



Advisory Commission on Childhood Vaccines (ACCV) Welcome and Introduction

130th ACCV Meeting

July 11, 2024

CDR Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs
Health Systems Bureau (HSB)

Vision: Healthy Communities, Healthy People



Meeting Logistics

- Please mute your lines at all times until you are called on for discussion
- When the Chair opens the meeting for discussion, please virtually raise your hand
- During the discussion period, the Chair will take questions first from ACCV voting members, then from ex officio members
- Please disable your video



Roll Call

ACCV members – state your first and last name

Ex officio – state your first and last name and affiliation



Welcome and Chair Report



Public Comment on Agenda



Approval of Minutes for March Meetings



130th ACCV Meeting Agenda (1)

- Welcome and Chair Report
- Public Comment on Agenda
- Approval of Meeting Minutes for March 7, 2023, and March 8, 2023
- Update on Health Resources and Services Administration (HRSA) VICP Activities
- Update from the Department of Justice (DOJ) Vaccine Litigation Office



128th ACCV Meeting Agenda (2)

- Updates from ACCV Ex Officio Members including:
 - Centers for Disease Control and Prevention (CDC)
 - National Institutes of Health (NIH)
 - Food and Drug Administration (FDA)
 - Office of Infectious Disease and HIV/AIDS Policy
- National Academy of Medicine, Engineering, and Sciences (NASEM)
 - Review of Relevant Literature Regarding Adverse Events Associated with Vaccines Committee



128th ACCV Meeting Agenda (3)

- Future Agenda Items & New Business
- Public Comment





National Vaccine Injury Compensation Program (VICP) Update

July 11, 2024

CDR Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs
Health Systems Bureau (HSB)

Vision: Healthy Communities, Healthy People



National Vaccine Injury Compensation Program

Purpose

The purpose of the VICP is to provide a no-fault alternative to the traditional tort system by providing compensation to people found to be injured by certain vaccines.

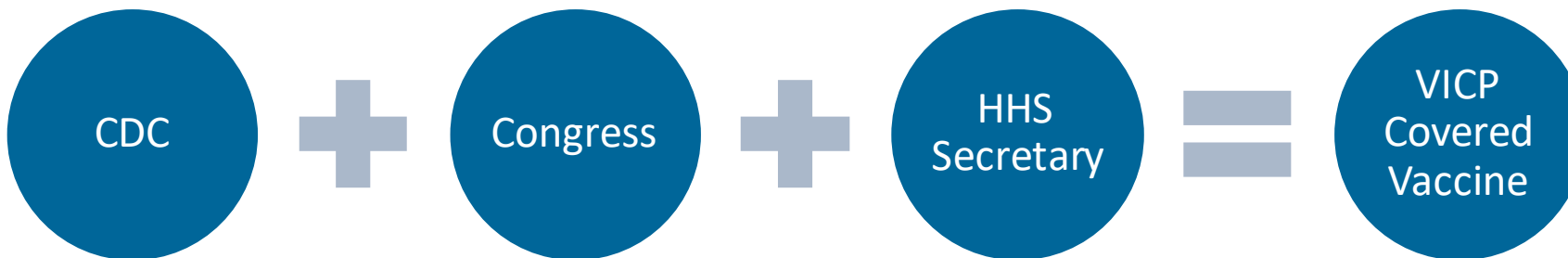
The VICP

- ensures an adequate supply of vaccines;
- stabilizes vaccine costs; and
- establishes and maintains an accessible and efficient forum for individuals found to be injured by certain vaccines.



Criteria to be a Covered Vaccine in VICP

- The Centers for Disease Control and Prevention (CDC) must recommend the vaccine for routine administration to children or pregnant people;
- Congress must approve an excise tax on the vaccine, which funds the administration of the VICP; and
- The Secretary of Health and Human Services (HHS) must add the vaccine by regulation.



Vaccine Injury Table

- The Vaccine Injury Table lists injuries and/or conditions associated with covered vaccines.
- If the first symptom of these injuries and/or conditions occurs within the specified time periods and the injury meets the definition included in the Table, it is presumed that the vaccine caused the injury or condition unless another cause is proven.
- If an injury and/or condition is not on the Table, or if the injury and/or condition does not meet the Table requirements, the petitioner must prove that the vaccine caused the injury and/or condition.



Vaccine Injury Table Provisions

Vaccine Injury Table - Sample

VII. Vaccines containing polio inactivated virus (e.g., IPV)	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.

Qualification and aids to interpretation

Anaphylaxis. Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without sequela. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.



ACCV Guiding Principles for Recommending Changes to the Vaccine Injury Table (ACCV, 2006)

- The Table should be **scientifically and medically credible**, and
- Where there is credible **scientific and medical evidence**, both to support and to reject a proposed change (addition or deletion) to the Table, the change should be made to the benefit of petitioners (whenever possible)
- To the extent that the Institute of Medicine (i.e., National Academy of Medicine) has studied the possible association between a vaccine and an adverse effect, the conclusions should be considered by the ACCV and deemed credible
 - However, those conclusions should not limit the deliberations of the ACCV
 - *Review of Relevant Literature Regarding Adverse Events Associated with Vaccines* underway



VICP July 11, 2024 Updates



VICP Update

Number of VICP Petitions Filed as of June 1, 2024

Fiscal Year (FY)	Adult	Child*	Total
FY 2020	1,084	108	1,192
FY 2021	1,931	126	2,057
FY 2022	898	131	1,029
FY 2023	1,019	148	1,167
FY 2024	698	85	783

*Child defined as a person under 18 years of age.



VICP Update

Number of VICP Petitions Filed for Influenza Vaccines as of June 1, 2024

Fiscal Year (FY)	Adult	Child*	Total
FY 2020	859	22	881
FY 2021	1,536	17	1,553
FY 2022	700	16	716
FY 2023	760	14	774
FY 2024	540	8	548

*Child defined as a person under 18 years of age.



VICP Update

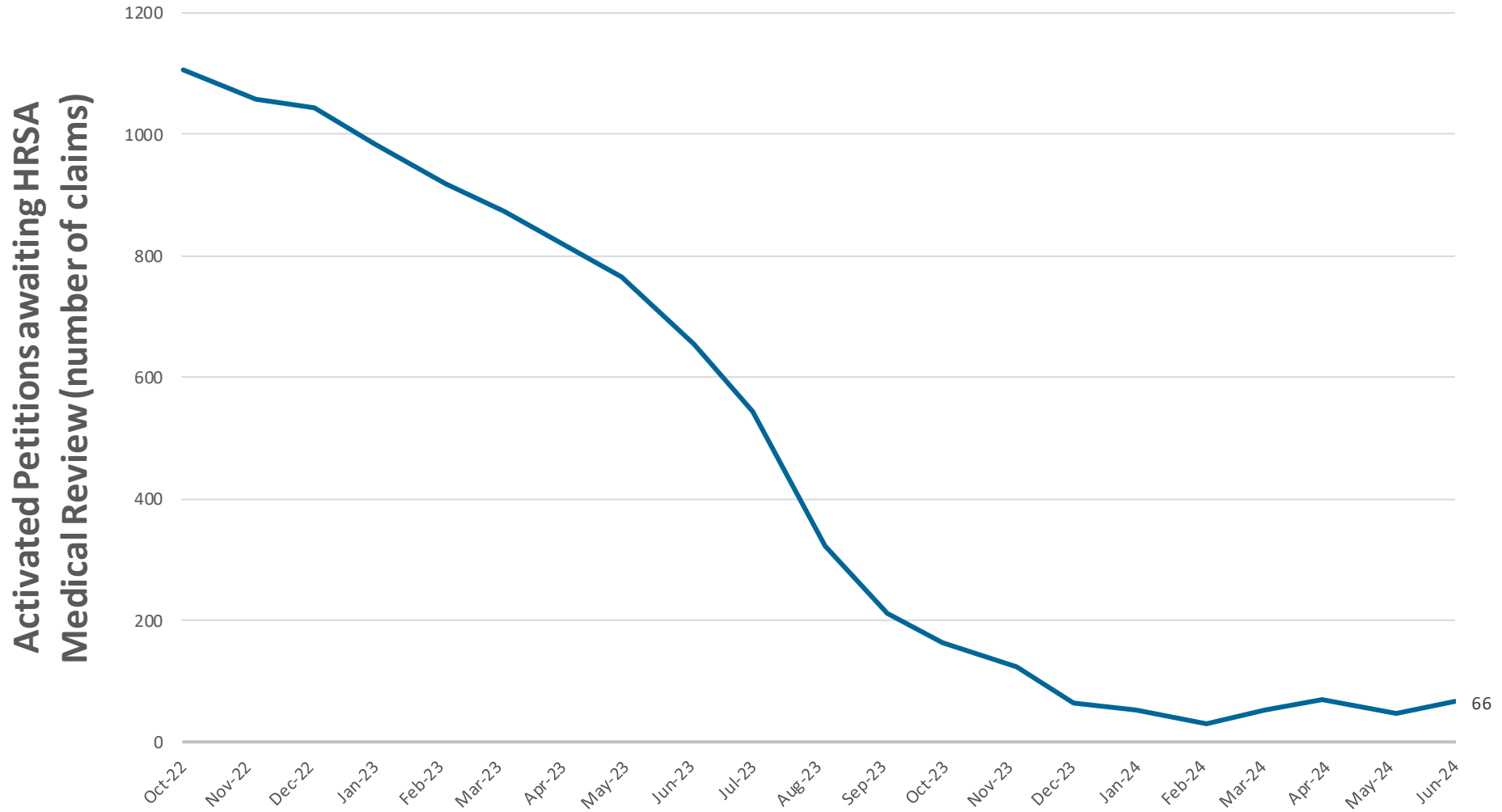
Number of VICP Petitions Awaiting Activation as of June 1, 2024

Fiscal Year (FY)	Adult	Child	Petitions Awaiting Activation
FY 2020	1	1	2
FY 2021	7	0	7
FY 2022	27	12	39
FY 2023	110	43	153
FY 2024	336	50	386
Total	481	106	587



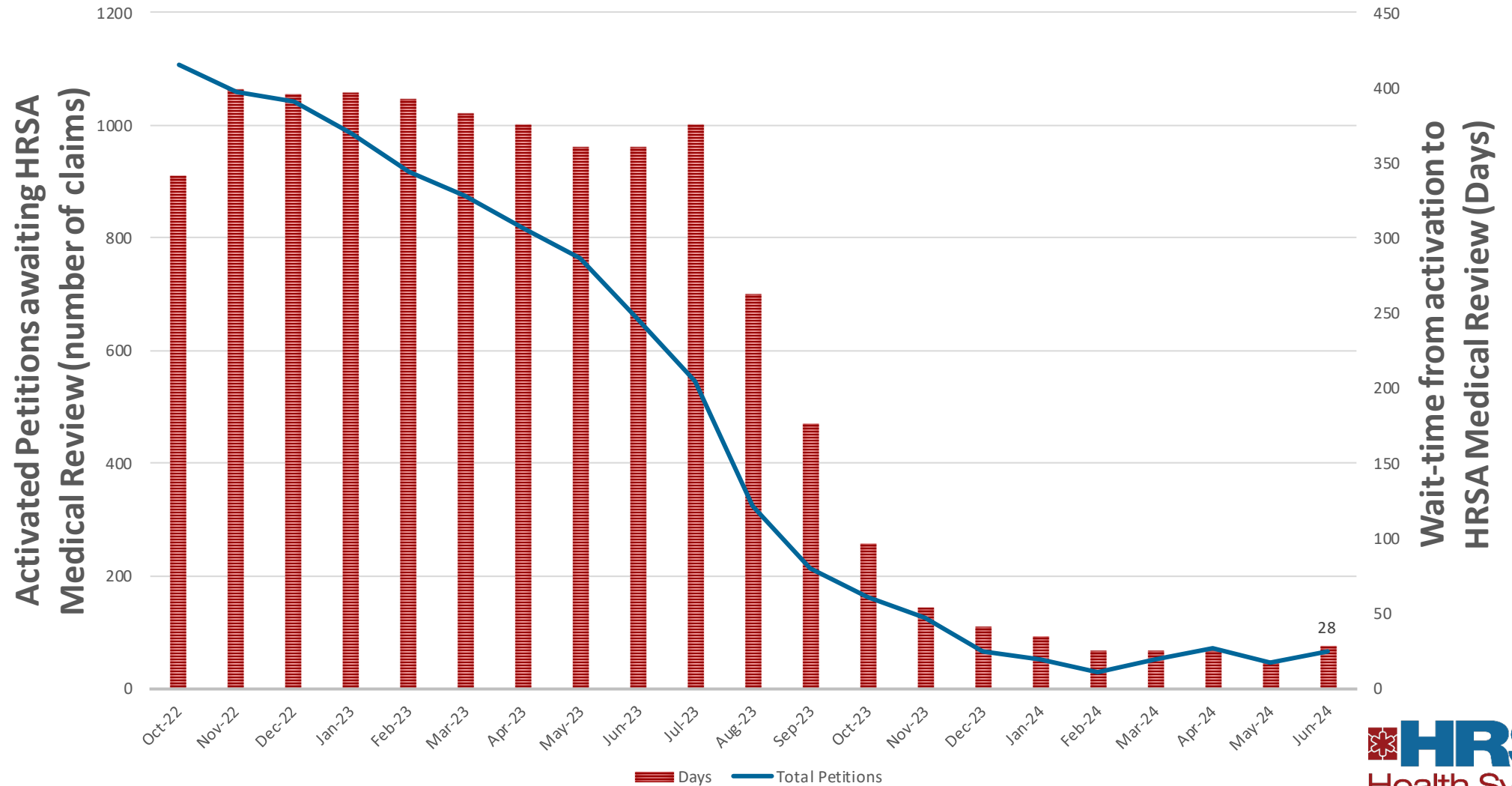
VICP Update

Number of Activated Petitions Awaiting HRSA Medical Review



VICP Update

HRSA Medical Review (FY 2023 – Present)



VICP Update

Award Amounts Paid as of June 1, 2024

Fiscal Year (FY)	Petitioners' Award	Attorneys' Fees & Costs	Total Outlays*
FY 2020	\$186,860,678	\$31,030,110	\$217,890,787
FY 2021	\$208,258,401	\$36,114,069	\$244,372,470
FY 2022	\$195,693,890	\$34,190,913	\$229,884,802
FY 2023	\$123,810,693	\$50,074,827	\$173,885,521
FY 2024	\$118,643,620	\$36,238,206	\$158,161,052

*Outlays are rounded, so numbers may not add exact



VICP Update

Vaccine Injury Compensation Trust Fund

- Balance as of May 31, 2024
 - \$ 4,548,211,490
- Activity from October 1, 2023, to May 31, 2024
 - Interest on Investments: \$101,551,556
 - Excise Tax Revenue: \$174,704,000
 - Total Income: \$276,255,556
 - Interest as a Percentage of Total Income: 37%

Source: U.S. Treasury, Bureau of the Fiscal Service



VICP Update

Summary

- The National Academies of Sciences, Engineering, and Medicine's *Evidence Review of the Adverse Effects of COVID-19 Vaccination and Intramuscular Vaccine Administration* published
 - Sent to ACCV members in April 2024
- Approximately 89% of petitions were filed for adults over the last five fiscal years
 - 72% that are influenza vaccines over this period
- Timeliness for HRSA medical review has been significantly reduced



VICP Update

Seeking Nominations for All ACCV Positions

- Three members who are health professionals who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians;
- Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death; and
- Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

Send nominations to ACCV@hrsa.gov.



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