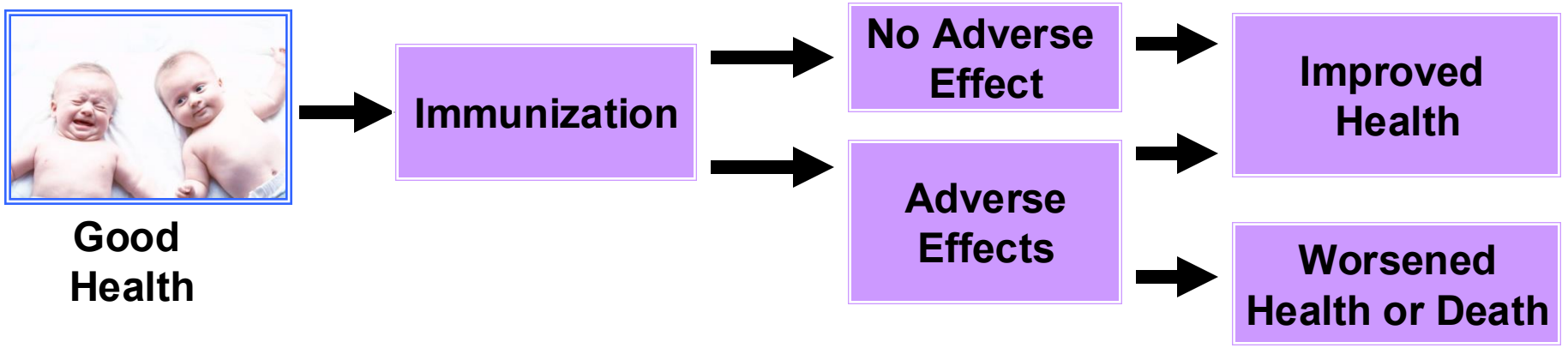
consideration of disease epidemiology and burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of evidence reviewed, economic analyses, and implementation issues.

The Committee may revise or withdraw their recommendation(s) regarding a particular vaccine as new information on disease epidemiology, vaccine effectiveness or safety, economic considerations, or other data become available..

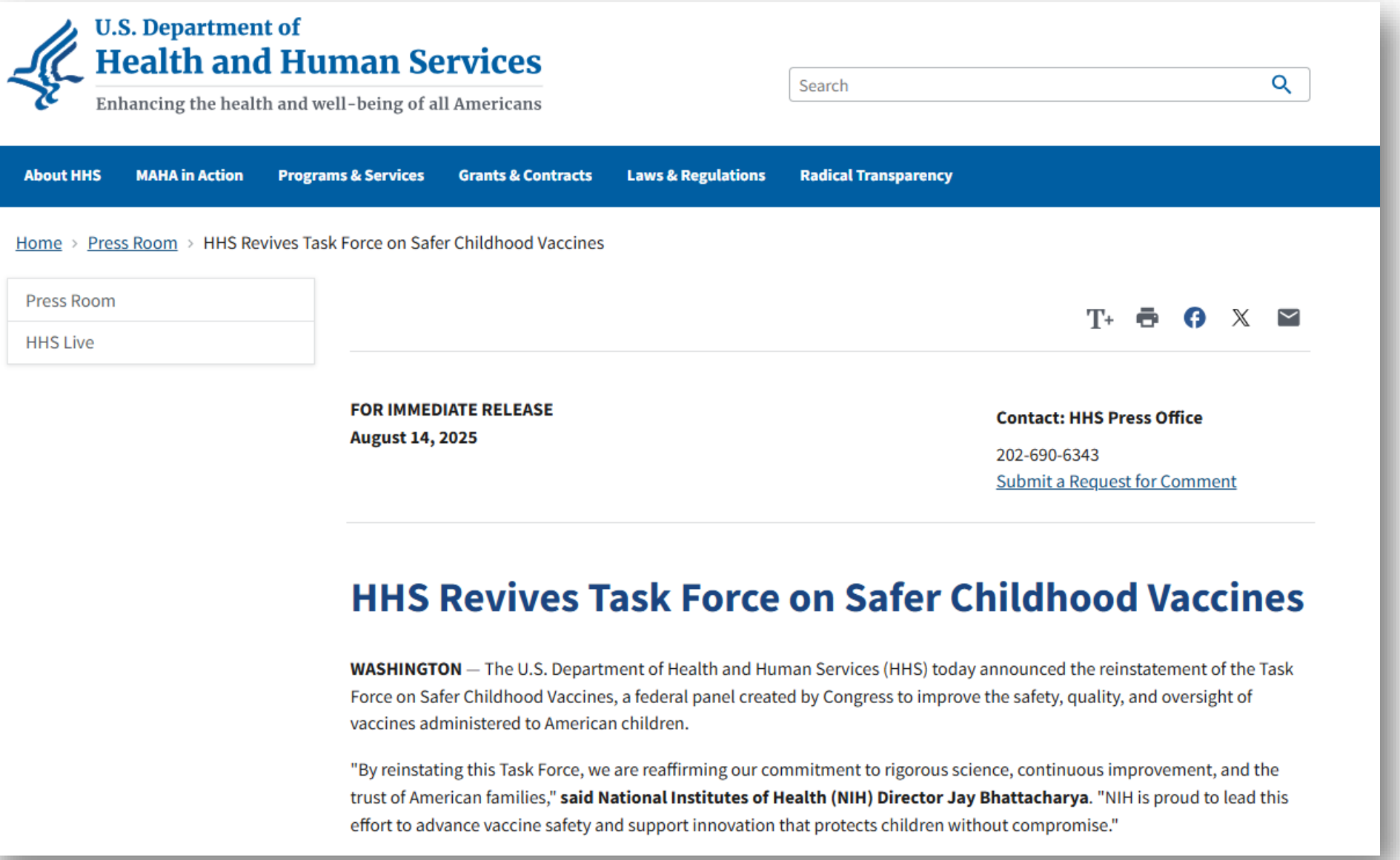
ACIP Charter – last updated April 1, 2024
www.cdc.gov/acip/about/acip-charter.html

Immunization Paradigm

high burden of safety required



- Immunization of “healthy” individuals
- Adverse effects can occur
  - Minor and transient
  - Significant



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Home › Press Room › HHS Revives Task Force on Safer Childhood Vaccines

Press Room
HHS Live

FOR IMMEDIATE RELEASE
August 14, 2025

Contact: HHS Press Office
202-690-6343
Submit a Request for Comment

HHS Revives Task Force on Safer Childhood Vaccines

WASHINGTON — The U.S. Department of Health and Human Services (HHS) today announced the reinstatement of the Task Force on Safer Childhood Vaccines, a federal panel created by Congress to improve the safety, quality, and oversight of vaccines administered to American children.

"By reinstating this Task Force, we are reaffirming our commitment to rigorous science, continuous improvement, and the trust of American families," **said National Institutes of Health (NIH) Director Jay Bhattacharya**. "NIH is proud to lead this effort to advance vaccine safety and support innovation that protects children without compromise."

https://www.hhs.gov/press-room/hhs-reinstates-task-force-on-safer-childhood-vaccines.html

Immunization Policy Product: Two Immunization Schedules

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- ACIP, AAP, and AAFP produce a “harmonized” childhood and adolescent immunization schedule
  - First harmonized in 1994
  - Before 1994, differing schedules existed
- ACIP, AAFP, ACOG, ACNM and ACP produce a harmonized adult immunization schedule
- Both schedules are updated annually and are published in January
- Display the complete schedule, with each vaccine in the context of other vaccines

ACIP Immunization Schedules

https://www.cdc.gov/vaccines/hcp/imz-schedules/index.html

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- Childhood 0 – 18 years
- Adult
- Catch-up schedules
- Footnotes

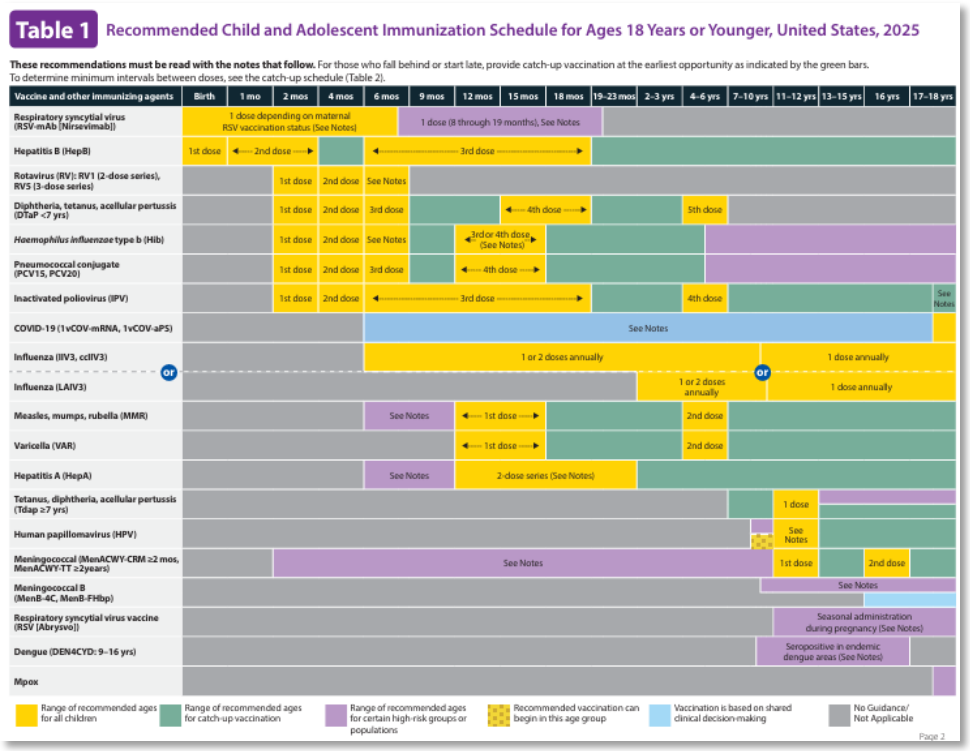

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

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

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs
Respiratory syncytial virus (RSV-mAb [Nirsevimab])	1 dose depending on maternal RSV vaccination status (See Notes)					1 dose (8 through 19 months), See Notes											
Hepatitis B (HepB)	1st dose	2nd dose			3rd dose												
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1st dose	2nd dose	See Notes												
Diphtheria, tetanus, acellular pertussis (DTaP <7 yrs)			1st dose	2nd dose	3rd dose			4th dose				5th dose					
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	See Notes		3rd or 4th dose (See Notes)										
Pneumococcal conjugate (PCV15, PCV20)			1st dose	2nd dose	3rd dose		4th dose										
Inactivated poliovirus (IPV)			1st dose	2nd dose	3rd dose							4th dose					See Notes
COVID-19 (1vCOV-mRNA, 1vCOV-aPS)					See Notes												
Influenza (IIV3, ccIIV3)					1 or 2 doses annually									1 dose annually			
or																	
Influenza (LAIV3)												1 or 2 doses annually		1 dose annually			
Measles, mumps, rubella (MMR)					See Notes		1st dose					2nd dose					
Varicella (VAR)							1st dose					2nd dose					
Hepatitis A (HepA)					See Notes		2-dose series (See Notes)										
Tetanus, diphtheria, acellular pertussis (Tdap ≥7 yrs)														1 dose			
Human papillomavirus (HPV)														See Notes			
Meningococcal (MenACWY-CRM ≥2 mos, MenACWY-TT ≥2years)						See Notes								1st dose		2nd dose	
Meningococcal B (MenB-4C, MenB-FHbp)														See Notes			
Respiratory syncytial virus vaccine (RSV [Abrysvo])														Seasonal administration during pregnancy (See Notes)			
Dengue (DEN4CYD: 9–16 yrs)														Seropositive in endemic dengue areas (See Notes)			
Mpox																	

Range of recommended ages for all children | Range of recommended ages for catch-up vaccination | Range of recommended ages for certain high-risk groups or populations | Recommended vaccination can begin in this age group | Vaccination is based on shared clinical decision-making | No Guidance/ Not Applicable

Page 2

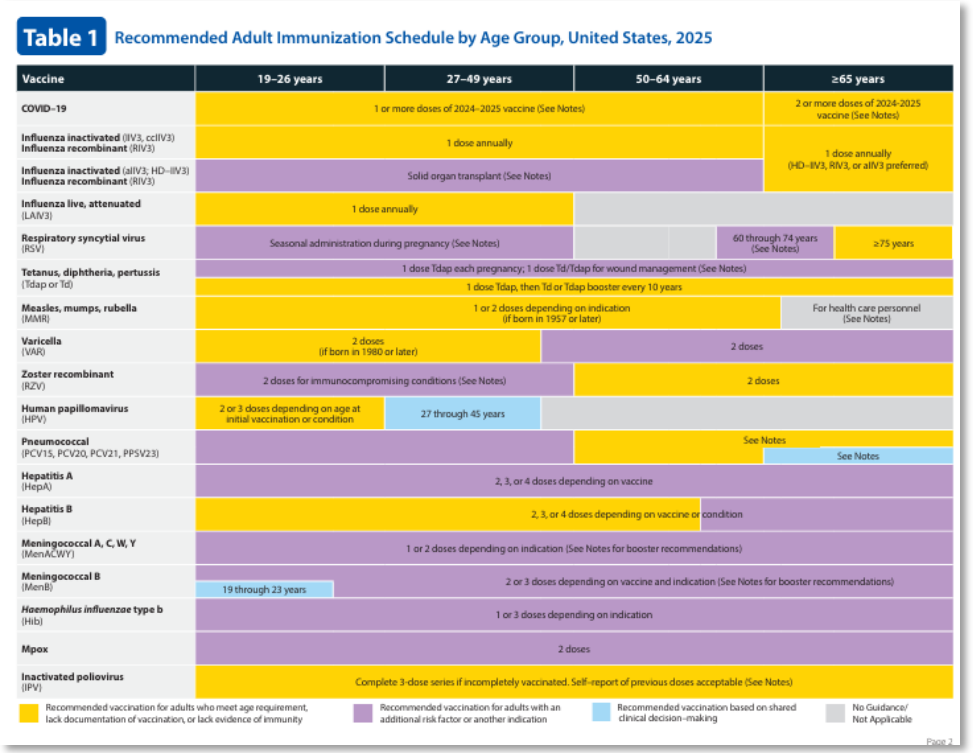

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2025

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
COVID-19	1 or more doses of 2024–2025 vaccine (See Notes)			2 or more doses of 2024-2025 vaccine (See Notes)
Influenza inactivated (IIV3, ccIIV3) Influenza recombinant (RIV3)	1 dose annually			1 dose annually (HD–IIV3, RIV3, or aIIV3 preferred)
Influenza inactivated (aIIV3; HD–IIV3) Influenza recombinant (RIV3)	Solid organ transplant (See Notes)			
Influenza live, attenuated (LAIV3)	1 dose annually			
Respiratory syncytial virus (RSV)	Seasonal administration during pregnancy (See Notes)		60 through 74 years (See Notes)	≥75 years
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (See Notes)			
	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			For health care personnel (See Notes)
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV)	2 doses for immunocompromising conditions (See Notes)		2 doses	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal (PCV15, PCV20, PCV21, PPSV23)			See Notes	See Notes
Hepatitis A (HepA)	2, 3, or 4 doses depending on vaccine			
Hepatitis B (HepB)	2, 3, or 4 doses depending on vaccine or condition			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication (See Notes for booster recommendations)			
Meningococcal B (MenB)	19 through 23 years	2 or 3 doses depending on vaccine and indication (See Notes for booster recommendations)		
Haemophilus influenzae type b (Hib)	1 or 3 doses depending on indication			
Mpox	2 doses			
Inactivated poliovirus (IPV)	Complete 3-dose series if incompletely vaccinated. Self-report of previous doses acceptable (See Notes)			

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of immunity | Recommended vaccination for adults with an additional risk factor or another indication | Recommended vaccination based on shared clinical decision-making | No Guidance/ Not Applicable

Page 2

ACIP Recommended Immunization Schedules are available at https://www.cdc.gov/vaccines/hcp/imz-schedules/index.html

Evidence-Based Recommendations

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- On October 28, 2010, the ACIP voted to adopt an explicit evidence-based approach vaccine recommendations
  - vaccine safety
  - vaccine efficacy/effectiveness
  - burden of disease.
  - Other elements:
    - Economic analyses, such as cost-effectiveness studies
- Key features
  - focus on transparency
  - use of evidence of varying strengths
  - consideration of both individual and community health
- Adoption of GRADE methodology

MAKE OUR CHILDREN HEALTHY AGAIN STRATEGY

Recommendations of the MAHA Commission to President Donald J. Trump

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- **Autism:** HHS through NIH in collaboration with CMS will study the root causes of autism, including through the Real-World Data (RWD) Platform and related initiatives.
- **Vaccine Injury:** HHS in collaboration with NIH/NIAID will investigate vaccine injuries with improved data collection and analysis, including through a new vaccine injury research program at the NIH Clinical Center that may expand to centers around the country.

- **Vaccine Framework:**
  - DPC and HHS will develop a framework focused on:
    - Ensuring America has the Best Childhood Vaccine Schedule
    - Addressing Vaccine Injuries
    - Modernizing American Vaccines with Transparent, Gold-Standard Science
    - Correcting Conflicts of Interest and Misaligned Incentives
    - Ensuring Scientific and Medical Freedom
    -

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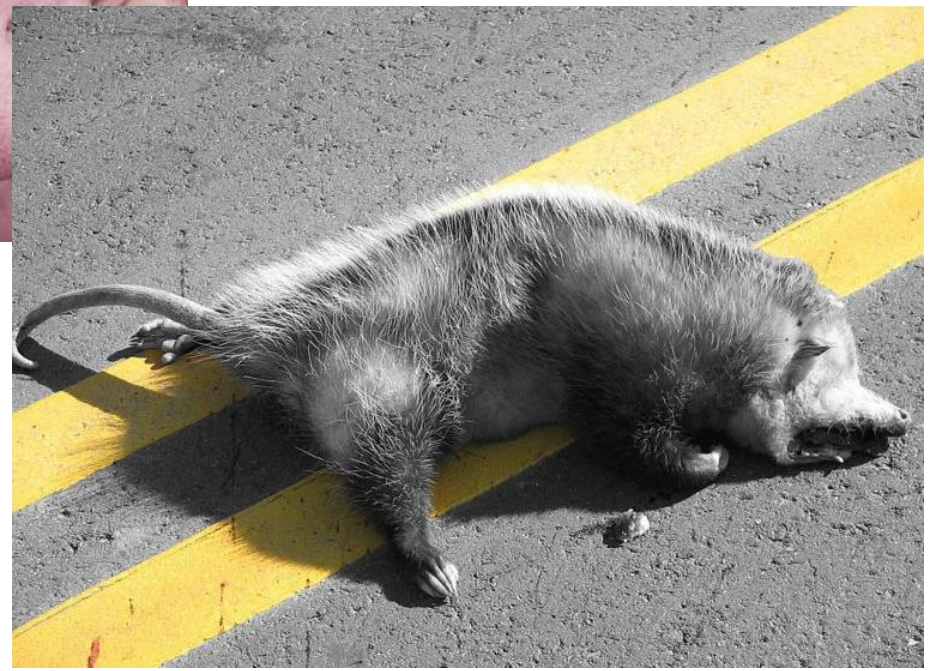

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Vaccine 29 (2011) 9171–9176

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Review

Methods for developing evidence-based recommendations by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC)

Faruque Ahmed[a,*], Jonathan L. Temte[b], Doug Campos-Outcalt[c], Holger J. Schünemann[d], for the ACIP Evidence Based Recommendations Work Group (EBRWG)[1]

[a] *Immunization Services Division, Centers for Disease Control and Prevention, 1600 Clifton Rd. NE, Mailstop A-19, Atlanta, GA 30333, USA*
[b] *Department of Family Medicine, University of Wisconsin School of Medicine and Public Health, 777 South Mills Street, Madison, WI 53715, USA*
[c] *Department of Family & Community Medicine, University of Arizona College of Medicine, 550 E. Van Buren Street, Phoenix, AZ 85004, USA*
[d] *Department of Clinical Epidemiology and Biostatistics, McMaster University Health Sciences Centre, Room 2C10B, 1200 Main Street West, Hamilton, ON L8N 3Z5, Canada*

No New Evidence to Support HHS Vaccine Changes, 'Shadow' Group Says

— The Vaccine Integrity Project's massive evidence review finds no new safety signals

by Kristina Fiore, Director of Enterprise & Investigative Reporting, MedPage Today
August 19, 2025 · 4 min read

A sweeping review by the Vaccine Integrity Project (VIP) suggests no new evidence that would prompt the recent changes to fall COVID vaccine recommendations made by HHS.

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Functional Anatomy of the
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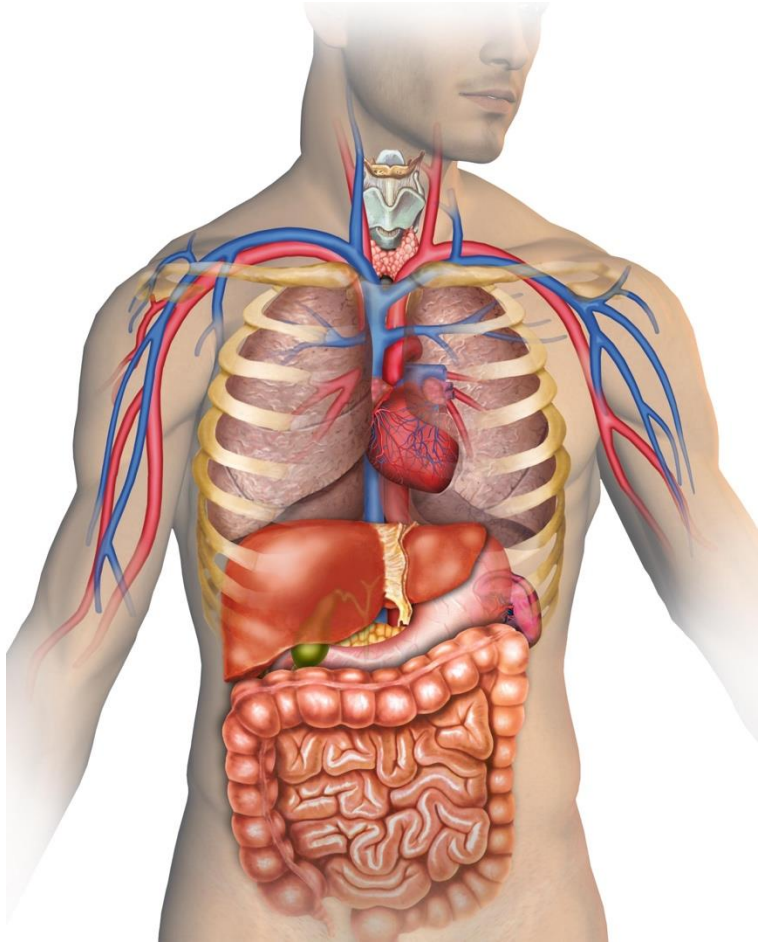

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Location

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ACIP Structure

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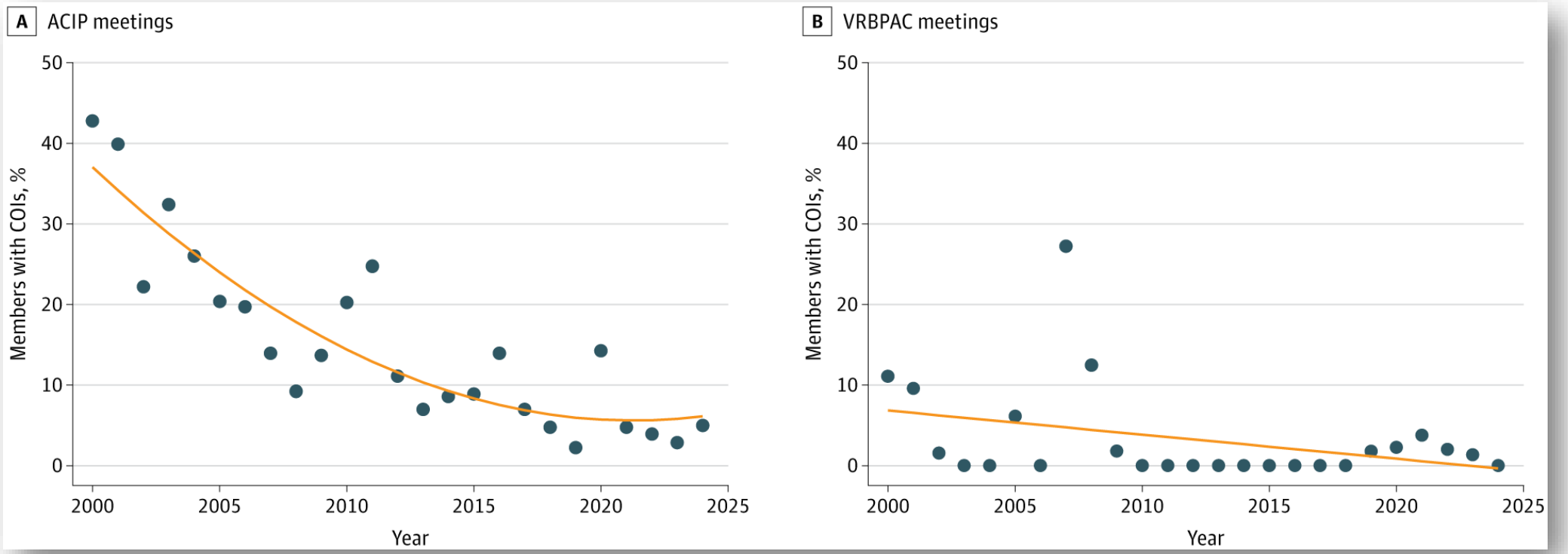
- Up to 19 voting members (including Chair)
  - External to government
  - 4-year terms - overlapping
  - ACIP Steering Committee reviews nominees, OS DHHS selects
  - Chair - selected from current members
  - One consumer representative
  - Voting members screened for Conflicts of Interest
- 6 *ex officio* members
  - representing other government agencies - non-voting*
  - CMS, FDA, HRSA, IHS, NIH, OID&HIV/AIDS Policy
- 30 liaison organizations
  - representatives of professional societies and organizations
  - vaccine development and immunization programs - non-voting

•*Ex officio* members may be called upon to vote in the situation that there is not a quorum of voting ACIP members



Kanter GP, Mankowitz T, Lurie P. Conflicts of Interest in Federal Vaccine Advisory Committees. JAMA. Published online August 18, 2025. doi:10.1001/jama.2025.13245

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Table. ACIP and VRBPAC Meeting Sample Characteristics and Reported COI Conflict Rates, 2000-2024[a]

	ACIP				VRBPAC			
	Full sample, 2000-2024	2000-2007	2008-2015	2016-2024	Full sample, 2000-2024	2000-2007	2008-2015	2016-2024
Sample statistics								
No. of meetings	99	25	27	47				
Annual No. of meetings								
Mean (SD)	4.0 (2.2)	3.1 (0.4)	3.3 (0.5)	5.				
Median (IQR)	3.0 (3.0-4.0)	3.0 (3.0-3.0)	3.0 (3.0-4.0)	3.				
No. of voting attendees per meeting								
Mean (SD)	13.5 (1.8)	12.5 (2.1)	14.4 (1.0)	13				
Median (IQR)	14.0 (13.0-15.0)	12.0 (11.0-14.0)	15.0 (14.0-15.0)	14 (1				
Meeting-level COI statistics								
Reported COI prevalence rate, % (SD)								
Any conflict type	13.5 (12.5)	27.8 (12.8)	13.1 (7.6)	6.				
Research or investigator support	10.1 (8.5)	17.1 (8.2)	12.6 (7.6)	4.				
Data and safety monitoring board or end-point reviewer	1.4 (3.9)	5.4 (6.4)	0.0 (0.0)	0.				
Consulting	1.4 (4.0)	5.0 (6.3)	0.2 (1.3)	0.				
Stock, royalties, or ownership	1.4 (3.5)	4.4 (5.5)	0.0 (0.0)	0.6 (2.0)	0.3 (1.4)			
Recusal rate, % (SD)	1.3 (3.9)	0.3 (1.3)	0.9 (2.5)	2.1 (5.2)	7.4 (9.1)[b]			

Abbreviations: ACIP, Advisory Committee on Immunization Practices; COI, conflict of interest; VRBPAC, Vaccines and Related Biological Products Advisory Committee.

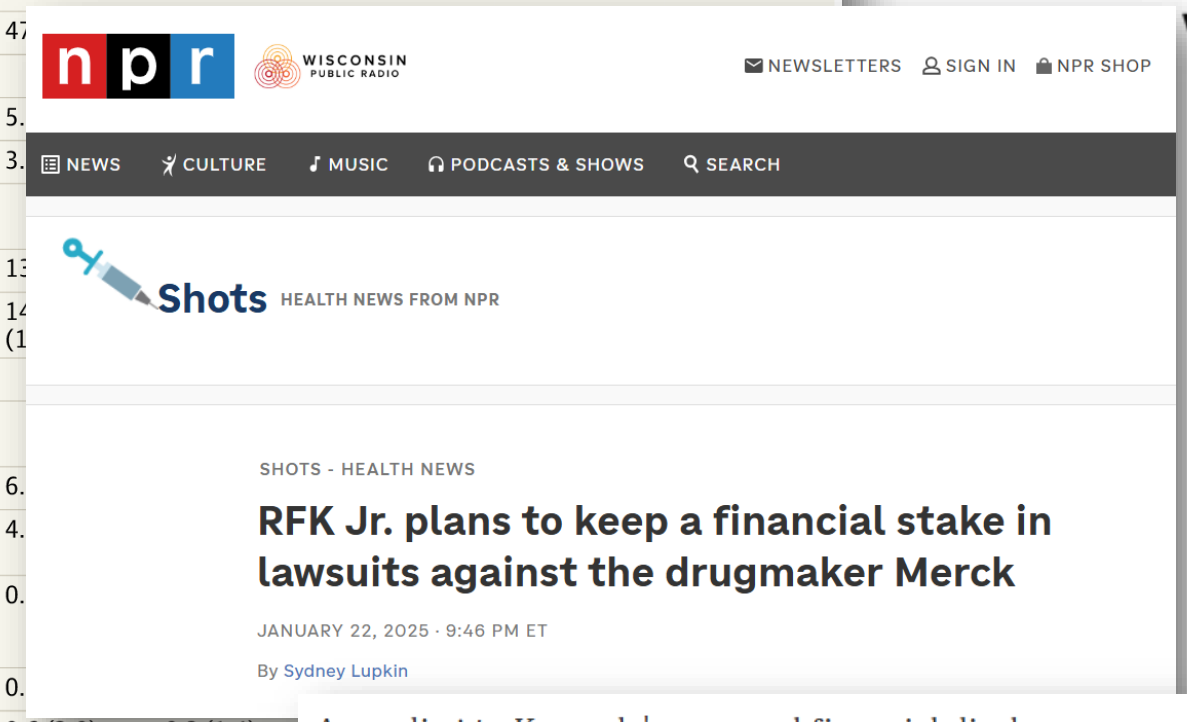
[a] Sample includes only voting meetings. Average prevalence of COIs in a given year was calculated as the unweighted mean of meeting-level COI prevalence rates for all meetings in that year (ie, prevalence was not weighted by the number of meeting attendees). Rates for 4 leading conflict types are reported.

Additional conflict types ir relationship, paid speaking (as a participant), and no c

[b] Includes meetings from No

[c] Includes meetings from No

[d] Includes meetings from Ja



According to Kennedy's personal financial disclosure report, he made $856,559 in referral fees from the law firm. That's in addition to $326,056 in salary and benefits he earned from the nonprofit Children's Health Defense, an organization Kennedy chaired and that has been influential in the anti-vaccine movement. The nonprofit has filed nearly 30 federal and state lawsuits since 2020, including some that target the federal agencies he would oversee at HHS. Many of the legal actions taken by CHD challenged vaccines and public health mandates.

Expertise of ACIP Members

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- Infectious diseases
- Immunology
- Epidemiology
- Virology
- Pediatrics
- Internal medicine
- Family medicine
- Public health, preventive medicine
- Vaccine research and policy
- Economics, cost-effectiveness
- Consumer concerns

*

THE HILL

Blumenthal calls for firing of RFK Jr. ally over violent rhetoric by Nathaniel Weixel - 08/14/25 12:09 PM ET

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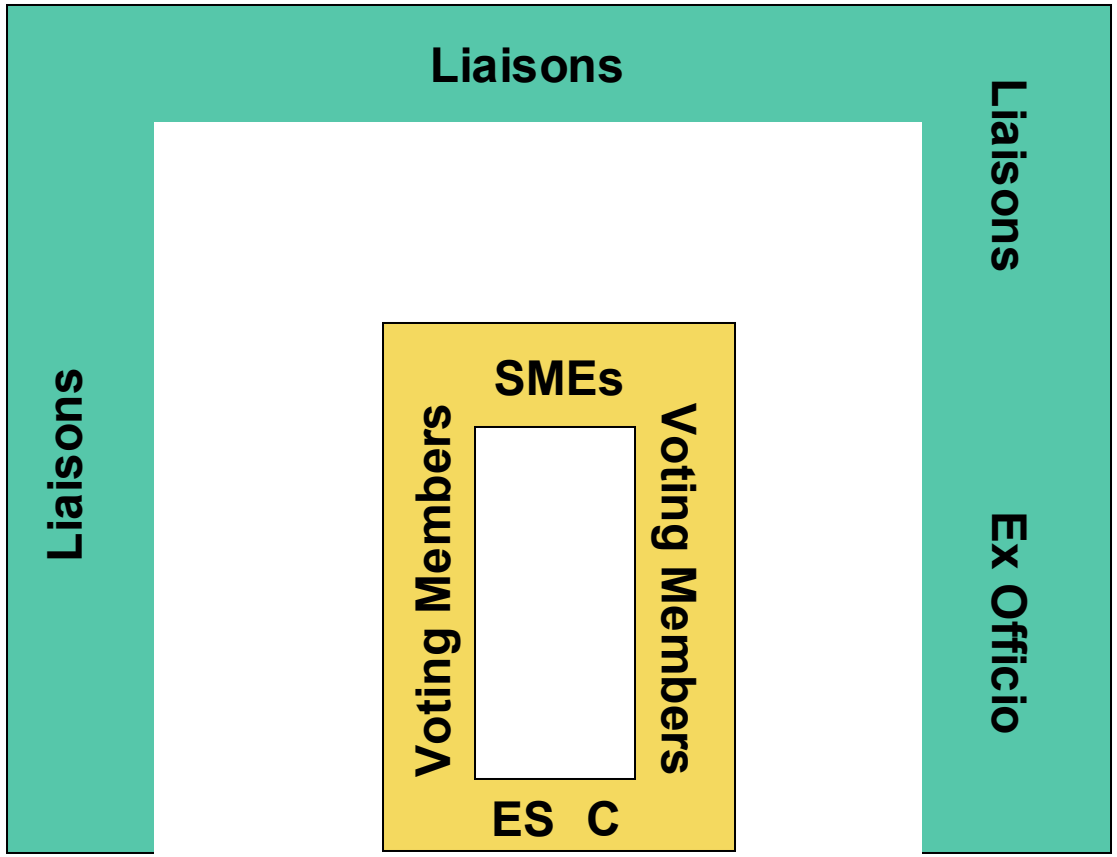
Sen. Richard Blumenthal (D-Conn.) is demanding Health and Human Services Secretary Robert F. Kennedy Jr. "immediately" fire a key ally from his role as vaccine advisor on a Centers for Disease Control and Prevention (CDC) panel due to "escalating and violent" rhetoric in the wake of an attack on CDC headquarters.

Blumenthal wrote a letter to Kennedy on Wednesday calling for him to fire Robert Malone from the CDC's Advisory Committee on Immunization Practices (ACIP). Blumenthal said Malone "issued a meme-filled post" on his personal blog "that included violent and threatening images that appeared to be directed at government officials."

https://thehill.com/policy/healthcare/5452254-blumenthal-demands-rfk-jr-fire-malone/

Historical Seating Chart



Audience

general public, international, manufacturers, interest groups

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ACIP Work Groups

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- Gather, analyze and prepare information for presentation to ACIP
- Develop draft policies/options for review/vote by full ACIP
- Work by teleconference throughout the year, and before/during ACIP meetings
- WG is chaired by an ACIP member; must include ≥1 other ACIP member
    - Other members: lead CDC staff, other CDC staff including Immunization Safety Office, *ex officio* members, liaison representatives, invited consultants
- Task-oriented WGs are disbanded when work complete; new WGs formed as required

Current ACIP Work Groups (Nov 2024)

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- Chikungunya Vaccines
- Combined Child/Adolescent and Adult Immunization Schedules
- COVID-19 Vaccines
- Cytomegalovirus Vaccines
- Human Papillomavirus Vaccine
- Influenza Vaccines
- Meningococcal Vaccines
- Mpox Vaccines
- Pneumococcal Vaccines
- Respiratory Syncytial Virus Vaccines – Pediatric/Maternal
- Respiratory Syncytial Virus Vaccines – Adult

ENDPOINTS NEWS

CHANNELS ▾ WEBINARS BIOPHARMA JOBS MORE ▾

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August 21, 2025 03:49 PM EDT | Pharma, FDA+, Coronavirus

CDC staff won't serve as members of ACIP's new Covid-19 working group

Max Bayer
Pharma Reporter

A reconstructed Covid-19 working group serving the CDC's outside vaccine advisors won't have any agency staffers as members, according to a new document that appears ...

https://endpoints.news/cdc-staff-wont-serve-as-members-of-acips-new-covid-19-working-group/

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ACIP

AC

Advisory Committee on Immunization Practices (CDC) <acip@cdc.gov>

To Advisory Committee on Immunization Practices (CDC)

Reply | Reply All | Forward

Fri 8/8/2025 3:28 PM

Vaccine

You forwarded this message on 8/8/2025 3:35 PM.

Dear ACIP Liaison Organizations,

We thank you, the Advisory Committee on Immunization Practices (ACIP) liaisons and your organizations, for your ongoing contributions to ACIP. The liaison organizations play a critical role in ACIP's decision-making, and the liaisons and your organizations continue to provide essential input during the public ACIP parent committee meetings.

We would like to clarify last week's update to Federal Advisory Committee Act (FACA) workgroup practices. FACA workgroups operate under an exception to the FACA statute's open meeting requirements. CDC guidance on the administration of FACA committees recommends that workgroups be composed of subject matter experts representing individual viewpoints, rather than individuals representing the perspectives of an organization. This change is not specific to ACIP. It is a long-standing practice that is being adopted across CDC FACA committees.

We continue to encourage and welcome your participation and representation during the ACIP parent committee public meetings.

Functional Anatomy of the
U.S. Advisory Committee on Immunization Practices

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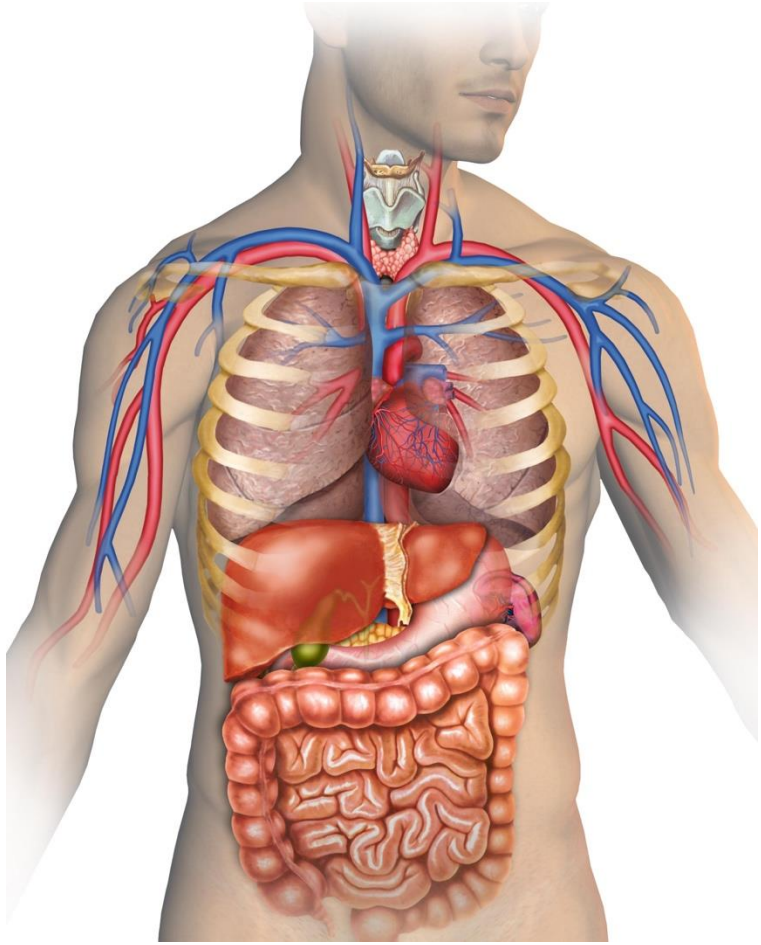

https://medlineplus.gov/anatomy.html

- Development
- Purpose
- Structure
- **Function of ACIP**
- Governmental authority
- Frequency of meetings
- Required reports
- Outcomes

Factors Considered in Recommendations

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- FDA Licensed indications and schedule
- Disease burden overall and in high-risk groups
- Data on safety and efficacy
  - general
  - specific groups
- Feasibility in the context of existing recommendations
- Equity in access and good use of public funds
  - cost effectiveness
- Recommendations of other groups
  - AAP, AAFP, ACP, ACOG

Events in Vaccine Development

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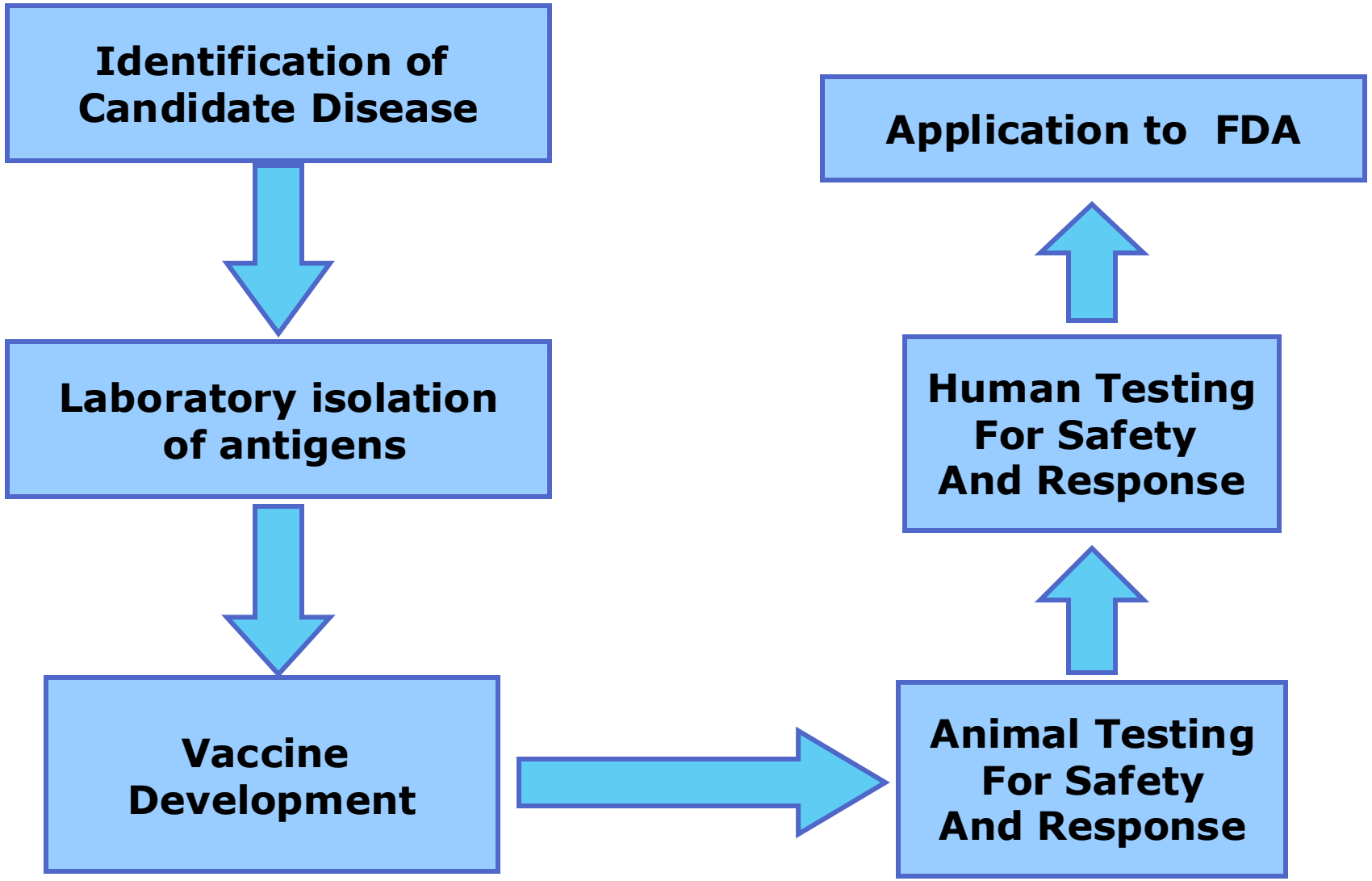

Events in Vaccine Development

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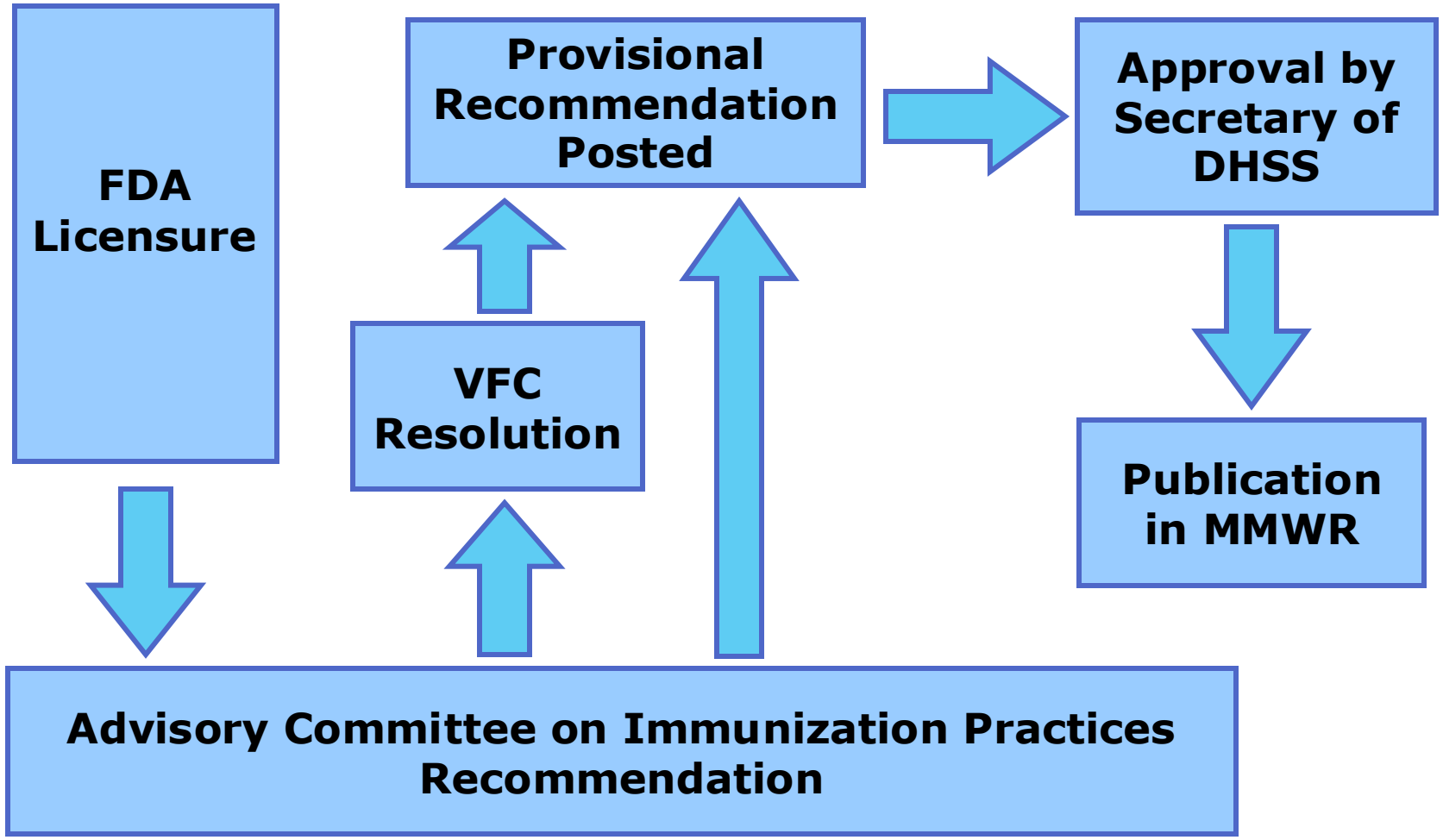

CDC Approval Process Following an ACIP Vaccine Recommendation

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Brief Recommendation

A Policy Note is published in *MMWR Weekly* within 1 month of an ACIP vote

*all provisional recommendations, final recommendations, and updates are posted on ACIP website: www.cdc.gov/vaccines/recs/acip

Full Recommendation ("ACIP Statement")

Provisional recommendations are posted on ACIP website within 3 weeks of an ACIP vote

Final recommendations are published in *MMWR Recommendations & Reports* within 6-8 months of an ACIP vote

Immunization Policy Recommending Bodies in the U.S.

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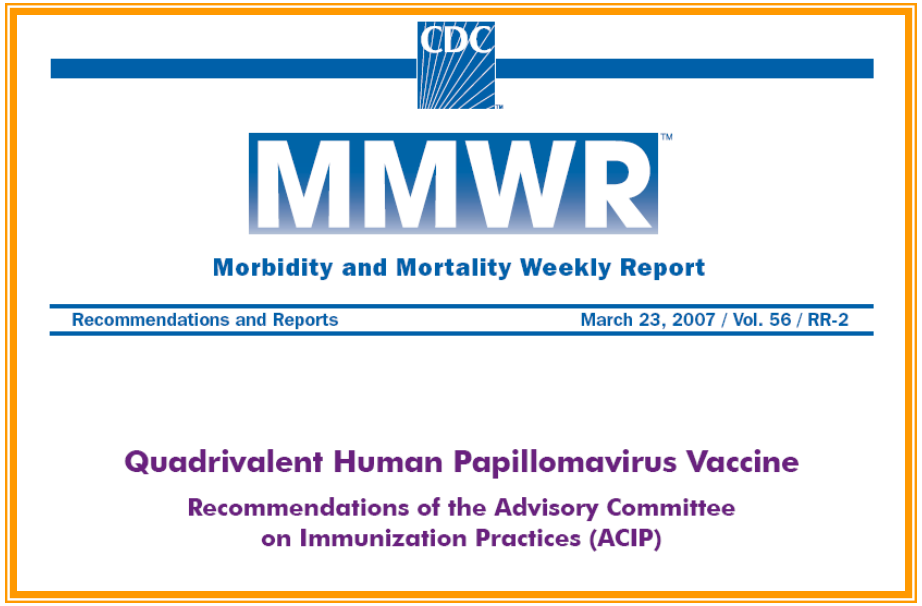
- U.S. Advisory Committee on Immunization Practices (ACIP)
- American Academy of Pediatrics Committee on Infectious Diseases (AAP-COID)
- American Academy of Family Physicians (AAFP)
- American College of Physicians (ACP)
- American College of Obstetricians and Gynecologists (ACOG)
- American College of Nurse-Midwives (ACNM)

Implementation Considerations



- Organizational Endorsement (e.g., AAP, AAFP)
- State Program Purchase – 317 Program
- Clinician Buy-in
- General Public Interest
- Administrative Rules and State Mandates

Background – VFC Program

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- Vaccines for Children (VFC) Program
  - established in August 1993
    - operational since October 1994
  - Unique statutory authority established by Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. § 1396a) gives ACIP authority to determine the vaccines that will be provided in the VFC Program
  - Eligible children (through age 18 yrs): Medicaid eligible, uninsured, American Indian/Alaska native, underinsured
  - VFC is a federal entitlement program
    - 2014 cost >$4 billion annually

https://www.cdc.gov/vaccines-for-children/about/index.html

Functional Anatomy of the
U.S. Advisory Committee on Immunization Practices

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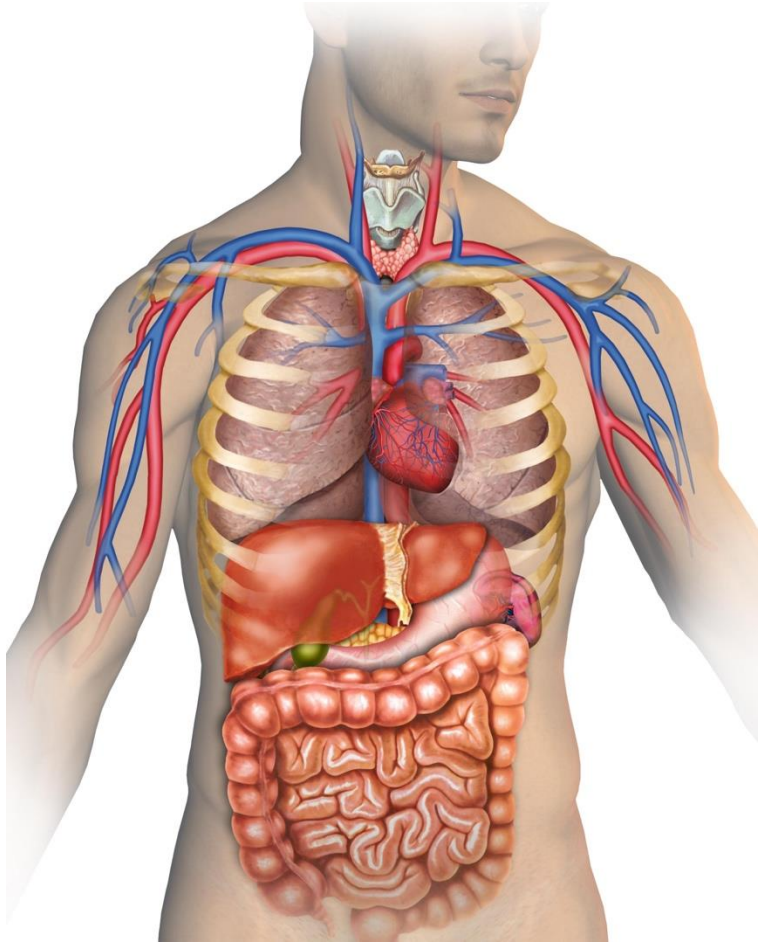

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CDC Management - ACIP Secretariat

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- Executive Secretary (Office of the Director/NCIRD)
  - Assures meetings follow guidelines, approves meeting agendas, guides development/revision of procedures, charter, and other documents
  - Provides briefing to the CDC Director
- Asst. to the Director for Immunization Policy, NCIRD
  - Leads CDC management of ACIP; WG coordination
  - Facilitates linkages with liaison organizations and international counterparts
- ACIP Committee Management Specialists
  - Ensure program compliance with FACA rules
  - Provides administrative and logistic support

CDC Management

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- ACIP Steering Committee
- CDC Federal Advisory Committee Management Branch, MASO*
  - Provides FACA support and liaison with DHHS
- CDC Office of General Counsel
  - Advice on legal questions (e.g., potential conflicts of interest; VFC program compliance)
- NCIRD/OD: funding for ACIP operations

* Management Analysis and Services Office, CDC

ACIP Steering Committee Responsibilities

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- 14 members from CDC and FDA
  - ACIP Chair & Vice–Chair
- Prepare meeting agenda 3 times a year
- Recommend to Secretary, DHHS nominees for ACIP membership
- Review and make recommendations for ACIP processes
  - economic analyses
  - EB recommendations
  - consideration of immunization safety
  - update of recommendations

Other Activities of ACIP Steering Committee

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- Refine policies and procedures, including those related to conflicts of interest
- Forum for considering how to prioritize development of new recommendations
- Consider requests for new liaison organizations
- Deal with structure, function and activities of Work Groups

Key Documents

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- ACIP Charter
  - Renewed by DHHS every 2 yrs: details purpose, structure, function of ACIP, governmental authority over the Committee; frequency of meetings, annual costs, required reports; termination of committee if Charter not maintained.
- ACIP Policies and Procedures
- Guidelines for Work Groups
  - Describe WG purpose, composition, approach to potential conflicts of interest
  - Continuously updated
  - Membership list of Work Groups
  - Calendar of ACIP activities

Background – FACA

- Federal Advisory Committee Act (FACA)
  - enacted by Public Law 92–463 on October 6, 1972
- Mechanism to seek advice and recommendations of US citizens in Federal Government's decision- making process
  - Provide relevant, objective advice
  - Meetings open to public; all committee documents available for public inspection
- ACIP designated as FACA committee in 1972

Functional Anatomy of the
U.S. Advisory Committee on Immunization Practices

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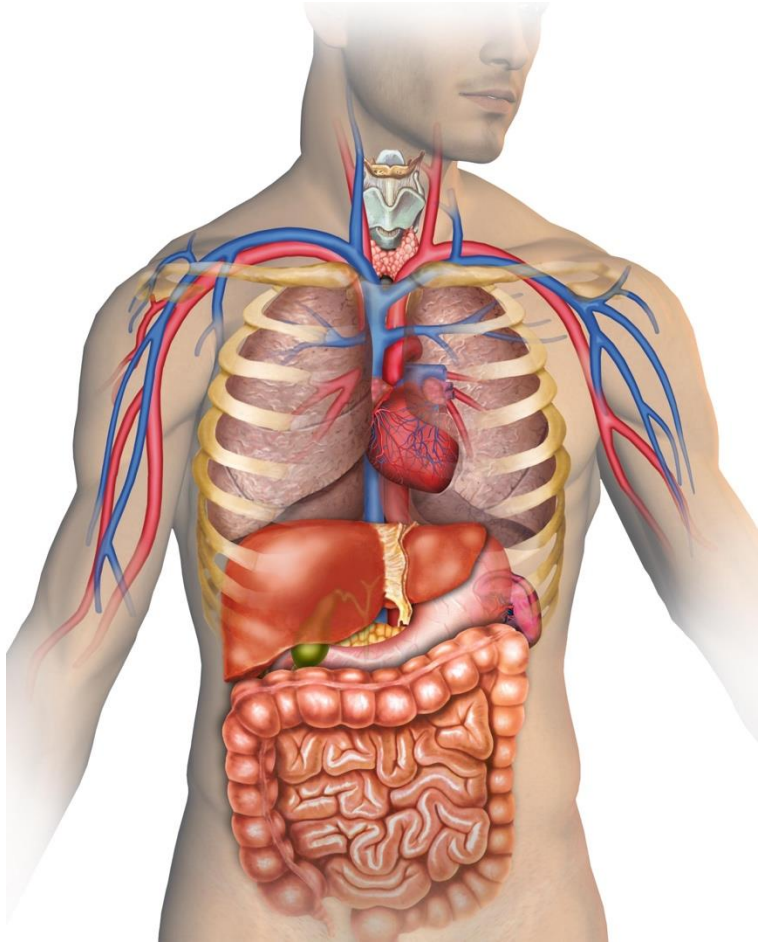

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Routine Meetings

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- 3 meetings annually
  - February, June, and October
  - Occasional ad hoc meeting
    - e.g. H1N1 response
- Agenda items
  - Topics solicited from ACIP members, liaisons, CDC staff and others using standard format
  - Finalized by ACIP Steering Committee
- Follow FACA* rules and procedures
  - meetings must be open to the public
  - allow time for public comment

* Federal Advisory Committee Act, 1972 (Public Law 92-463)

Upcoming meetings

2025

- June 25-26
  - Final ACIP June 25-26, 2025 Meeting Agenda (posted 06-24-2025) PDF
  - Draft ACIP June 25-26, 2025 Meeting Agenda (posted 06-23-2025) PDF
  - Draft ACIP June 25-26, 2025 Meeting Agenda (posted 06-18-2025) PDF
  - Meeting Materials
  - YouTube Live Stream Link 6-25-2025
  - YouTube Live Stream Link 6-26-2025
- August/September (dates TBD)
- October 22-23

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https://www.cdc.gov/acip/meetings/index.html

Reporting of ACIP

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- Follow FACA* rules and procedures
    - publish meeting minutes within 90 days of every meeting
- Agendas, presentations and minutes posted and regularly updated on ACIP website
- Recommendations become final once approved by CDC Director and published in MMWR

* Federal Advisory Committee Act, 1972 (Public Law 92-463)

ACIP agenda

as posted 1 week prior to June 25/26, 2025, meeting

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Draft Agenda

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
Centers for Disease Control and Prevention
Atlanta, Georgia 30329

Wednesday, June 25, 2025

10:00	**Welcome and Roll Call**	Dr. Mina Zadeh (ACIP Executive Secretary, CDC)
10:20	**Update on Work Groups**	TBD
11:00	**COVID-19 Vaccines**	
	Introduction	TBD
	COVID-19 epidemiology	Dr. Adam MacNeil (CDC/NCIRD)
	COVID-19 vaccine effectiveness update	Dr. Adam MacNeil (CDC/NCIRD)
	COVID-19 safety update	TBD
	COVID-19 vaccine coverage and implementation	Dr. Georgina Peacock (CDC/NCIRD)
	Evidence to recommendations (partial)	Dr. Adam MacNeil (CDC/NCIRD)
1:00	***Lunch***	
1:30	**Agency Updates**	*CDC, CMS, FDA, HRSA, IHS, NIH*
2:00	**RSV Vaccines- Maternal/Pediatric**	
	Introduction	TBD
	Updates on uptake of maternal vaccine and nirsevimab	Dr. Georgina Peacock (CDC/NCIRD)
	Updates on the impact and epidemiology of maternal vaccine and nirsevimab	Dr. Adam MacNeil (CDC/NCIRD)
	Updates on the effectiveness of maternal vaccine and nirsevimab	Dr. Adam MacNeil (CDC/NCIRD)
	Updates on safety of maternal vaccine and nirsevimab	TBD
	Updates and summary of the Evidence to Recommendation Framework for clesrovimab	Dr. Adam MacNeil (CDC/NCIRD)
	Updates on clinical considerations for clesrovimab	Dr. Adam MacNeil (CDC/NCIRD)
	Proposed Recommendations	Dr. Adam MacNeil (CDC/NCIRD)
	Updates to RSV vaccines VFC resolution	Dr. Georgina Peacock (CDC/NCIRD)
4:00	***Break***	
4:15	Public Comment	
5:00	**Votes**	
	RSV Vaccines- Maternal/Pediatric	Dr. Adam MacNeil (CDC/NCIRD)
	RSV Vaccines- VFC	Dr. Georgina Peacock (CDC/NCIRD)
5:30	**Adjourn**	

Thursday, June 26, 2025

8:00	**Welcome and Roll Call**	Dr. Mina Zadeh (ACIP Executive Secretary, CDC)
8:15	**Influenza Vaccines**	
	Introduction	TBD
	Flublok in older children and adolescents: immunogenicity and safety	Dr. Pedro Folegatti (Sanofi Pasteur)
	Estimates of influenza burden and burden averted through vaccination	Dr. Vivien Dugan (CDC/NCIRD)
	Proposed recommendations for 2025-26	Dr. Vivien Dugan (CDC/NCIRD)
	Presentation regarding thimerosal in vaccines	TBD
	Proposed recommendations regarding thimerosal containing influenza vaccine	TBD
10:15	***Break***	
10:30	**Chikungunya Vaccines**	
	Introduction	TBD
	EtR (partial) for use of live attenuated and virus-like particle chikungunya vaccines in U.S territories	Dr. Lyle Peterson (CDC/NCEZID)
	Safety update on live attenuated chikungunya vaccine and use among older persons	Dr. Lyle Peterson (CDC/NCEZID)
10:45	**Anthrax Vaccine**	Dr. Brenden Jackson (CDC/NCEZID)
10:50	**MMRV Vaccine**	
	Presentation on MMRV vaccine in children under under 4 years of age	TBD
	Proposed recommendations regarding MMRV in children under 4 years of age	TBD
11:20	***Break***	
11:30	Public Comment	
12:15	***Break***	
12:30	**Votes**	
	Influenza Vaccines	Dr. Vivien Dugan (CDC/NCIRD)
	Thimerosal containing influenza vaccine recommendations	TBD
1:00	**Adjourn**	

ACIP Meeting Website

https://www.cdc.gov/acip/meetings/index.html

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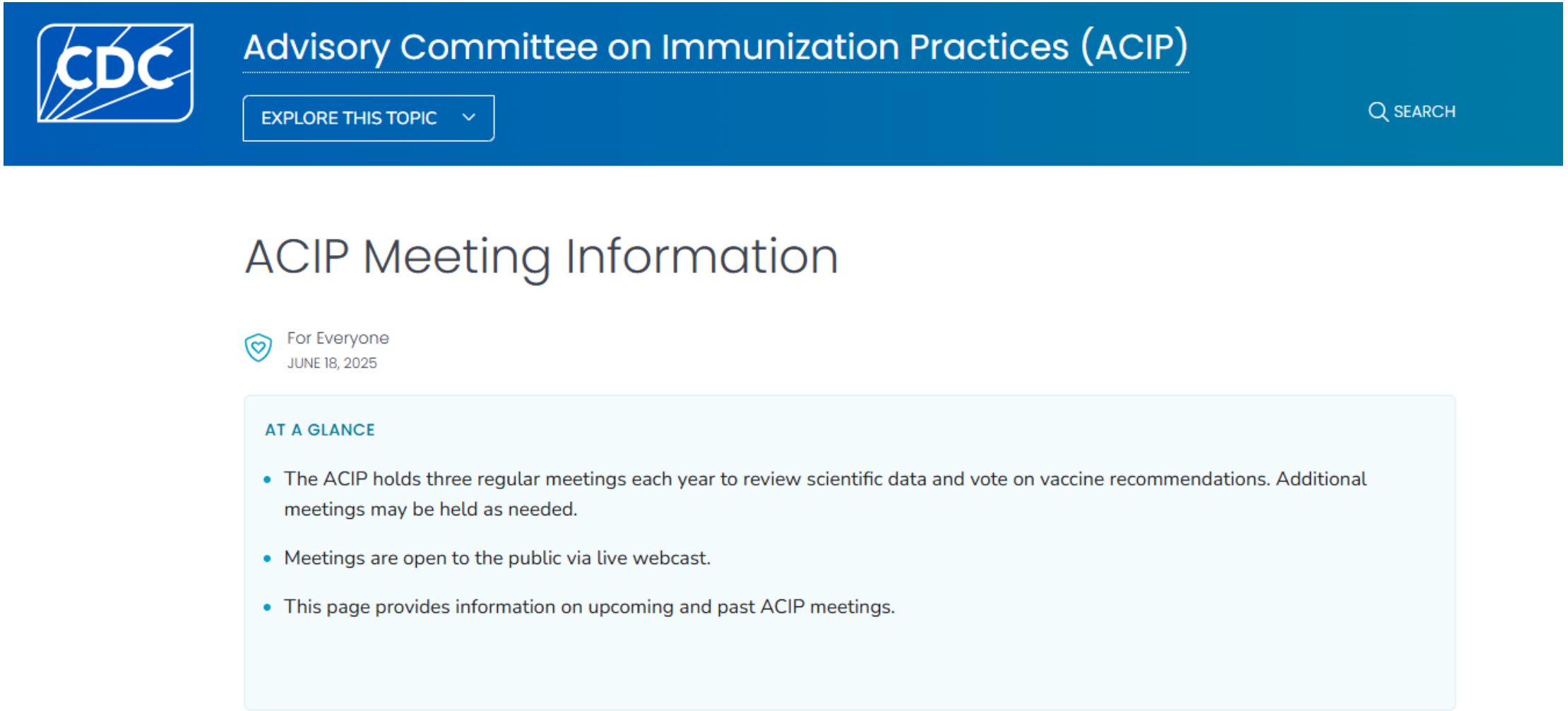

Conclusions

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- Routine immunization provides a tremendous benefit to infants, children, adolescents, adults and to society
- Immunization is a shared public / private responsibility
- The ACIP was a well functioning, well respected FACA committee
- Many challenges face the newly configured ACIP in terms of legitimacy of process, temperament, sidestepping of the established evidence-to-recommendation framework, and conflicts of interest.

What Next
in “Gold-Standard” Vaccine Recommendations?

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- Vaccine Integrity Project
    - CIDRAP: Center for Infectious Disease Research and Policy
- Immunize.org
- American Academy of Pediatrics

TO BE NAMED

No single organization can carry it alone. It requires collaboration, coordination, communication and commitment to develop and communicate clinical vaccine guidance grounded in credible science.

CDC ADVISORY COMMITTEE ON IMMUNIZATION PRACTCES (ACIP)

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CIDRAP

VACCINE INTEGRITY PROJECT (VIP)

FOCUS: Fall respiratory vaccine season schedule.

ensuring that vaccine use in the US remains anchored in the best available science (safety, efficacy, epidemiology, and feasibility), focused on safeguarding individuals, families, and communities from vaccine-preventable diseases.

PROCESS: Panel of ___ subject matter experts

National Adult and Influenza Immunization Summit

NAIIS SUMMIT COUNCIL

FOCUS: Adult Immunization Schedule

independent, multidisciplinary body tasked with evaluating scientific evidence and formulating evidence-based best practice in immunization, and providing best practice guidance to health care professionals and the public.

PROCESS: Panel of up to 11 members who are independent experts in evidence-based decision-making and immunization clinical practice.

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

AMERICAN ACADEMY OF PEDIATRICS (Committee in Infectious Diseases)

FOCUS: Pediatric Immunization Schedule

develops evidence-based vaccine policy and guidance to protect children and adolescents from preventable diseases. It monitors vaccine safety, promotes immunization access and equity, and supports practitioners in addressing vaccine hesitancy and emerging infectious threats.

PROCESS: Panel of up to 15 members who are experts in evidence-based decision-making and immunization clinical practice.

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https://www.cidrap.umn.edu/vaccine-integrity-project/immunization-info

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From Data to Decisions: The Evidence Base for 2025 Fall/Winter Immunizations

Summary of Preliminary Findings

Key Findings

- Respiratory viruses, including influenza, COVID-19, and respiratory syncytial virus (RSV) pose a significant threat to the health of all populations studied in this review.
- This initial systematic review and meta-analysis reviewed the evidence for children, immunocompromised adults, and pregnancy, and searched for more than 15 severe adverse events of special interest.
- Immunizations are an effective tool to reduce health risks for all populations from flu, COVID, and RSV, and have a strong safety profile. The studies reviewed since the 2023/2024 Advisory Committee on Immunization Practices (ACIP) meeting found no significantly elevated safety risks from US-licensed immunizations for these conditions.

AP

WORLD U.S. POLITICS SPORTS ENTERTAINMENT BUSINESS SCIENCE FACT CHECK ODDITIES MORE

LIVE: Trump -Zelenskyy meeting Air Canada strike Hurricane tracker HD stock MSNBC

HEALTH

US pediatricians' new COVID-19 shot recommendations differ from CDC advice

A pharmacist holds a Pfizer and BioNTech COVID-19 vaccine shot on Thursday, April 24, 2025, in Portland, Ore. (AP Photo/Jenny Kane, File)

BY MIKE STOBBE
Updated 11:09 PM CDT, August 18, 2025

Share

NEW YORK (AP) — For the first time in 30 years, the American Academy of Pediatrics is substantially diverging from U.S. government vaccine recommendations.

The group's new COVID-19 recommendations — released Tuesday — come amid a tumultuous year for public health, as vaccine skeptics have come into power in the new Trump administration and government guidance has become increasingly confusing.

This isn't going to help, acknowledged Dr. James Campbell, vice chair of the AAP infectious disease committee.

"It is going to be somewhat confusing. But our opinion is we need to make the right choices for children to protect them," he added.

The AAP is strongly recommending COVID-19 shots for children ages 6 months to 2 years. Shots also are advised for older children if parents want their kids vaccinated, the AAP said.

That differs from guidance established under U.S. Health Secretary Robert F. Kennedy Jr., which doesn't recommend the shots for healthy children of any age but says kids may get the shots in consultation with physicians.

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How do CIDRAP-AAP-AAFP-ACOG recommendations differ from ACIP?

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- **To be determined** - but there are past examples where they did not always align exactly in the past. AAP was the only organization making Synagis recommendations for many years, since ACIP declined to assume responsibility until recently.
- **CIDRAP/AAP/AAFP/ACOG** recommendations are based on scientific evidence that has been thoroughly review by experts in immunology, epidemiology, clinical trials, and the logistics of implementing vaccination programs in clinical and public health practice.
    - The ideologically reconstituted ACIP has abandoned evidence and thoughtful review by experts and instead issued recommendations based on misinterpretation of studies presented by anti-vaccine advocates.

As a Wisconsin clinician, is there is a problem if I follow AAP guidelines when they differ from ACIP guidelines for example?

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- From a legal & prescribing standpoint NO, but theoretically could have insurance/financial coverage issues for some insurers & potentially VFC? That's up to the state or the insurer.
- There is a moral obligation to provide patients with medical care that is most likely to prevent suffering and premature death. There is a legal responsibility to provide medical care that follows the standard of care. The recommendations of the ideologically reconstituted ACIP that are not evidence based are not the standard of care. The evidenced-based recommendations of the medical specialty societies are standard of care.

Can I vaccinate pregnant persons with COVID-19 vaccines despite the fact that there is no ACIP recommendation? Will it be covered by insurance? Will I be covered for liability if there is an adverse reaction?

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- YES, vaccine is licensed and pregnancy still listed on CDCs own site as a risk factor
- There is a moral obligation to provide patients with medical care that is most likely to prevent suffering and premature death. There is a legal responsibility to provide medical care that follows the standard of care. The recommendations of the ideologically reconstituted ACIP that are not evidence based are not the standard of care. The evidenced-based recommendations of the medical specialty societies are standard of care

MEDPAGETODAY

Pediatrics > Vaccines

RFK Jr. Warns Docs of Liability if They Stray From CDC on Vaccines

— "Misleading," expert says

by Joyce Frieden, Washington Editor, MedPage Today

August 22, 2025 · 4 min read

The American Academy of Pediatrics' (AAP) recent pediatric COVID-19 vaccine recommendations, which differ from those of the CDC, have raised concerns from HHS Secretary Robert F. Kennedy Jr., who responded with an oblique warning to any physicians who might follow the AAP's advice.

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As a patient in Wisconsin, can I still find a place to get all vaccines recommended by CIDRAP-AAP-AAFP-ACOG if they are not recommended by ACIP or if ACIP recommends against them?

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- The vaccines are FDA approved and can be prescribed by providers – both on license and off license. That's how medicine works once things are FDA approved! Insurer coverage is another story – but a non-scientific poll of regional insurers sure seems to indicate interest in providing coverage still since vaccines are cost effective prevention, after all!
- FDA approved vaccines will be available in the United States. Vaccines that should be approved FDA based on evidence, but are not available in the United States, will likely be available in Canada, Mexico, Europe, and many other places in the world. Importing and administering vaccines not approved by the FDA would be illegal even though providing these vaccines to patients would be standard of care and a moral obligation.

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https://www.ahip.org/news/articles/health-plans-continued-commitment-to-vaccine-access

Reference

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Questions?