



# Overview of Injury Compensation Programs

## NASEM Committee to Review Relevant Literature Regarding Adverse Events Associated with Vaccines

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**Vision: Healthy Communities, Healthy People**



# Outline of Presentation

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- Overview of the National Vaccine Injury Compensation Program (VICP)
- Overview of the Public Readiness and Emergency Preparedness Act (PREP Act) and the Countermeasures Injury Compensation Program (CICP)
- Review the Statement of Task for the Committee

# VICP and the National Childhood Vaccine Injury Act



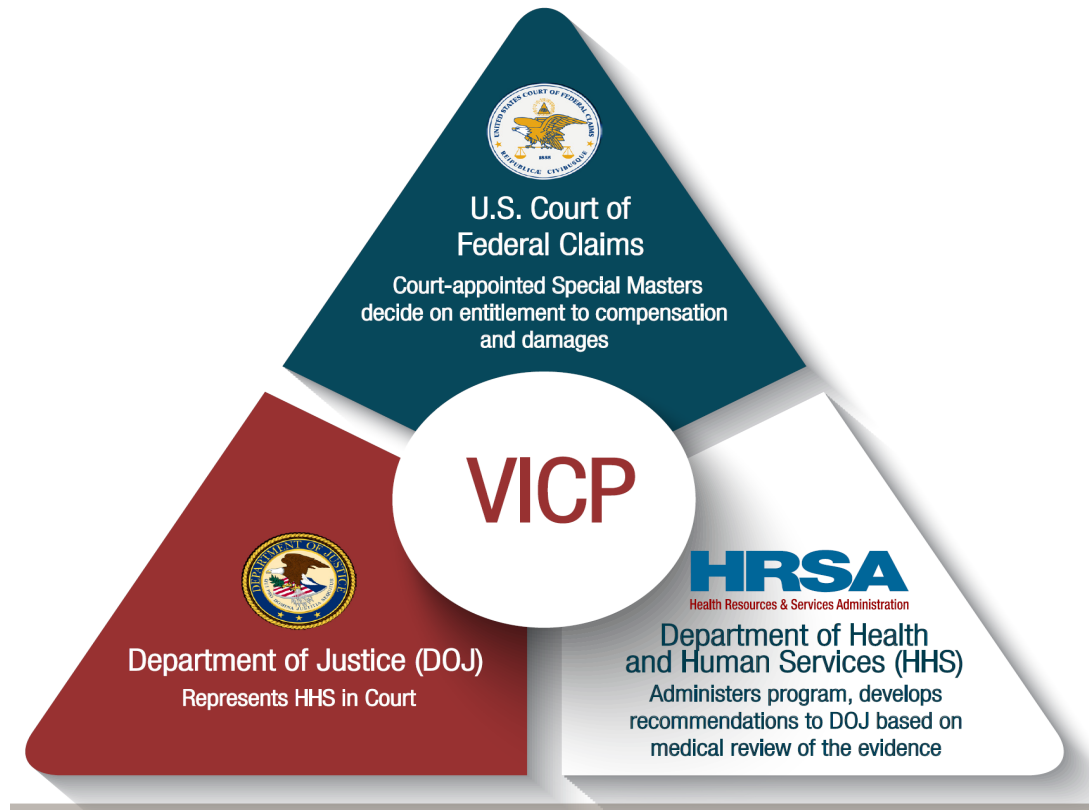
# National Childhood Vaccine Injury Act of 1986

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- The VICP was established in 1988
- Purpose of the VICP
  - To ensure that individuals injured by certain vaccines are provided with fair and efficient compensation
  - To ensure a stable vaccine supply by limiting liability for vaccine manufacturers and vaccine administrators
    - ✓ Claims generally must first be filed with VICP before seeking civil remedies

# THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (VICP)

## VICP ROLES

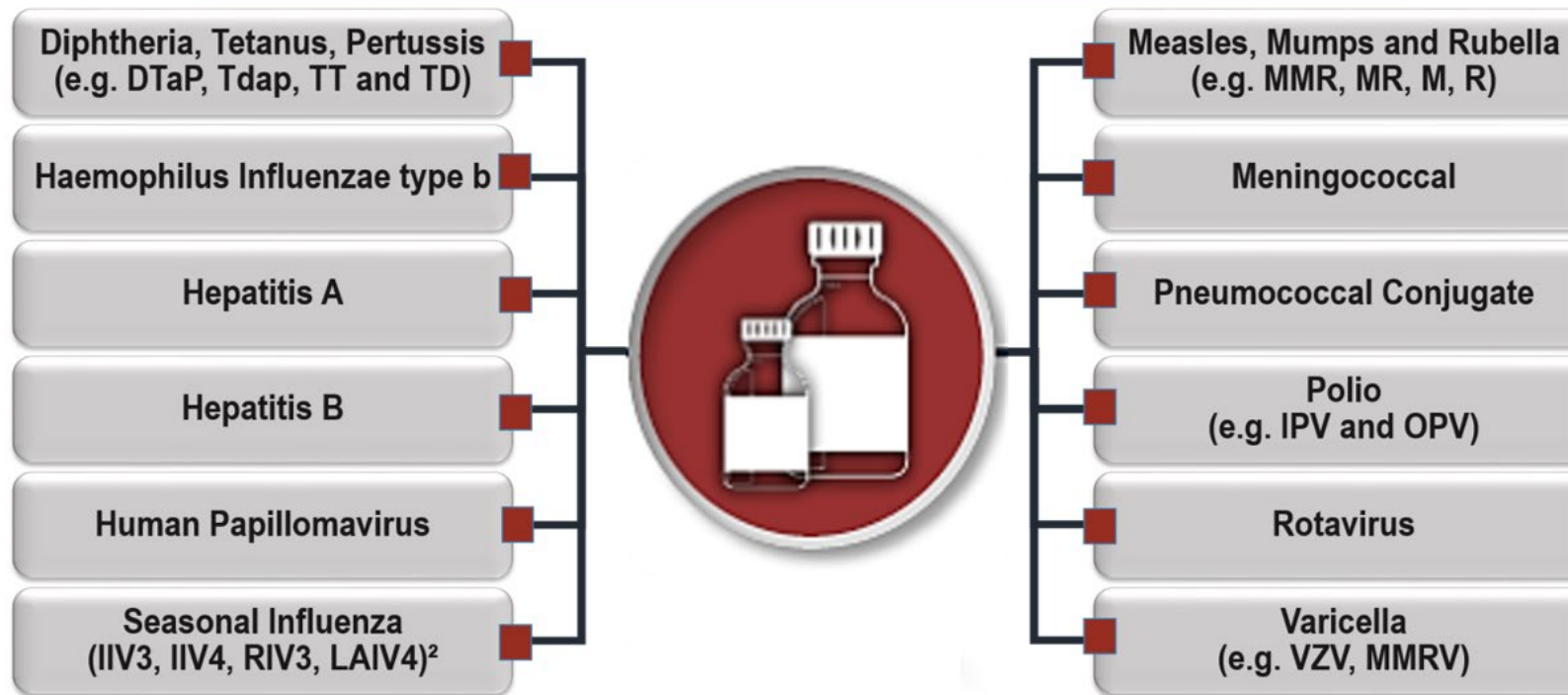


# Who May File a Petition?

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- Anyone who received a vaccine covered by the VICP and is thought to be injured by the vaccine
- Parent or legal guardian of a child or disabled adult or legal representative of the estate of the deceased person who received a vaccine

# COVERED VACCINES<sup>1</sup>



<sup>1</sup> Recommended by CDC for routine use in children and/or in pregnant women and subject to an excise tax

<sup>2</sup> Seasonal (trivalent, quadrivalent, inactivated, live attenuated and recombinant vaccines) only

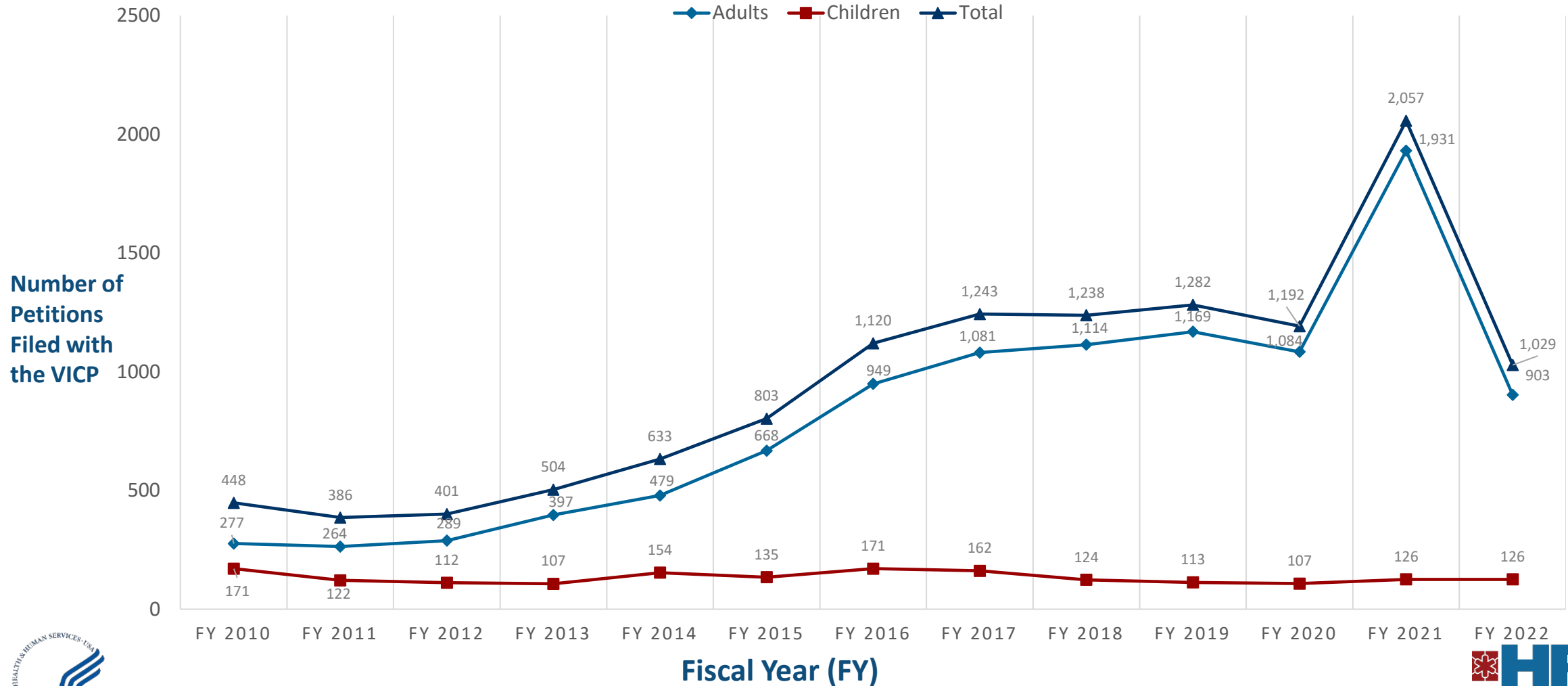
# VICP Claims Process

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1. Petitioner files a claim and supporting documents with the Court and the Department of Health and Human Services (HHS)
2. HHS reviews and sends recommendation to the Department of Justice (DOJ)
3. DOJ conveys the HHS Secretary's position to the U.S. Court of Federal Claims (the Court)
4. Court issues final decision



# VICP Petitions Filed for Adults and Children FY 2010 – FY 2022



# VICP Benefits

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- Reasonable unreimbursed medical expenses
- Lost earnings
- Pain and suffering (up to \$250,000)
- Attorney's fees and costs
- Death benefit

# VICP Criteria for Compensation

- To be compensated, one must demonstrate one of the following:
  - proof of an injury on Vaccine Injury Table
  - proof of causation
  - proof of significant aggravation
    - ✓ unless alternative cause unrelated to vaccine is found
- Standard of proof (civil standard) -- *preponderance of evidence* (*more likely than not*)
- Effects of injury must:
  - last greater than 6 months, or
  - have resulted in inpatient hospitalization AND surgical intervention, or
  - death



# Recent VICP Trends

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- 92% of petitions were filed for adults in the last two Fiscal Years (FYs)
- 74% of petitions filed in the last two FYs allege an injury from the influenza vaccine
- Over 63% of petitions filed in the last two FYs allege shoulder injury related to vaccine administration (SIRVA)
  - SIRVA is a broad term that encompasses shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm

# CICP and the PREP Act



# PREP Act Overview

- The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (HHS) to issue PREP Act Declarations
  - Declarations provide immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency
  - PREP Act authorizes a Covered Countermeasures Process Fund (i.e., CICP)



# CICP Covered Threats

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

- COVID-19
- Marburg
- Ebola
- Nerve Agents and Certain Insecticides (Organophosphorus and/or Carbamates)
- Zika
- Pandemic Influenza\*
- Anthrax
- Acute Radiation Syndrome
- Botulinum Toxin
- Smallpox and other orthopoxviruses\*

\*Published countermeasures injury table



# PREP Act Compensation Requirements

- Allows for compensation for serious physical injuries or deaths directly caused by the administration/use of countermeasures covered by declarations.
- Provides compensation to eligible individuals who sustain a covered injury
  - Covered injury means a serious injury, or a death, determined by the Secretary to be:
    - ✓ An injury that is the direct result of the administration or use of a covered countermeasure; or
    - ✓ An injury meeting the requirements of a covered countermeasures injury table, presumed to be directly caused by the administration/use of a covered countermeasure (unless a more likely alternate cause)
  - To establish a covered injury was sustained as the direct result of the administration or use of a covered countermeasure, the CICP may only make such determinations based on “compelling, reliable, valid, medical, and scientific evidence



# CICP Eligible Requesters

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- Injured countermeasure recipients
- Legal or personal representative on behalf of an injured countermeasure recipient
- Survivors of deceased injured countermeasure recipient
- Estates of deceased injured countermeasure recipient

# Summary of the CICP Process

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1. An individual submits an RFB Package.
2. The Package is reviewed by CICP medical staff to determine whether the requester is eligible for program benefits, including whether a covered injury was sustained.
3. If the requester is determined to be eligible for program benefits, the requester is asked to submit additional documentation to determine the type and amount of compensation the requester may be entitled to receive.
4. If the requester is found entitled to program benefits, the requester is notified in writing and payment is issued.
5. If the requester is found ineligible for program benefits, the requester is informed in writing of the disapproval.
6. Requesters may submit a reconsideration request. When a request for reconsideration is received, a qualified panel, independent of the program, is convened to review the program's determination. Requesters may not seek review of a decision made on reconsideration.



# CICP Benefits

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- Reasonable Unreimbursed Medical Expenses
- Lost Employment Income
- Death Benefit
- Of note, CICP is a payer of last resort

# CICP Data

## CICP Claims between FY2010-FY2023 *(as of January 1, 2023)*

- Claims Filed 11,596 (95% COVID-19 related)
- Decisions: 992 (496 COVID-19 related)
  - ✓ Eligible for Compensation: 54
  - ✓ Denied: 938
    - Requested Medical Records not Submitted: 174
    - Standard of Proof Not Met and/or Covered Injury not Sustained: 303
    - Missed Filing Deadline: 142
    - Not CICP Covered Product/Not Specified: 319
- Pending Review or In Review: 10,604



# Statement of Task

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- Review the epidemiological, clinical, and biological evidence regarding the relationship between
  - Intramuscular administration vaccines and shoulder injuries
  - COVID-19 vaccines and specific adverse events
- Committee's conclusions will help inform injury compensation recommendations and decisions when assessing whether specific adverse events are causally associated with vaccines

# Questions?



# Contact Information

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