



Advisory Commission on Childhood Vaccines (ACCV) Welcome and Introduction

128th ACCV Meeting

March 7, 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 first and last name, and affiliation



Welcome and Chair Report



Public Comment on Agenda



Approval of Minutes for September Meetings



128th ACCV Meeting Agenda (1)

- Welcome and Chair Report
- Public Comment on Agenda
- Approval of Meeting Minutes for September 7, 2023, and September 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
- Future Agenda Items & New Business
- Public Comment





National Vaccine Injury Compensation Program (VICP) Update

128th ACCV Meeting

March 7, 2024

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

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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.

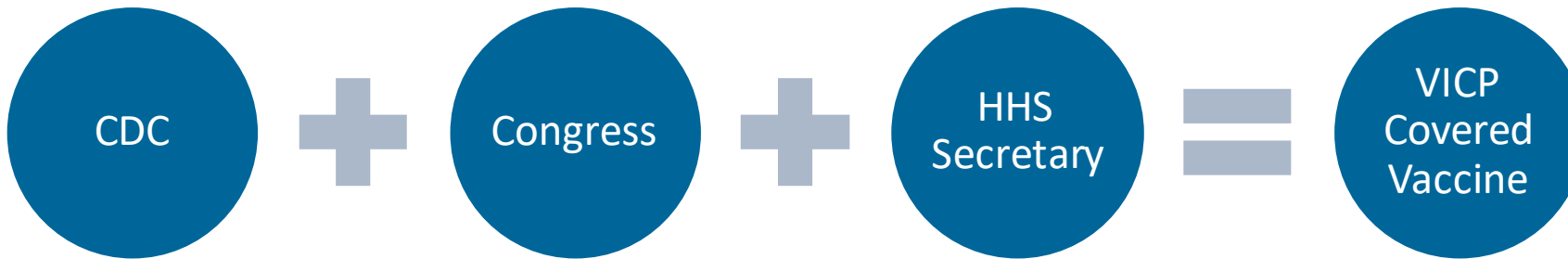
The VICP

- 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.

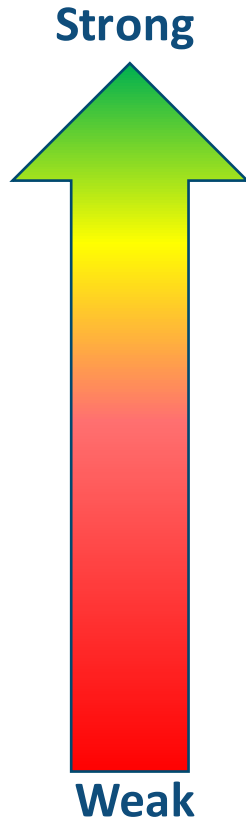


ACCV Guiding Principles for Recommending Changes to the Vaccine Injury Table (ACCV, 2006)

- 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



ACCV Strength of Data Sources (ACCV, 2006)



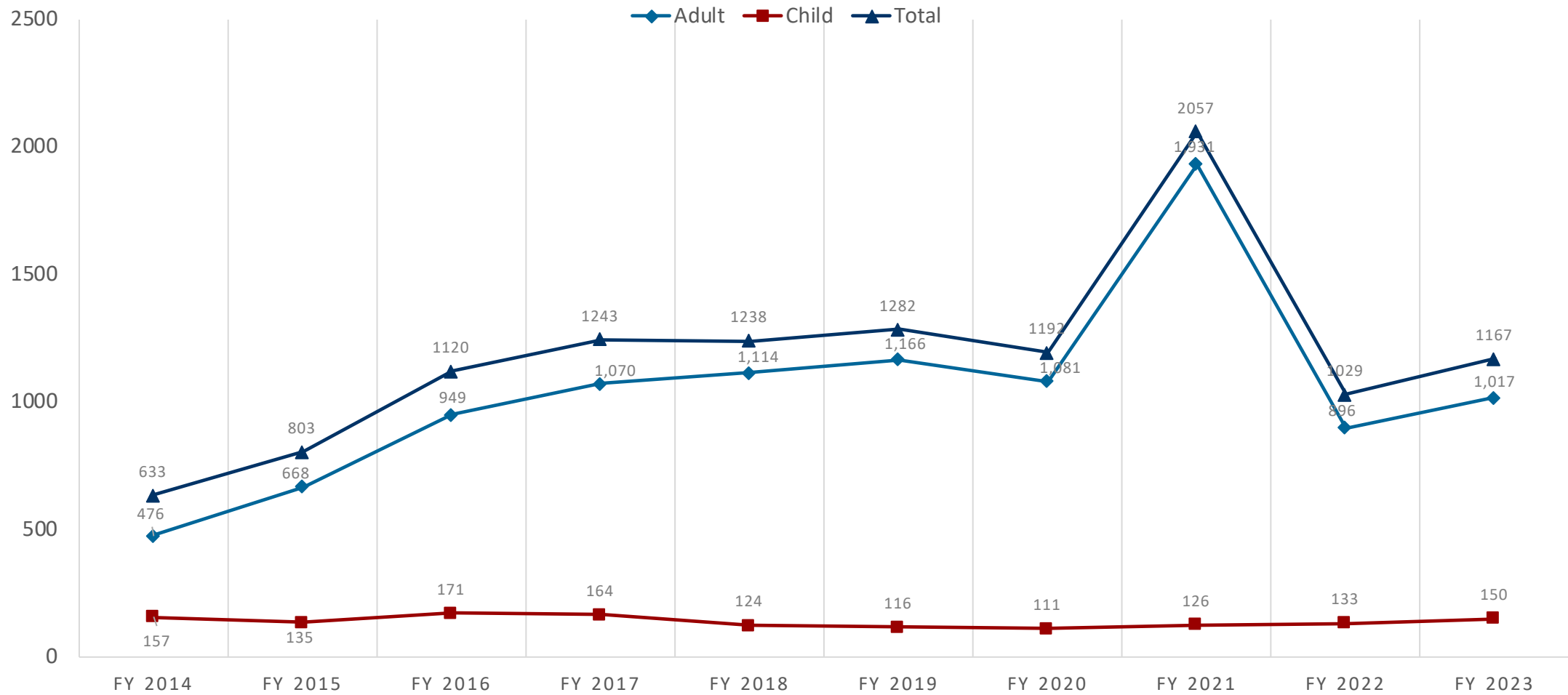
- Clinical laboratory data
- Challenge/re-challenge/de-challenge data involving non-relapsing symptoms or diseases
- Controlled clinical trials
- Controlled observational studies such as cohort and case control studies
- Uncontrolled observational studies such as ecological studies
- Case series
- Data from passive surveillance systems
- Case reports
- Editorial articles on scientific presentations
- Non-peer reviewed publications

VICP March 7th, 2024 Updates



VICP Update

VICP Petitions Filed by/for Adult vs. Child, Fiscal Year 2014 - FY 2023



VICP Update

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

| Fiscal Year (FY) | Adult | Child* | Total |
|------------------|-------|--------|-------|
| FY 2020 | 858 | 23 | 881 |
| FY 2021 | 1,536 | 17 | 1,553 |
| FY 2022 | 699 | 17 | 716 |
| FY 2023 | 759 | 14 | 773 |
| FY 2024 | 352 | 6 | 358 |

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



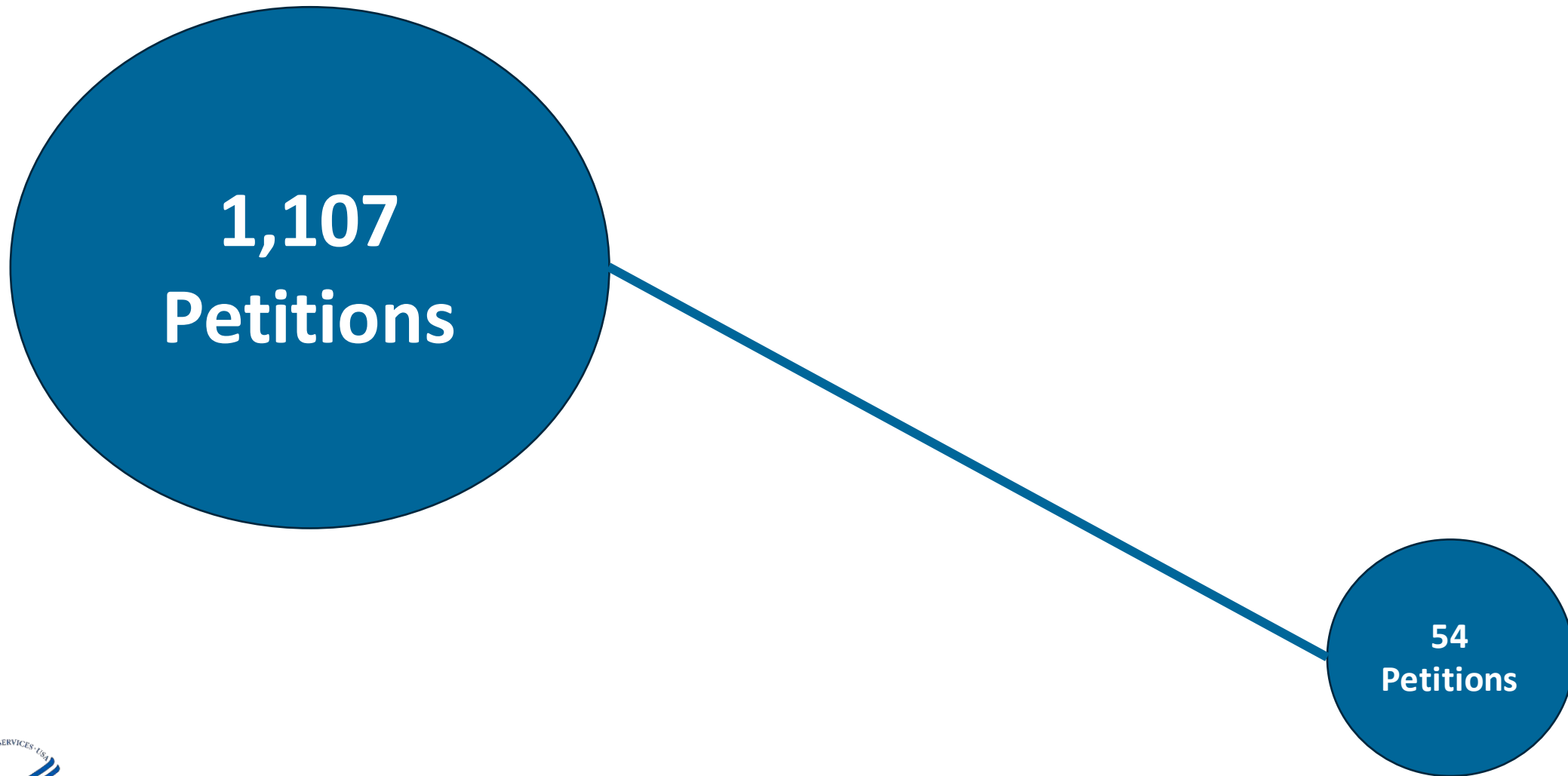
VICP Update

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

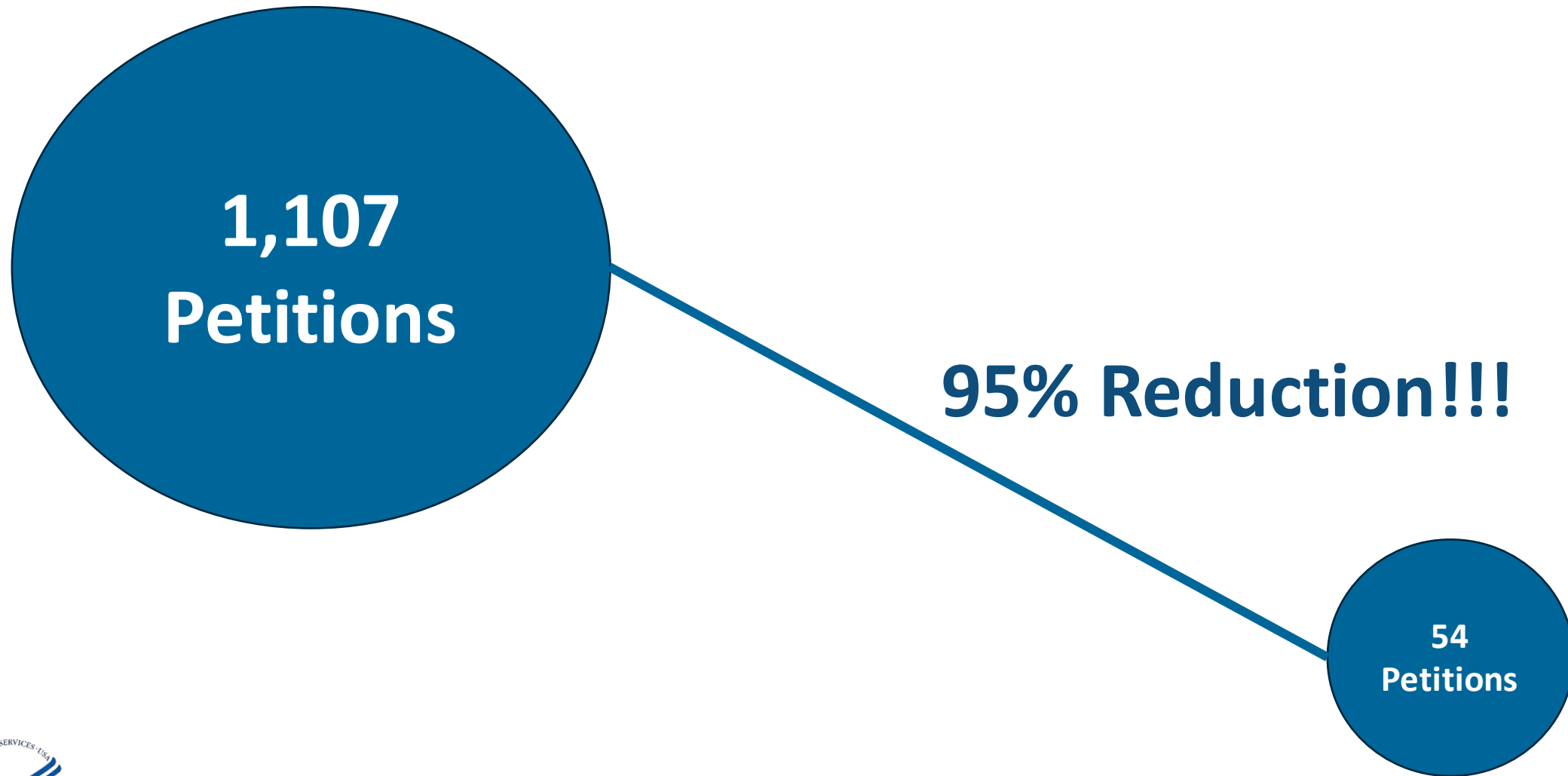
| Fiscal Year (FY) | Adult | Child | Petitions Awaiting Activation |
|------------------|-------|-------|-------------------------------|
| FY 2020 | 1 | 1 | 2 |
| FY 2021 | 13 | 2 | 15 |
| FY 2022 | 38 | 16 | 54 |
| FY 2023 | 167 | 58 | 225 |
| FY 2024 | 253 | 36 | 289 |
| Total | 472 | 113 | 585 |



Number of Activated Petitions Awaiting HRSA Medical Review, October 1, 2022 – March 1, 2024



Number of Activated Petitions Awaiting HRSA Medical Review, October 1, 2022 – March 1, 2024



VICP Update

Award Amounts Paid as of March 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 | \$36,192,807 | \$244,451,209 |
| FY 2022 | \$195,693,890 | \$34,190,913 | \$229,884,802 |
| FY 2023 | \$123,810,693 | \$50,031,308 | \$173,842,002 |
| FY 2024 | \$68,065,462 | \$20,388,096 | \$68,085,850 |

*Outlays are rounded, so numbers may not add exact



VICP Update

Vaccine Injury Compensation Trust Fund

- Balance as of December 31, 2023
 - \$ 4,506,173,505
- Activity from October 1, 2023, to December 31, 2023
 - Interest on Investments: \$37,683,034
 - Excise Tax Revenue: \$70,518,000
 - Total Income: \$108,201,034
 - Interest as a Percentage of Total Income: 34%

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



VICP Update

Summary

- The National Academies of Sciences, Engineering, and Medicine's *Review of Relevant Literature Regarding Adverse Events Associated with Vaccines* expected to be completed by end of March 2024
- Approximately 91% of petitions were filed for adults over the last five fiscal years
- Over the last 5 fiscal years, about 51% of compensated cases are compensated via negotiated settlement
- Number of activated petitions awaiting 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.



VICP Update

Contact Information

Public Comment/Participation in Commission Meetings

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