



Overview of the National Vaccine Injury Compensation Program (VICP)

January 16, 2025

Vision: Healthy Communities, Healthy People



National Childhood Vaccine Injury Act (NCVIA) of 1986

- Signed into law by President Ronald Reagan in November 1986
- NCVIA included many regulations related to informed consent and adverse event reporting; mandated the establishment of:
 - Vaccine Adverse Event Reporting System (VAERS)
 - National Vaccine Program Office
 - ✓ National Vaccine Advisory Committee
 - National Vaccine Injury Compensation Program (VICP)
 - ✓ Advisory Commission on Childhood Vaccines (ACCV)

National Vaccine Injury Compensation Program (VICP)

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.

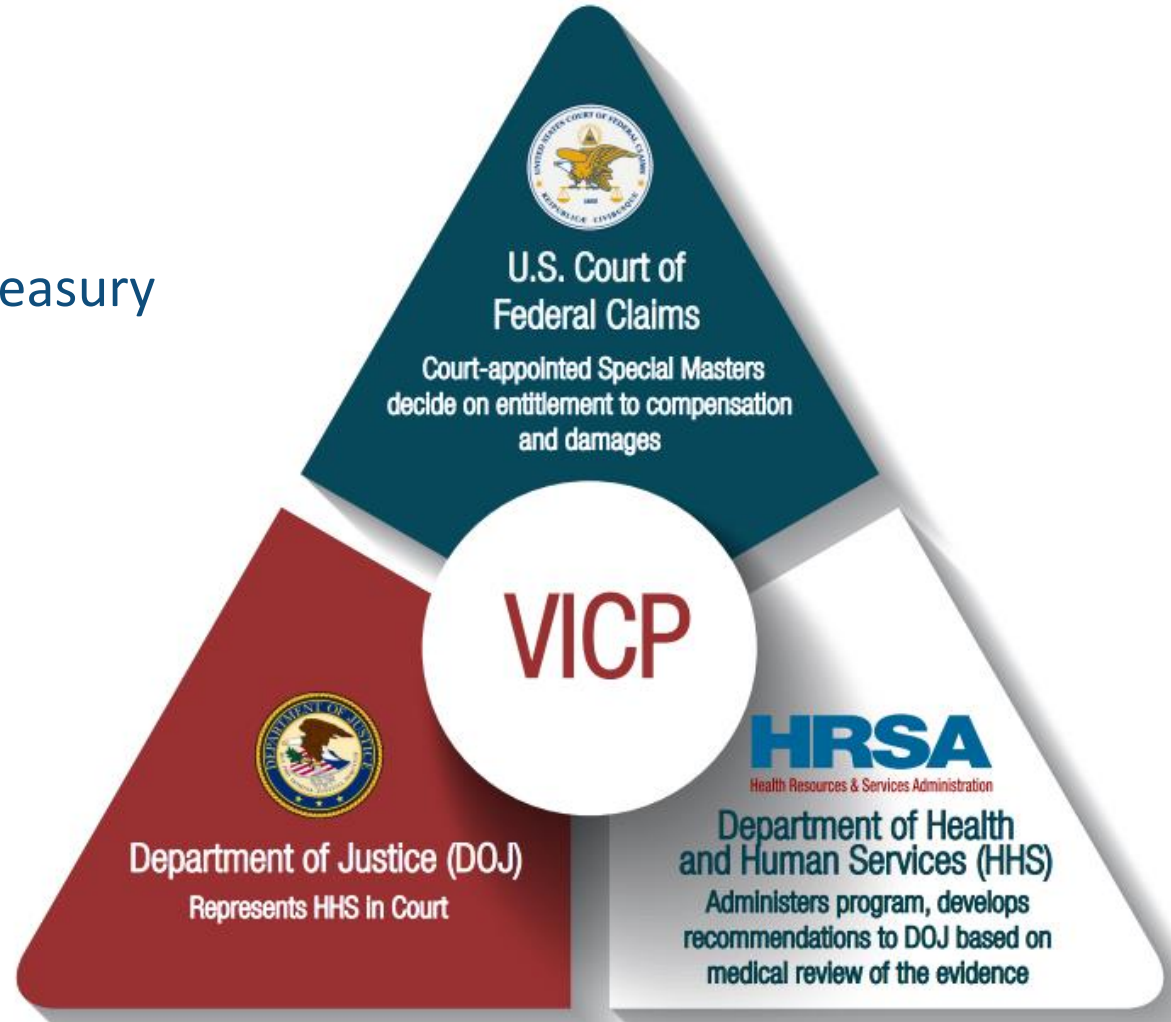
The VICP

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



VICP Roles

Department of Treasury



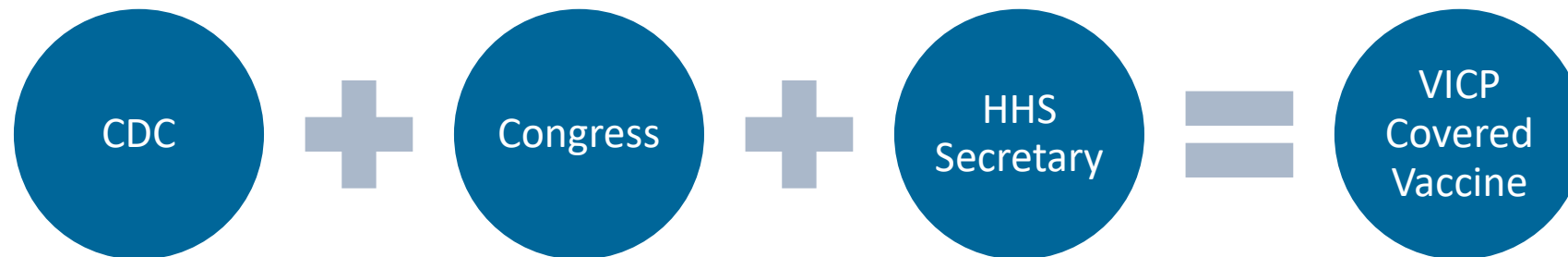
Vaccine Injury Compensation Trust Fund

- Vaccine Injury Compensation Trust Fund provides the funding
 - To compensate eligible petitions filed (mandatory funding)
 - To administer the Program (discretionary funding)
- Funded by a \$0.75 excise tax imposed on each dose of a vaccine, meaning each disease presented
- Internal Revenue Code language defines vaccine and specifies the specific categories of vaccine for taxation

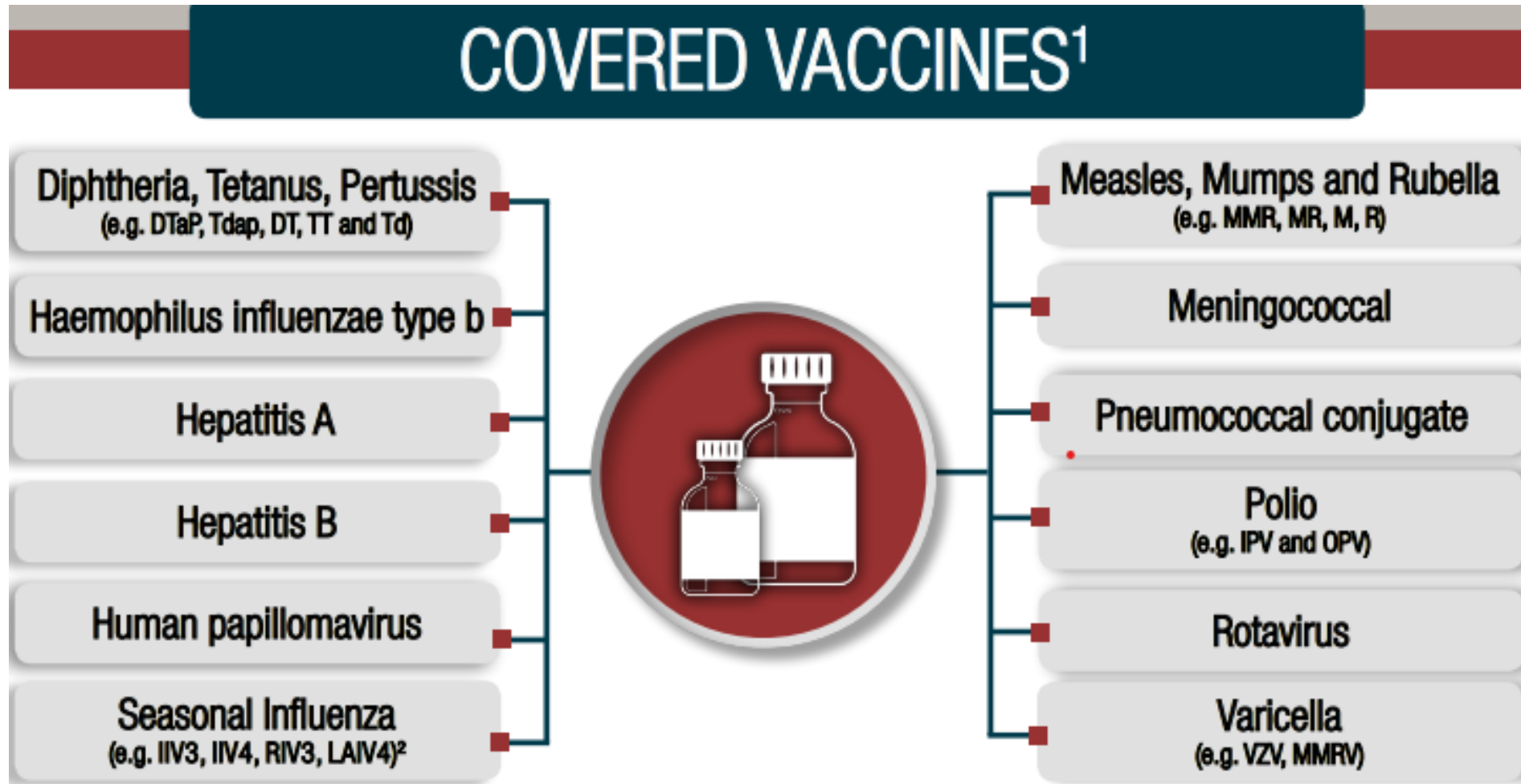


Criteria to be a Covered Vaccine in VICP

- 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
- HHS Secretary must add the vaccine by regulation.



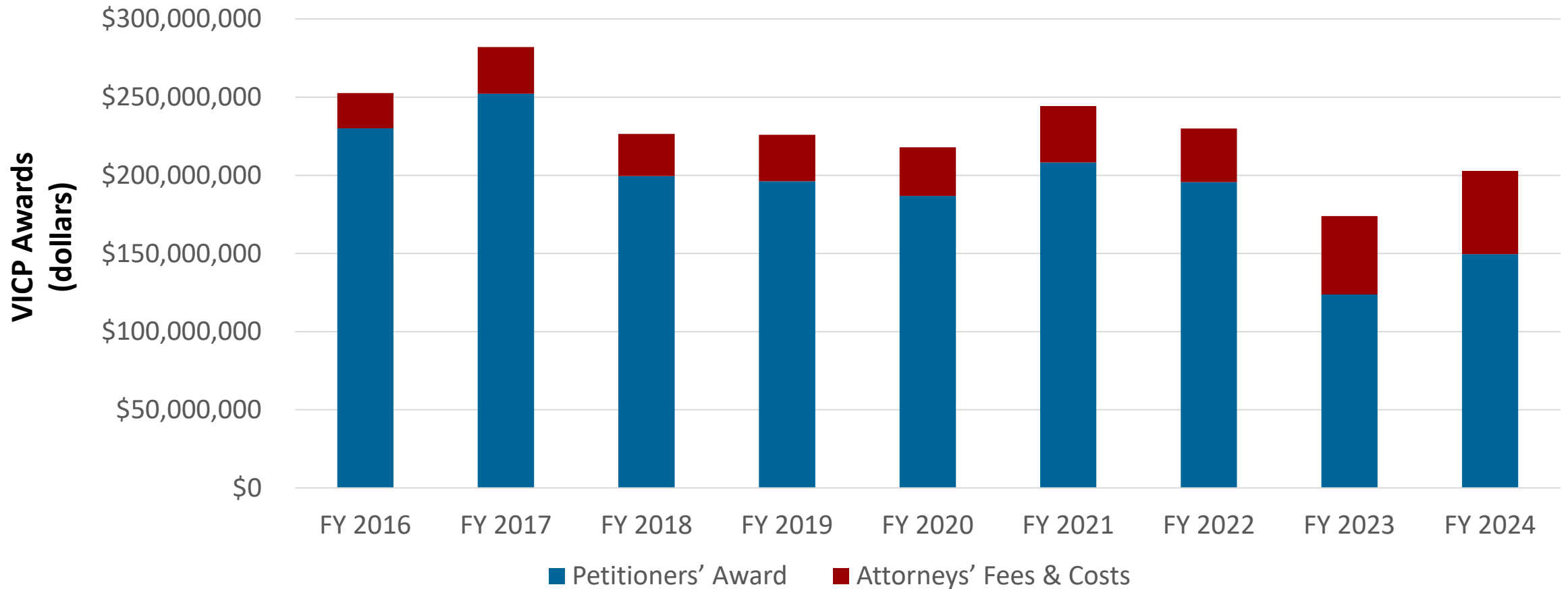
Covered Vaccines



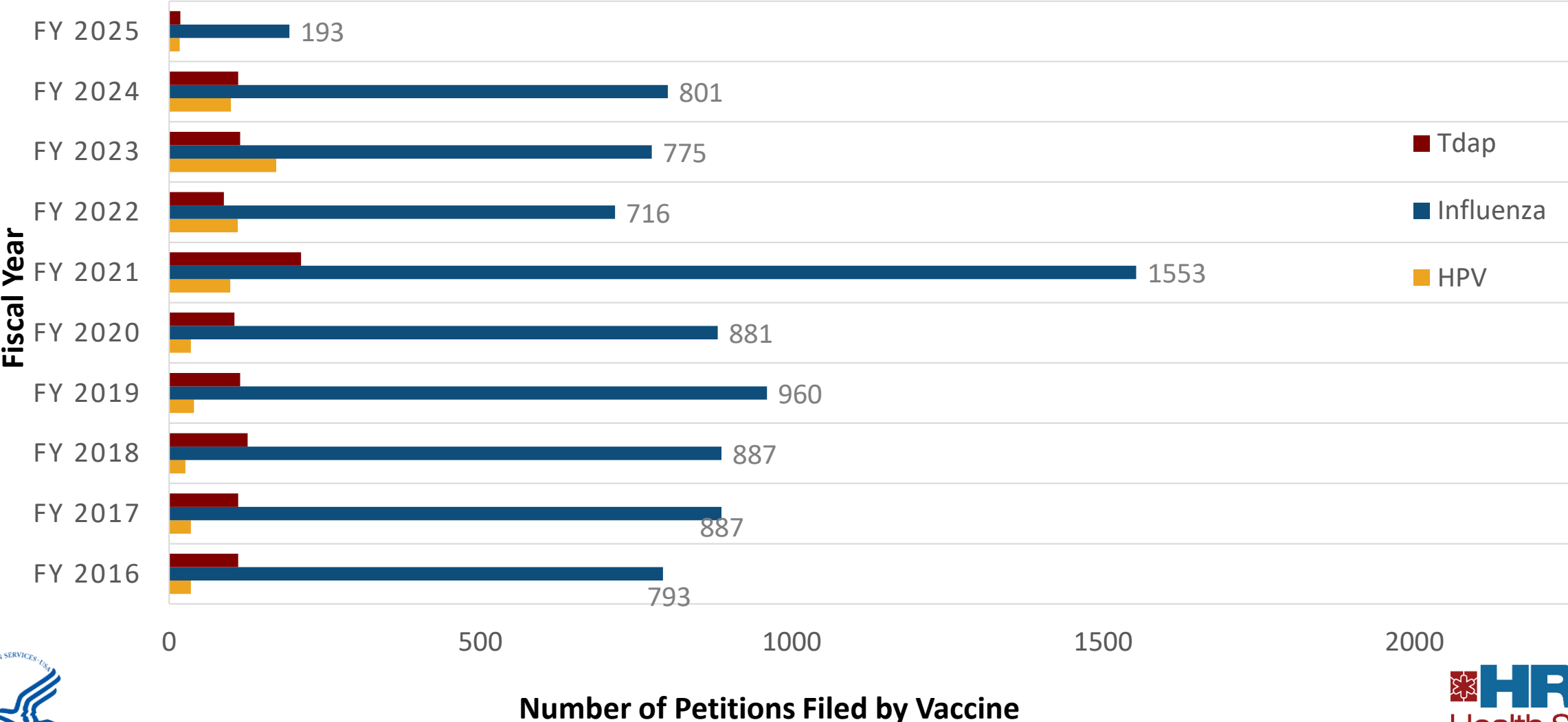
Types of Authorized Payments

- VICP petitions can be compensated for:
 - Medical expenses
 - Lost wages
 - Reasonable attorneys' fees
 - Pain and suffering (up to \$250,000)
 - Death benefit (\$250,000)

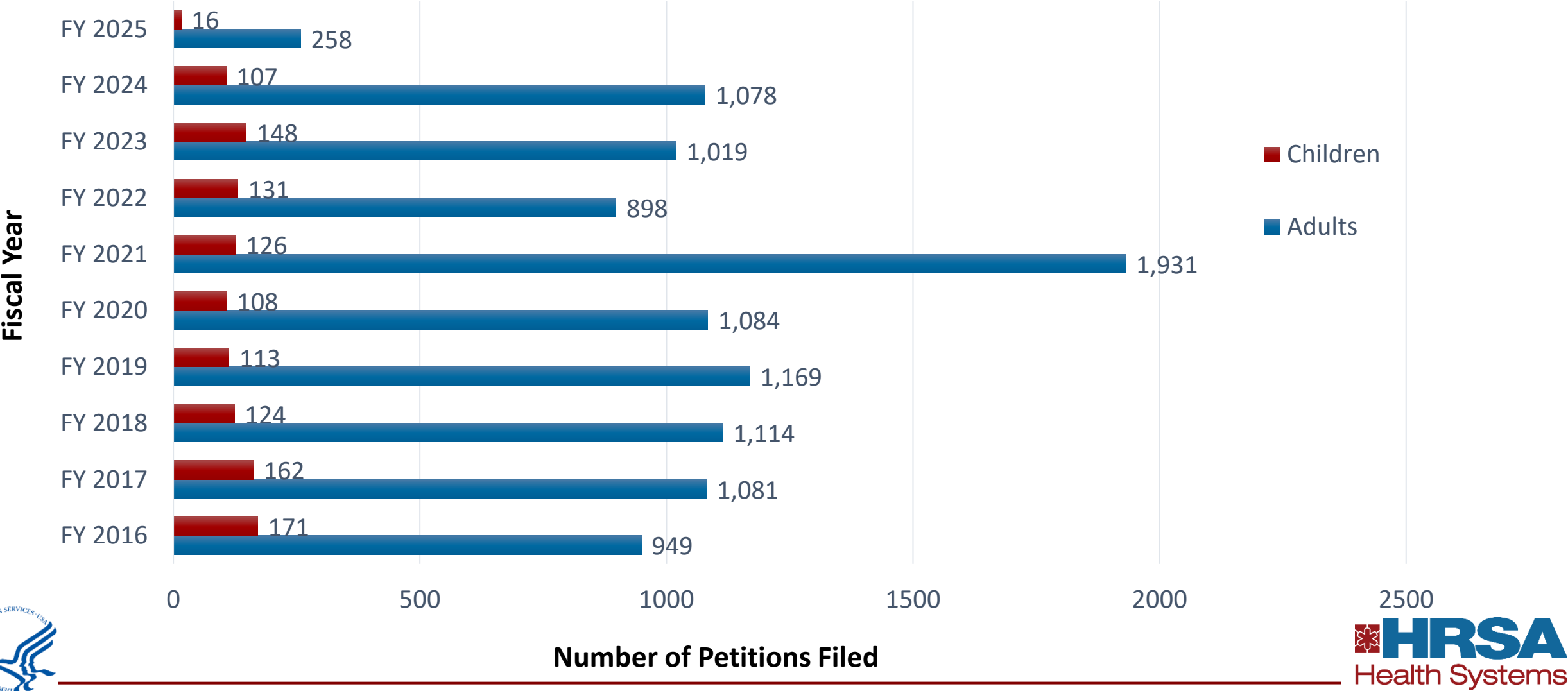
VICP Award Amounts for Petitioners' and Attorneys, FY 2016 – FY 2024



VICP Petitions Filed by Select Vaccines, FY 2016 – FY 2025



VICP Petitions Filed by/for Adults-vs- Children, FY 2016 – FY 2025



Advisory Commission on Childhood Vaccines (ACCV)



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.

Nominations are accepted on an ongoing basis and can be sent to ACCV@hrsa.gov.



ACCV Duties

- ACCV shall:
 - advise the Secretary on the implementation of the Program;
 - on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table;
 - advise the Secretary in implementing the Secretary's responsibilities under Section 2127 of the PHS Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions;
 - survey federal, state, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of Section 2125(b), and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines;
 - recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the Program; and
 - consult regarding the development or revision of vaccine information materials as required by Section 2126 of the PHS Act.



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 - Example

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.

Vaccine Injury Table Processes

- On its own initiative or as the result of the filing of a petition, ACCV can recommend changes in the Vaccine Injury Table
- If there is credible scientific and medical evidence to modify the Table, the Secretary can initiate the Federal Rulemaking process to add to, subtract from, or modify the Vaccine Injury Table
- Vaccine Injury Table changes require:
 - Publication of a notice of proposed rulemaking in the Federal Register
 - Six (6) month public comment period
 - Presentation/consultation with ACCV
 - Publication of a final rule

ACCV Guiding Principles for Recommending Changes

- The Vaccine Injury Table should be scientifically and medically credible
- 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 ACCV and deemed credible
 - However, those conclusions should not limit the deliberations of the ACCV

Select National Academy of Medicine Reviews

- National Academy of Medicine has periodically reviewed the literature and offered causality assessments
 - [Evidence Review of Adverse Effects on COVID-19 Vaccination and Intramuscular Vaccine Administration](#) – 2024
 - [Adverse Effects of Vaccines: Evidence and Causality](#) – 2012
 - [Adverse Effects Associated with Childhood Vaccines](#) – 1994
 - [Adverse Effects of Pertussis and Rubella Vaccines](#) – 1991



Countermeasures Injury Compensation Program (CICP)

Purpose

The purpose of CICP is to provide compensation for covered serious injuries or death that occur as the result of the administration or use of certain countermeasures.

The CICP establishes and maintains an accessible forum for timely, uniform, and adequate compensation for individuals found to be injured by covered countermeasures.



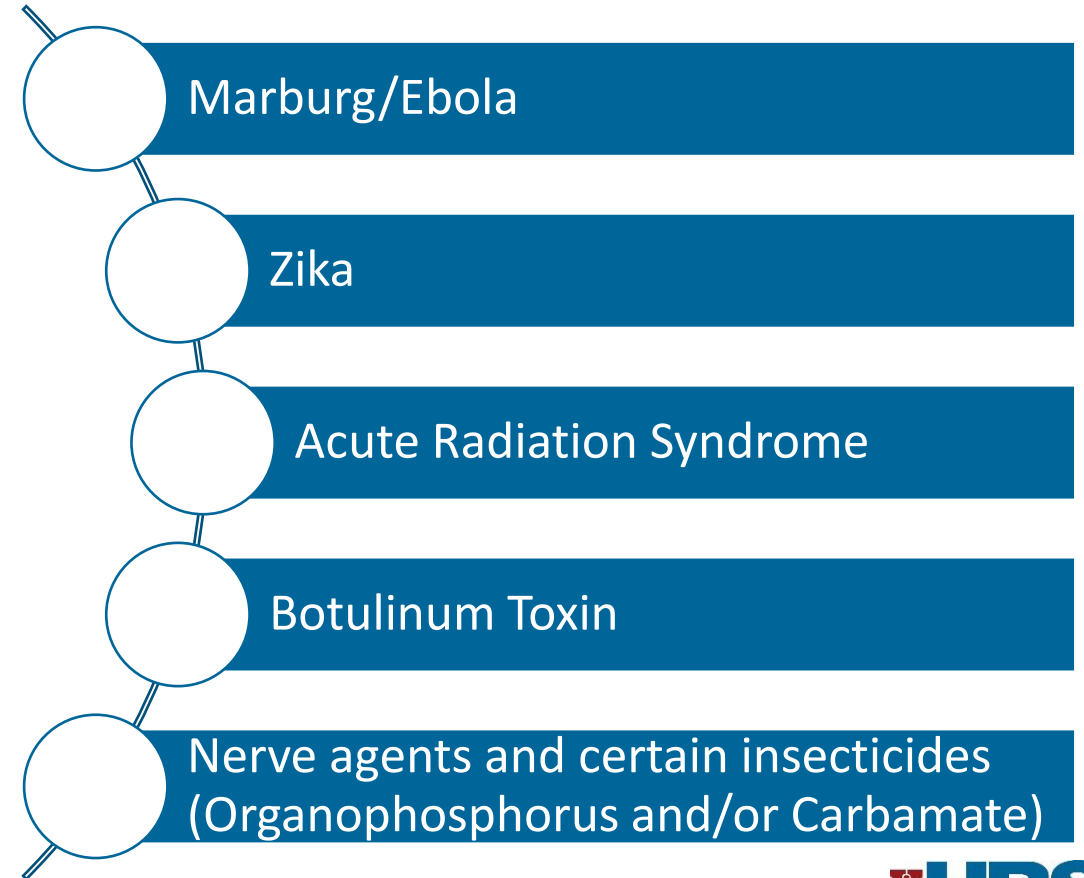
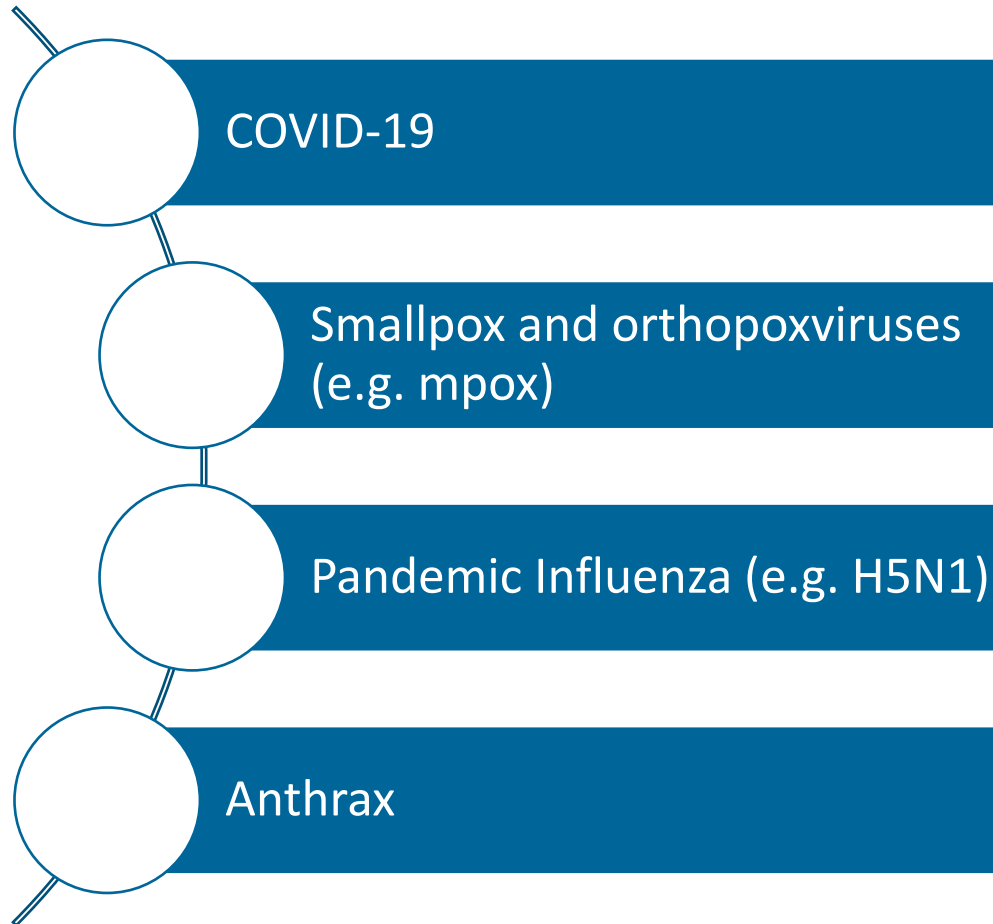
Public Readiness and Preparedness Act of 2005 (PREP Act)

- Public Readiness and Emergency Preparedness Act (PREP Act)
 - Signed into law by President George W. Bush in December 2005
 - Authorizes the Secretary of Health and Human Services (HHS) to issue PREP Act Declarations
 - Established the Covered Countermeasures Process Fund
 - Created targeted liability protections for persons or entities involved in emergency response efforts covered by PREP Act Declarations



PREP Act Declarations

PREP Act Declarations have been issued for medical countermeasures against the following:



Covered Countermeasures

- A vaccine, medication, device, or other item used to prevent, diagnose, or treat a public health emergency or a security threat
- Covered countermeasures are identified in PREP Act Declarations
- Injured countermeasure recipients must have received a covered countermeasure to be eligible for Program benefits
- Individuals who sustained an injury from the covered disease/threat (e.g., COVID-19) are not eligible for benefits
 - Must have been injured by a covered *countermeasure*



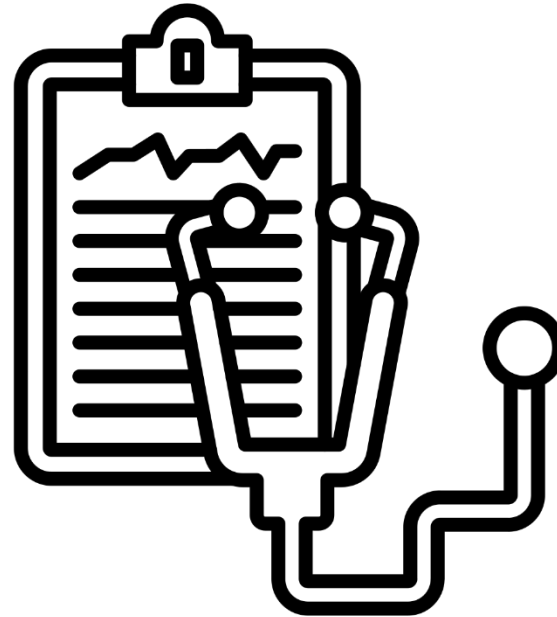
Types of payments authorized in CICP

- All benefits are secondary to any obligation of any third-party payer. Requesters can receive the following benefits:
 - 1) Payment or reimbursement for reasonable and necessary medical services and items to diagnose, treat, or prevent covered injury and/or health complications
 - 2) Lost employment income incurred as a result of a covered injury
 - 3) Death benefits to certain survivors, if determined that death was the direct result of covered injury (based on Public Safety Officers' Benefit Program)
- By statute, neither damages for pain-and-suffering nor attorney's fees are payable

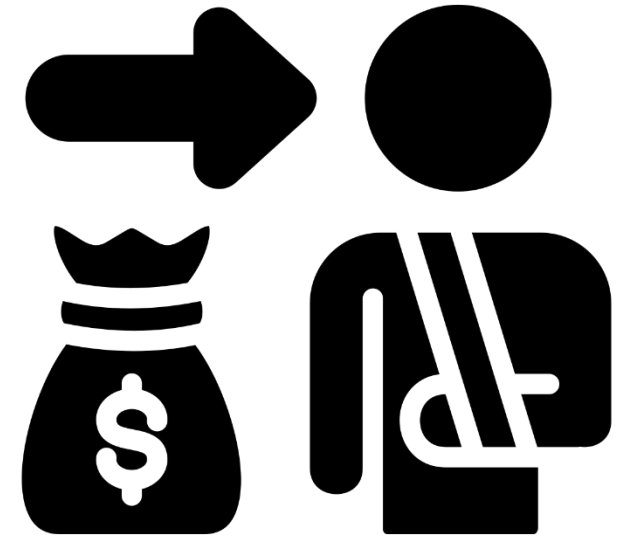
Review Process



Administrative (RFB) Review



Medical Eligibility Review



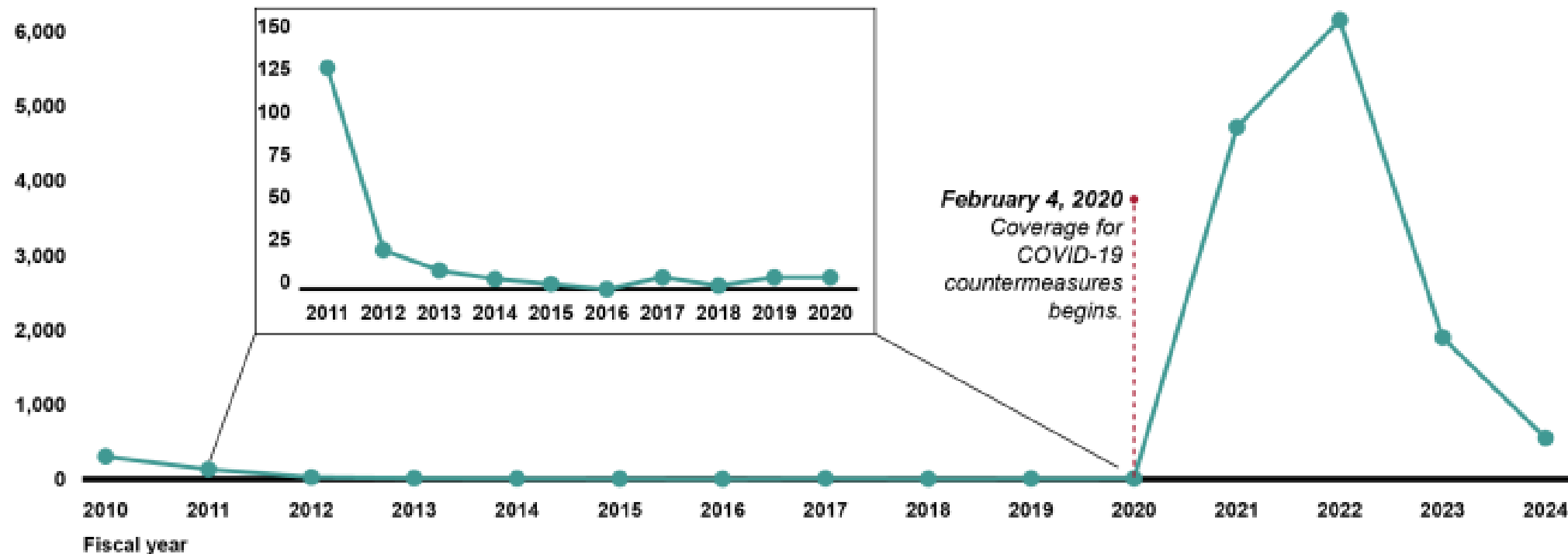
Benefits Determination

Number of CICP Total Claims, FY2010 – June 2024

Figure 2: Countermeasures Injury Compensation Program (CICP) Total Claim Submissions, by Fiscal Year, as of June 2024

Number of claims submitted

7,000



Source: GAO analysis of Health Resources and Services Administration data. | GAO-25-107388

Notes: Data reflect October 2009, when the agency began accepting CICP claims, through June 2024, the most recent data available when we conducted our analysis. Fiscal year 2024 includes claims through June.



CICP Resources

- At the beginning of the COVID-19 pandemic, CICP had four (4) staff supporting CICP operations
- CICP had not received a direct appropriation since its inception in FY 2009
 - First direct appropriation (\$5 million) in FY 2022
 - Received subsequent direct appropriations of \$7M in FY 2023 and FY 2024
- Available funding has allowed CICP to increase staff and expedite claim review throughput

Key Takeaways

VICP

- Provides a no-fault alternative to the traditional tort system by providing compensation to people found to be injured by certain vaccines
- VICP includes key roles for HHS, DOJ, and the U.S. Court of Federal Claims
- Funding for VICP is provided through the Vaccine Injury Compensation Trust Fund
- ACCV plays a key role in advising the Secretary on implementation of the VICP

CICP

- Developed to be a forum for timely, uniform, and fair compensation for serious physical injuries and/or deaths from covered countermeasures
- CICP is administered by HRSA
- Funding for CICP is provided by annual appropriations from Congress
- Major influx in claims in conjunction with the COVID-19 pandemic
- Recently allocated resources have improved decision throughput for COVID-19 claims, but more than 10,000 are still open



Contact Information

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Twitter: twitter.com/HRSAgov

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