



Overview and Updates of the National Vaccine Injury Compensation Program (VICP)

132nd ACCV Meeting

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Vision: Healthy Communities, Healthy People



Overview of the National Childhood Vaccine Injury Act and the National Vaccine Injury Compensation Program



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.

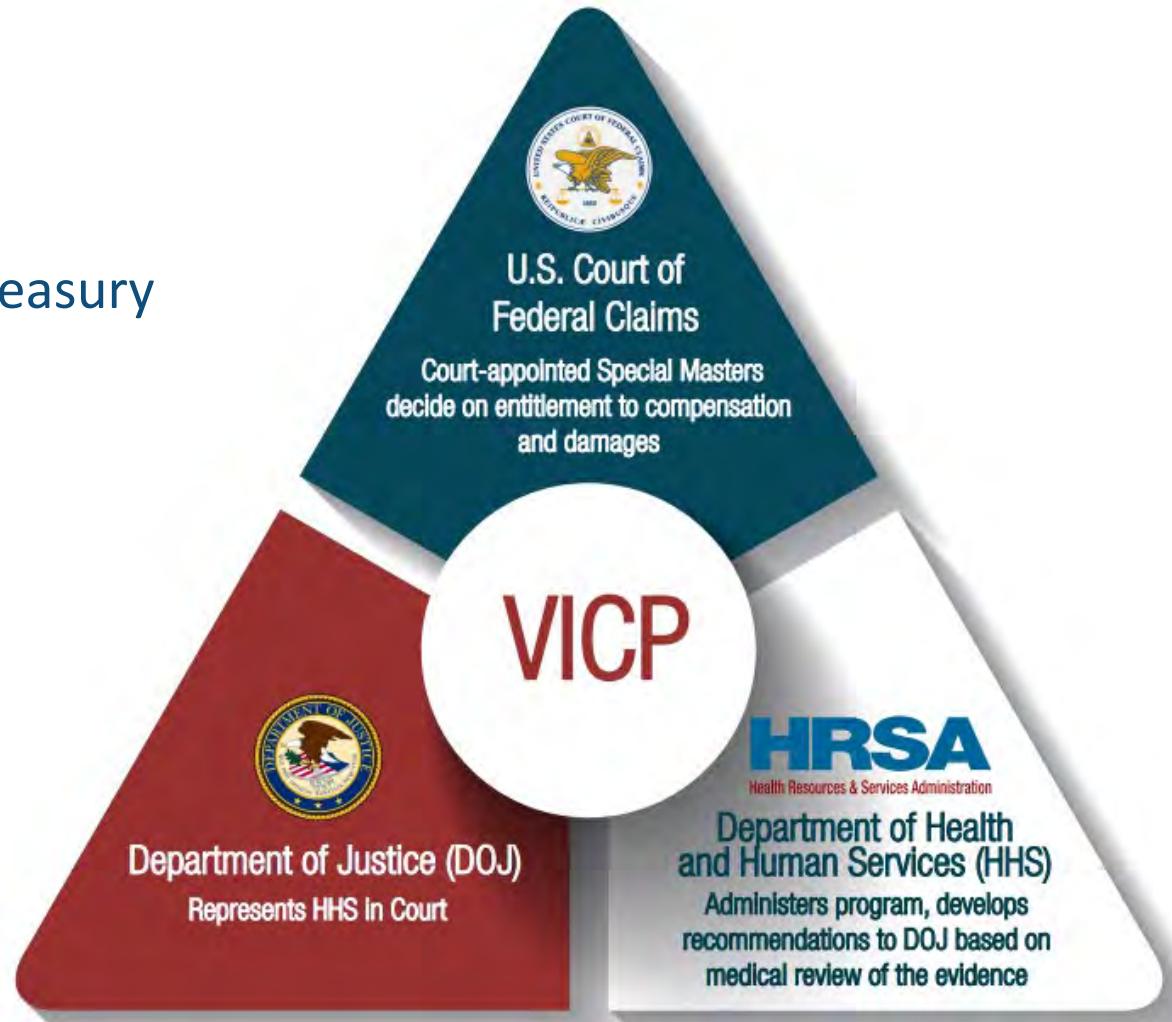
The VICP

- 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.



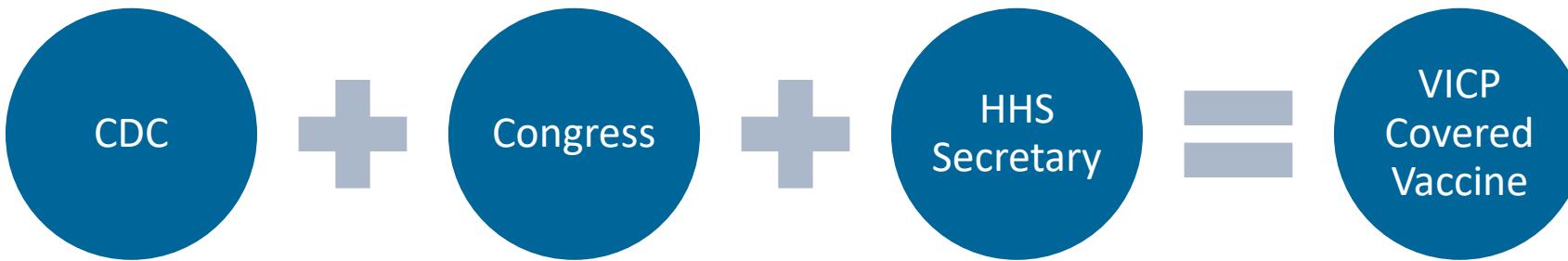
VICP Roles

Department of Treasury



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 women;
- 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

COVERED VACCINES¹

Diphtheria, Tetanus, Pertussis
(e.g. DTaP, Tdap, DT, TT and Td)

Haemophilus influenzae type b

Hepatitis A

Hepatitis B

Human papillomavirus

Seasonal Influenza
(e.g. IIV3, IIV4, RIV3, LAIV4)²

Measles, Mumps and Rubella
(e.g. MMR, MR, M, R)

Meningococcal

Pneumococcal conjugate

Polio
(e.g. IPV and OPV)

Rotavirus

Varicella
(e.g. VZV, MMRV)



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)
- No cap on the amount of an award in a vaccine injury case, but the law does provide certain restrictions



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 prevented
- Internal Revenue Code language defines vaccine and specifies the specific categories of vaccine for taxation



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.



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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.



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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:
 - Consultation with ACCV and request for recommendations and comments
 - Publication of a notice of proposed rulemaking in the Federal Register
 - Public comment period and hearing
 - Publication of a final rule

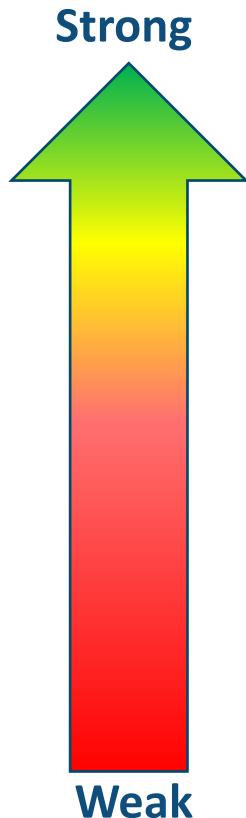


ACCV Guiding Principles for Recommending Changes

- 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



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



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*



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 - 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 Public Health Service Act (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;
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 - consult regarding the development or revision of vaccine information materials as required by Section 2126 of the PHS Act.



Section 2127 of the PHS Act

- Support the mandate for safer childhood vaccines
- Support HHS Secretary in promoting the development and refinement of childhood vaccines
- Provide consultation when/if reports to Congress are promulgated on safer childhood vaccines



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Section 2126 – Vaccine Information Statements

VACCINE INFORMATION STATEMENT

Tdap (Tetanus, Diphtheria, Pertussis) Vaccine: What You Need to Know

1. Why get vaccinated?

Tdap vaccine can prevent tetanus, diphtheria, and pertussis.

Diphtheria and pertussis spread from person to person. Tetanus enters the body through cuts or wounds.

- TETANUS (T)** causes painful stiffness of the muscles. Tetanus can lead to serious health problems, including being unable to open the mouth, having trouble swallowing and breathing, or difficulty breathing.
- DIPHTHERIA (D)** can lead to difficulty breathing, heart failure, paralysis, or death.
- PERTUSSIS (aP)**, also known as “whooping cough,” can cause uncontrollable, violent coughing that makes it hard to breathe, eat, or drink. Pertussis can be extremely serious, especially in babies and young children, causing pneumonia, convulsions, brain damage, or death. In teens and adults, it can cause weight loss, loss of bladder control, passing out, and rib fractures from severe coughing.

2. Tdap vaccine

Tdap is only for children 7 years and older, adolescents, and adults.

Adolescents should receive a single dose of Tdap, preferably at age 11 or 12 years.

Pregnant people should get a dose of Tdap during every pregnancy, preferably during the early part of the third trimester, to help protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.

Adults who have never received Tdap should get a dose of Tdap.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an allergic reaction after a previous dose of any vaccine that protects against tetanus, diphtheria, or pertussis, or has any severe, life-threatening allergies.
- Has had a coma, decreased level of consciousness, or prolonged seizures within 7 days after a previous dose of any pertussis vaccine (DTaP, or Tdap).
- Has seizures or another nervous system problem called “GBS”
- Has had severe pain or swelling after a previous dose of any vaccine that protects against tetanus or diphtheria

In some cases, your health care provider may decide to postpone Tdap vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting a Tdap vaccine.

Your health care provider can give you more information.

**U.S. Department of Health and Human Services
Centers for Disease Control and Prevention**



VACCINE INFORMATION STATEMENT

Polio Vaccine: What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immune.org/vis
Hoja de información sobre vacuna están disponibles en español y en muchas otras lenguas. Visite www.immune.org/vis

1. Why get vaccinated?

Polio vaccine can prevent polio.

Polio (or poliomyelitis) is a disabling and life-threatening disease caused by poliovirus, which can infect a person's spinal cord, leading to paralysis.

Most people infected with poliovirus have no symptoms, and many recover without complications. Some people will experience sore throat, fever, tiredness, nausea, headache, or stomach pain.

A smaller group of people will develop more serious symptoms that affect the brain and spinal cord:

- Paresthesia (feeling of pins and needles in the legs),
- Meningitis (infection of the covering of the spinal cord and/or brain), or
- Paralysis (can't move parts of the body) or weakness in the arms, legs, or both.

Paralysis is the most severe symptom associated with polio because it can lead to permanent disability and death.

Improvements in limb paralysis can occur, but in some people new muscle pain and weakness may develop 15 to 40 years later. This is called “post-polio syndrome.”

Polio has been eliminated from the United States, but it still occurs in other parts of the world. The best way to protect yourself and keep the United States polio-free is to maintain high immunity (protection) in the population against polio through vaccination.

2. Polio vaccine

Children should usually get 4 doses of polio vaccine at ages 2 months, 4 months, 6–18 months, and 4–6 years.

Most adults do not need polio vaccine because they were already vaccinated against polio as children. Some adults are at higher risk and should consider polio vaccination, including:

- People traveling to certain parts of the world
- Laboratory workers who might handle poliovirus
- Health care workers treating patients who could have polio
- Unvaccinated people whose children will be receiving oral poliovirus vaccine (for example, international adoptees or refugees)

Polio vaccine may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

Polio vaccine may be given at the same time as other vaccines.

VACCINE INFORMATION STATEMENT

MMRV Vaccine (Measles, Mumps, Rubella, and Varicella): What You Need to Know

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1. Why get vaccinated?

MMRV vaccine can prevent measles, mumps, rubella, and varicella.

MEASLES (M) causes fever, cough, runny nose, and red, watery eyes, commonly followed by a rash that covers the whole body. It can lead to seizures (often associated with fever), ear infections, diarrhea, and pneumonia.

MUMPS (M) causes fever, headache, muscle aches, tiredness, loss of appetite, and swollen and tender salivary glands under the ears. It can lead to deafness, swelling of the brain and/or spinal cord covering, and very rarely, death.

RUBELLA (R) causes fever, sore throat, rash, headache, and eye irritation. It can cause arthritis in up to half of teenage and adult women. If a person gets rubella while they are pregnant, they could have a miscarriage or the baby could be born with serious birth defects.

VARICELLA (V), also called “chickenpox,” causes an itchy rash, in addition to fever, tiredness, loss of appetite, and headache. Some people who get chickenpox of the brain and/or spinal cord covering, and infection of the blood, bones, or joints. Some people who get chickenpox as herpes zoster years later, known as “shingles,” also have made these diseases much less common in the United States.

2. MMRV vaccine

MMRV vaccine may be given to children 12 months through 12 years of age, usually:

- First dose at age 12 through 15 months
- Second dose at age 4 through 6 years.

MMRV vaccine may be given at the same time as other vaccines. Instead of MMRV, some children might receive separate shots for MMR (measles, mumps, and rubella) and varicella. Your health care provider can give you more information.



Summary

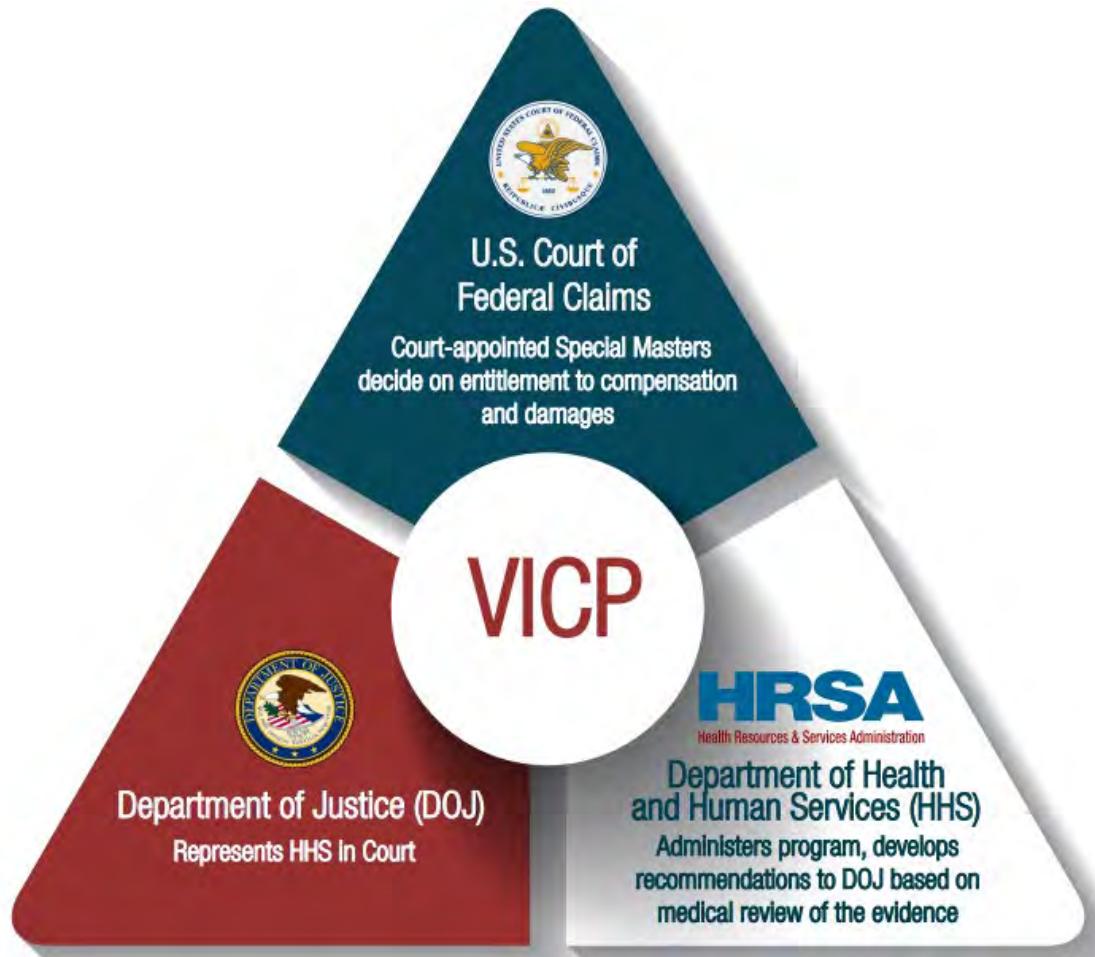
- The purpose of the VICP is to provide a no-fault alternative to the traditional tort system by providing compensation to people found to be injured by certain vaccines
 - VICP establishes and maintains an accessible and efficient forum for individuals found to be injured by certain vaccines
- VICP includes key roles within 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



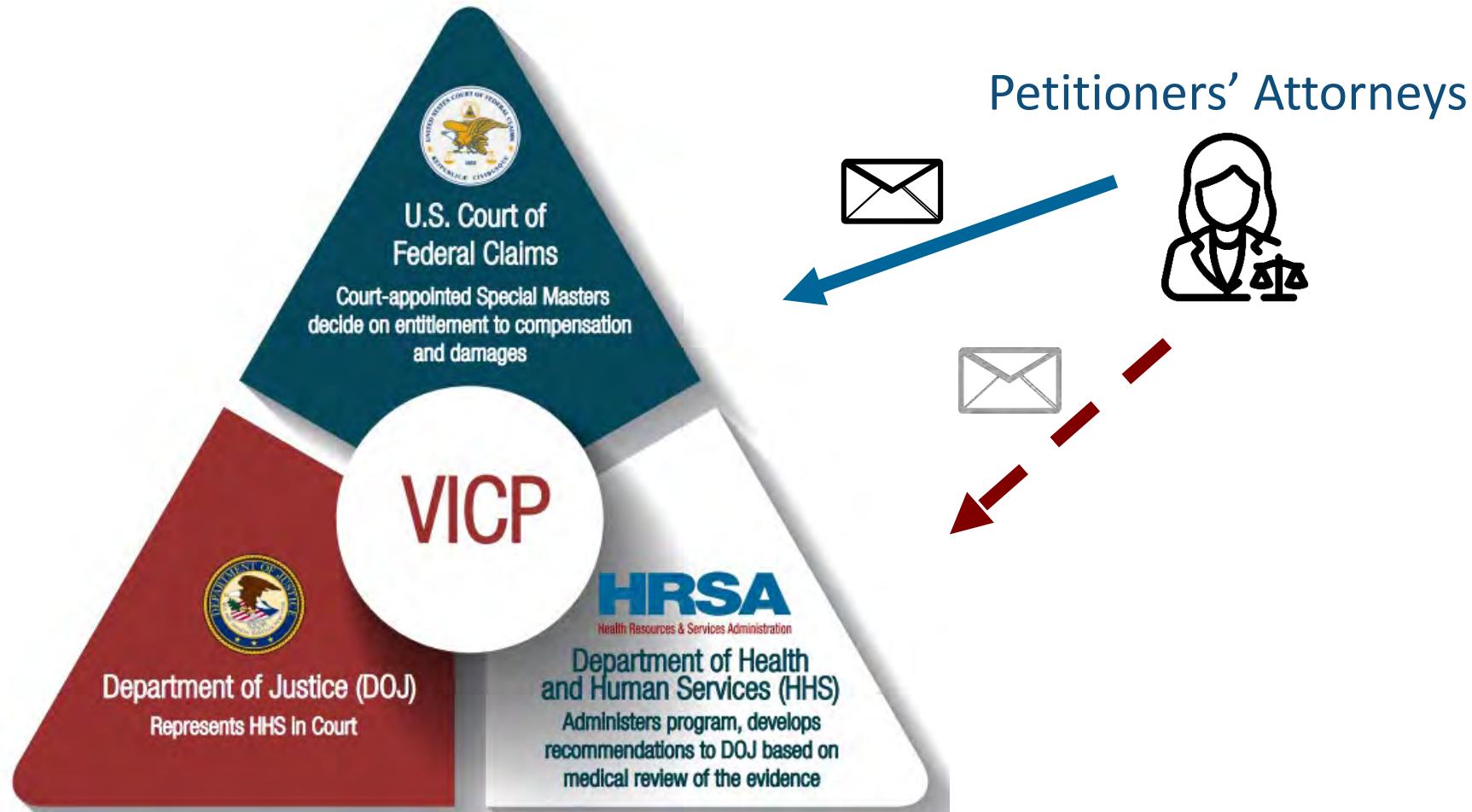
VICP Update



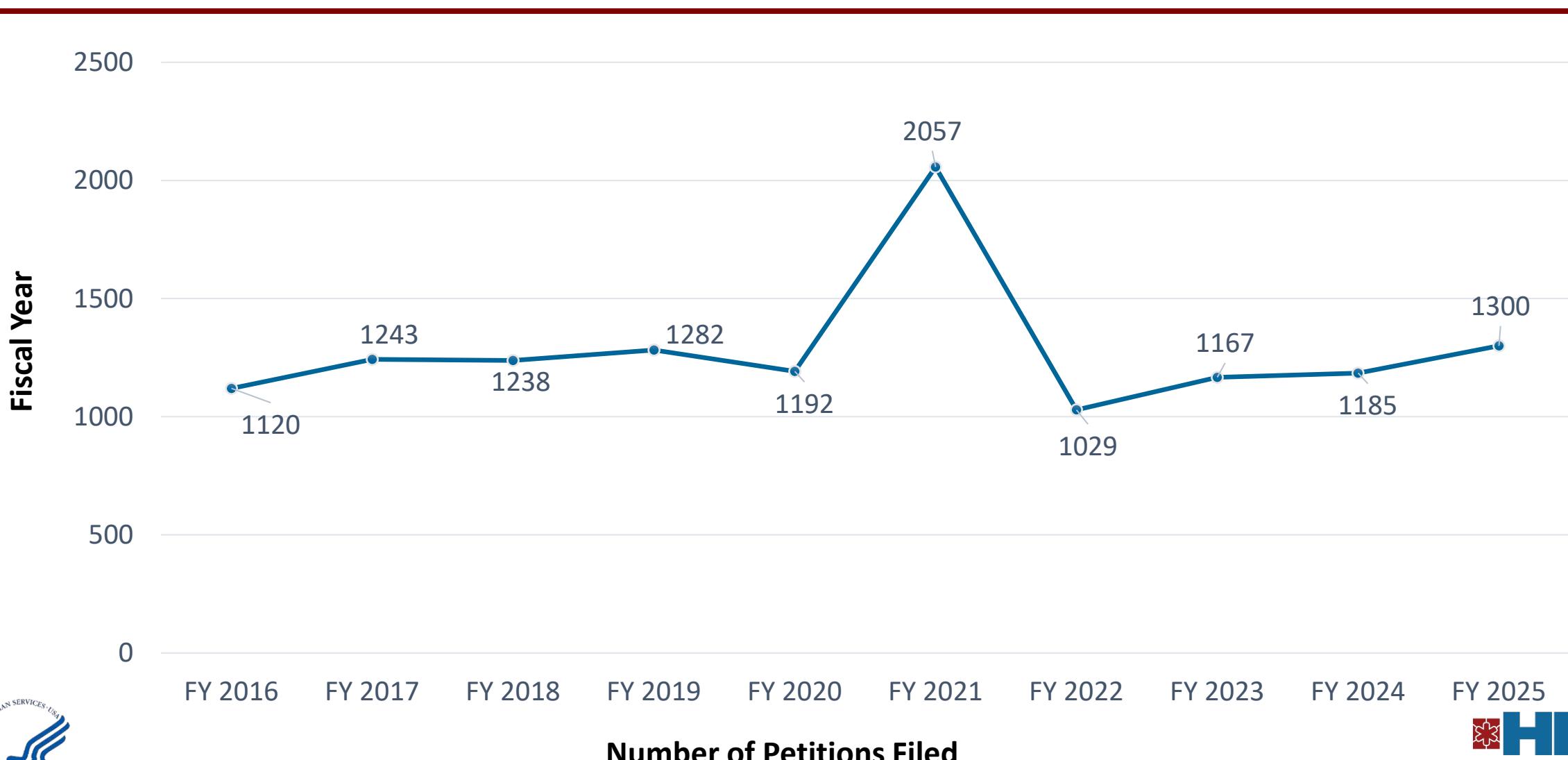
VICP Roles



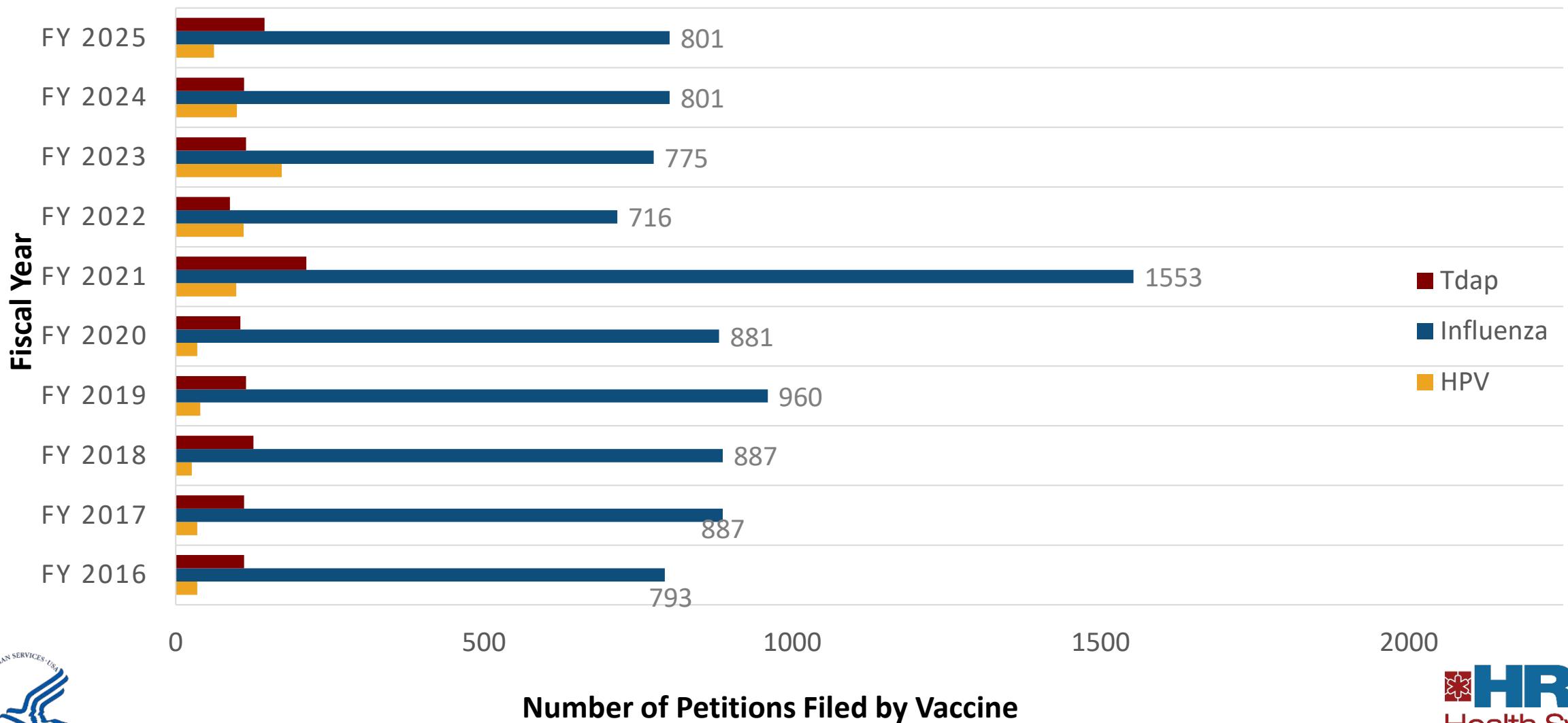
VICP Roles – Filing Petition



VICP Petitions Filed, FY 2016 – FY 2025



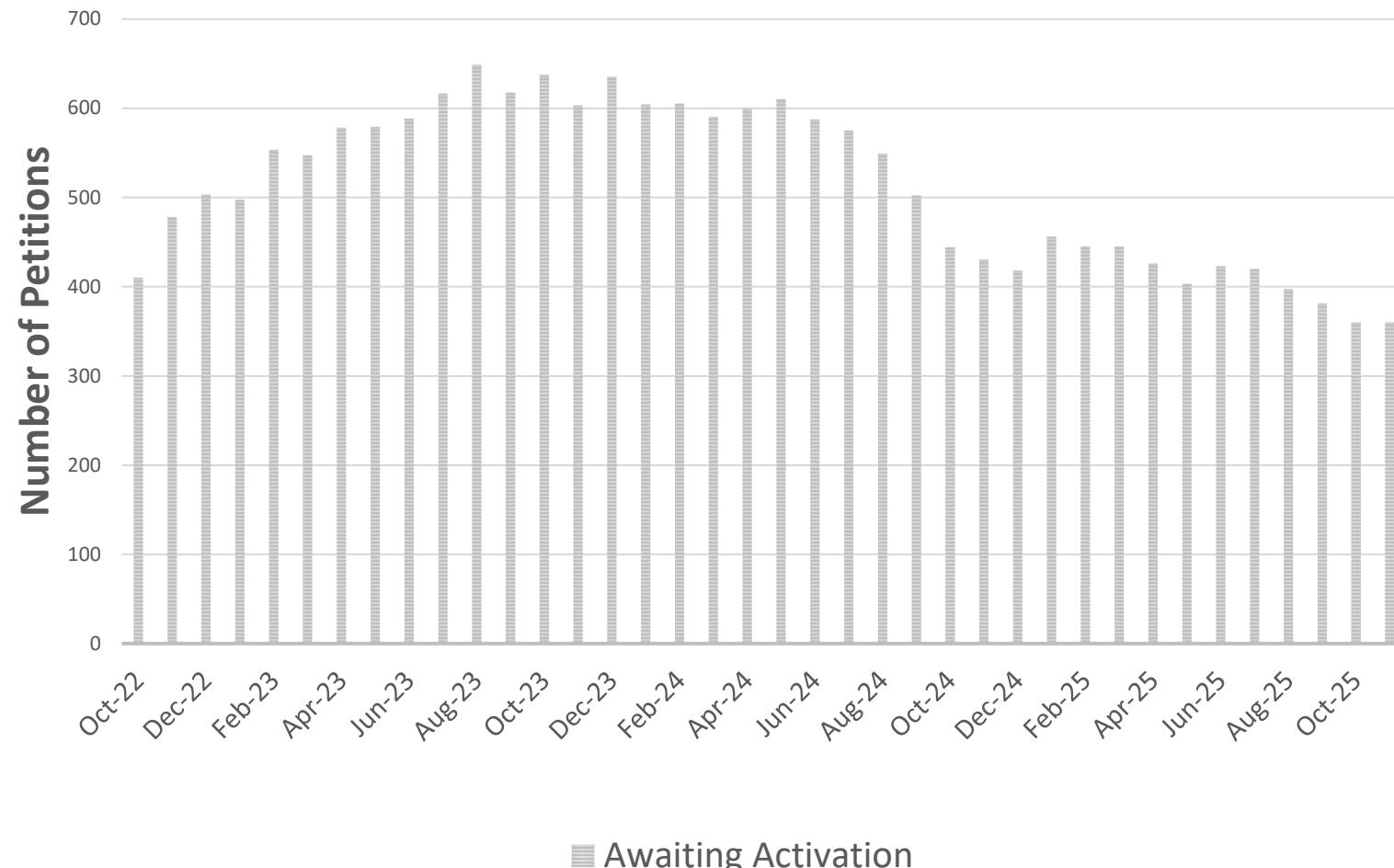
VICP Petitions Filed by Select Vaccines, FY 2016 – FY 2025



VICP Roles – Pre-Assignment Review (PAR)



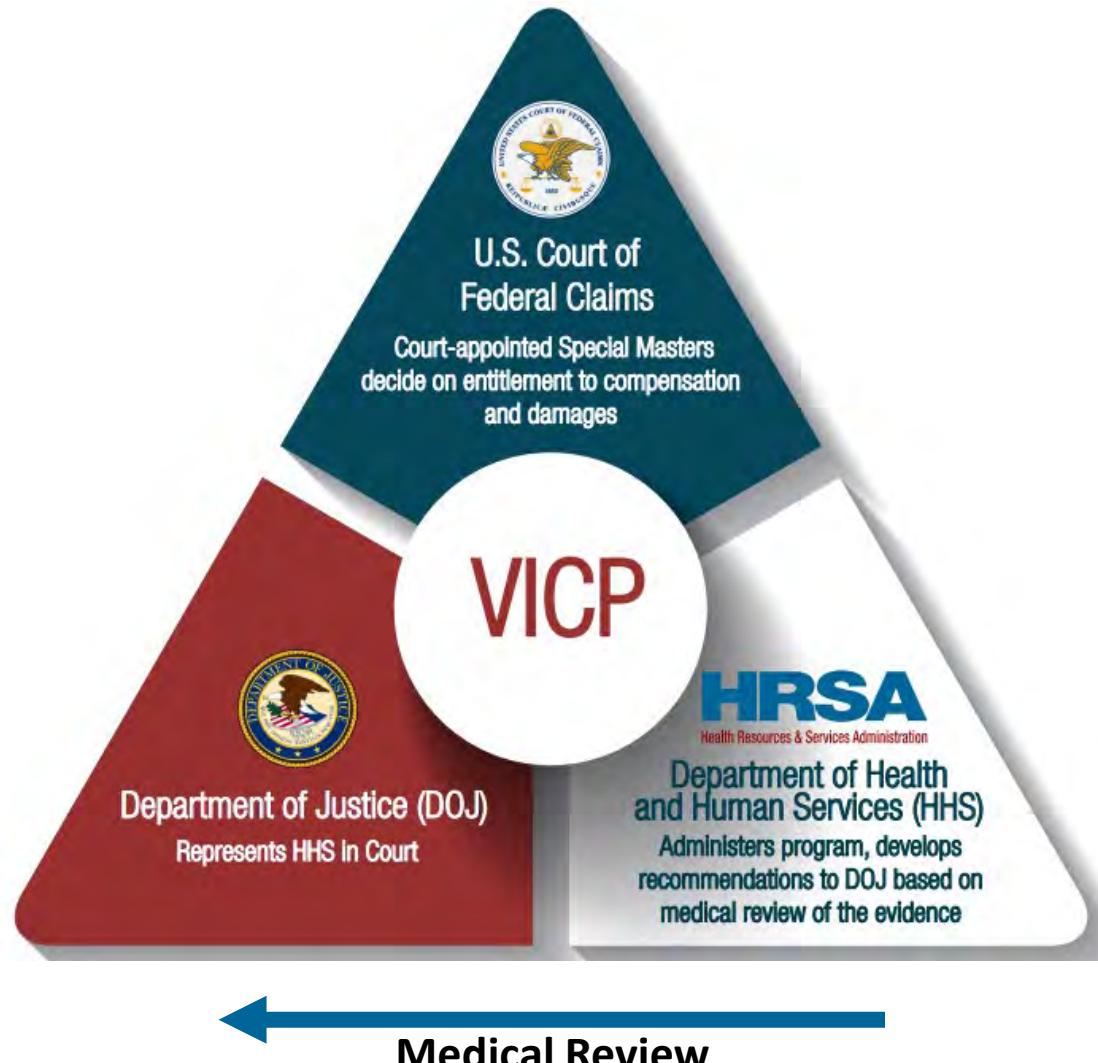
Number of Petitions in Pre-Assignment Review, FY 2023 – November 1, 2025



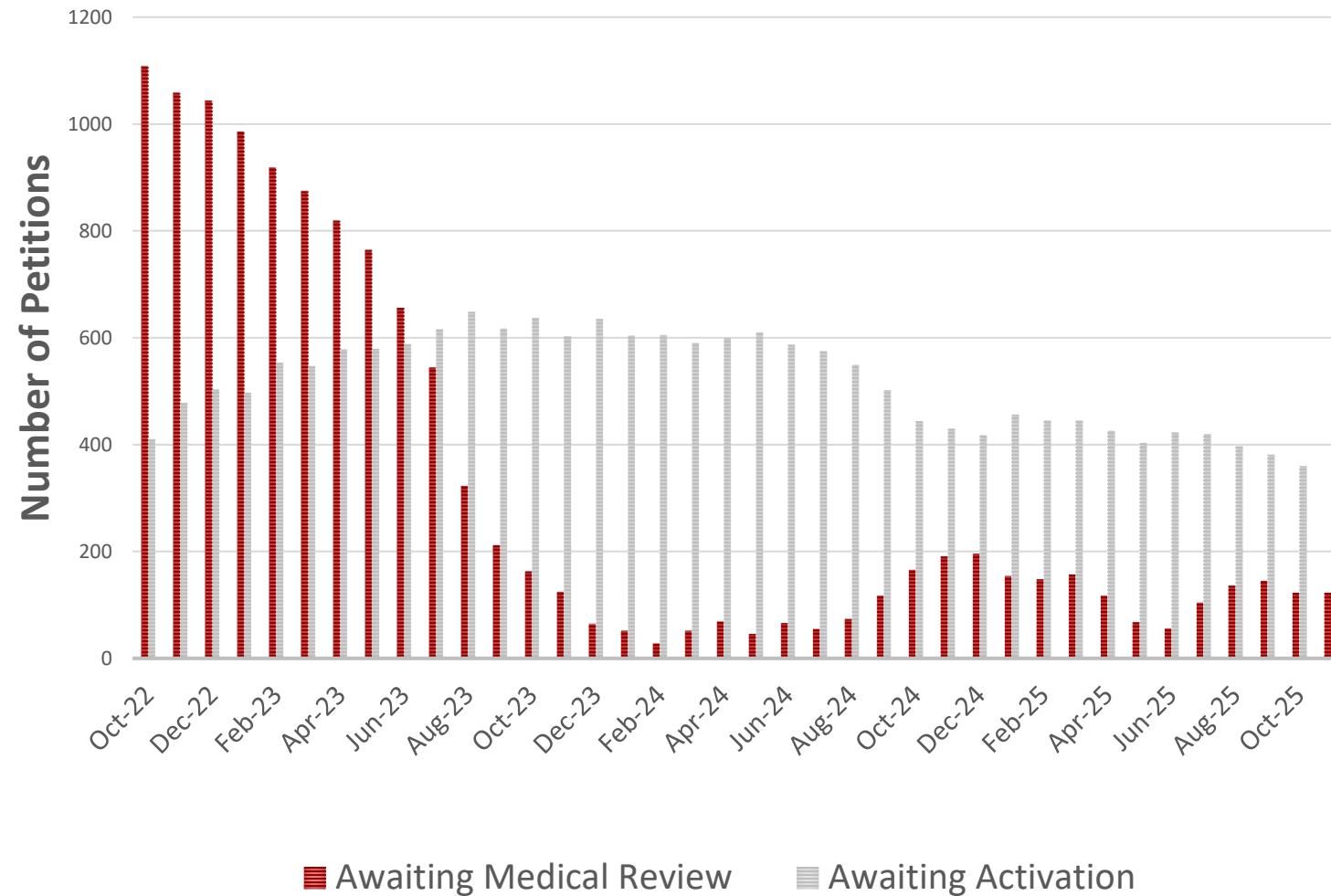
■ Awaiting Activation



VICP Roles – Awaiting Medical Review



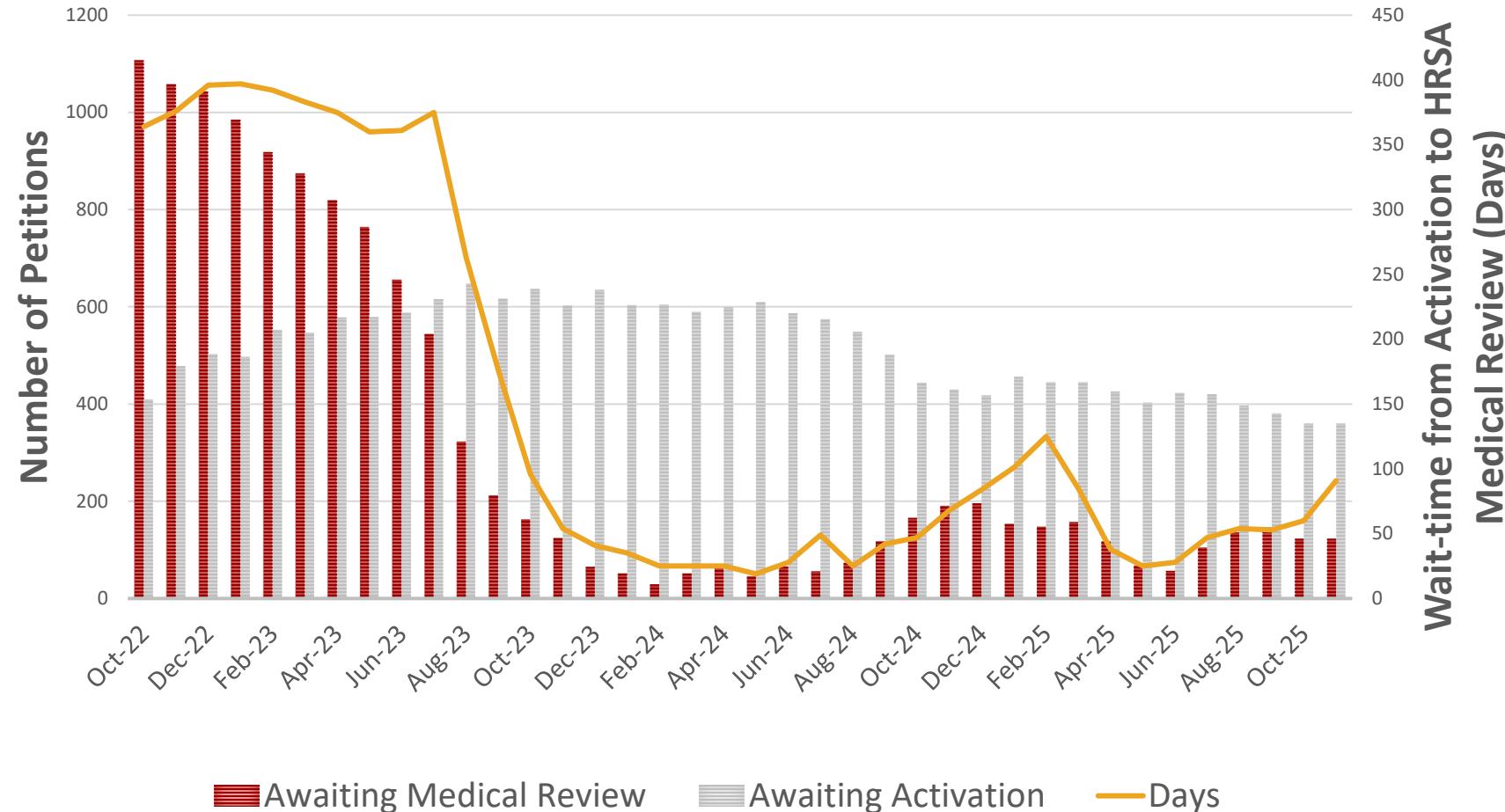
Number of Petitions Awaiting Medical Review, FY 2023 – November 1, 2025



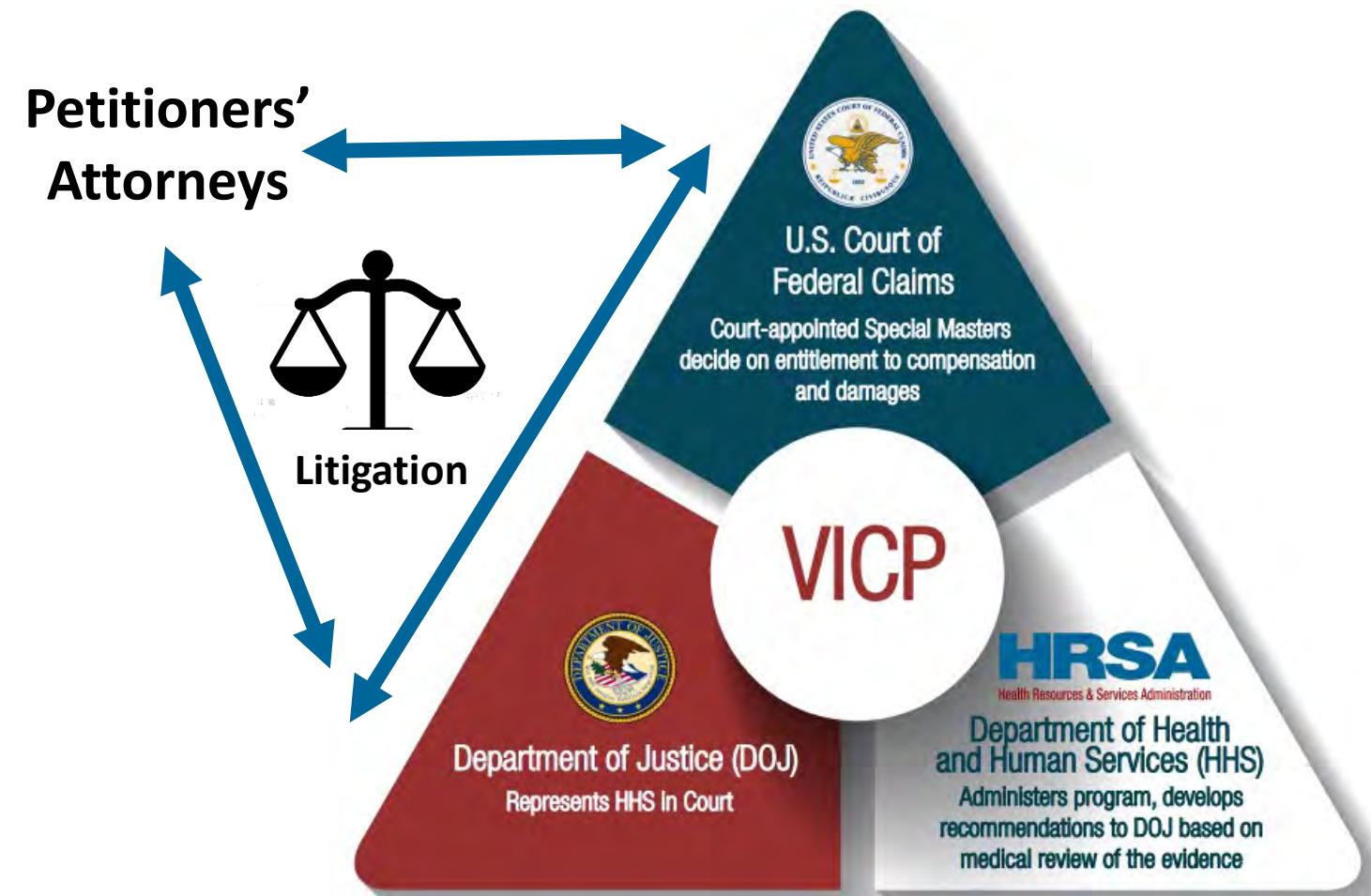
■ Awaiting Medical Review ■ Awaiting Activation

HRSA
Health Systems

Wait-time for Activation to HRSA Medical Review, FY 2023 – November 1, 2025



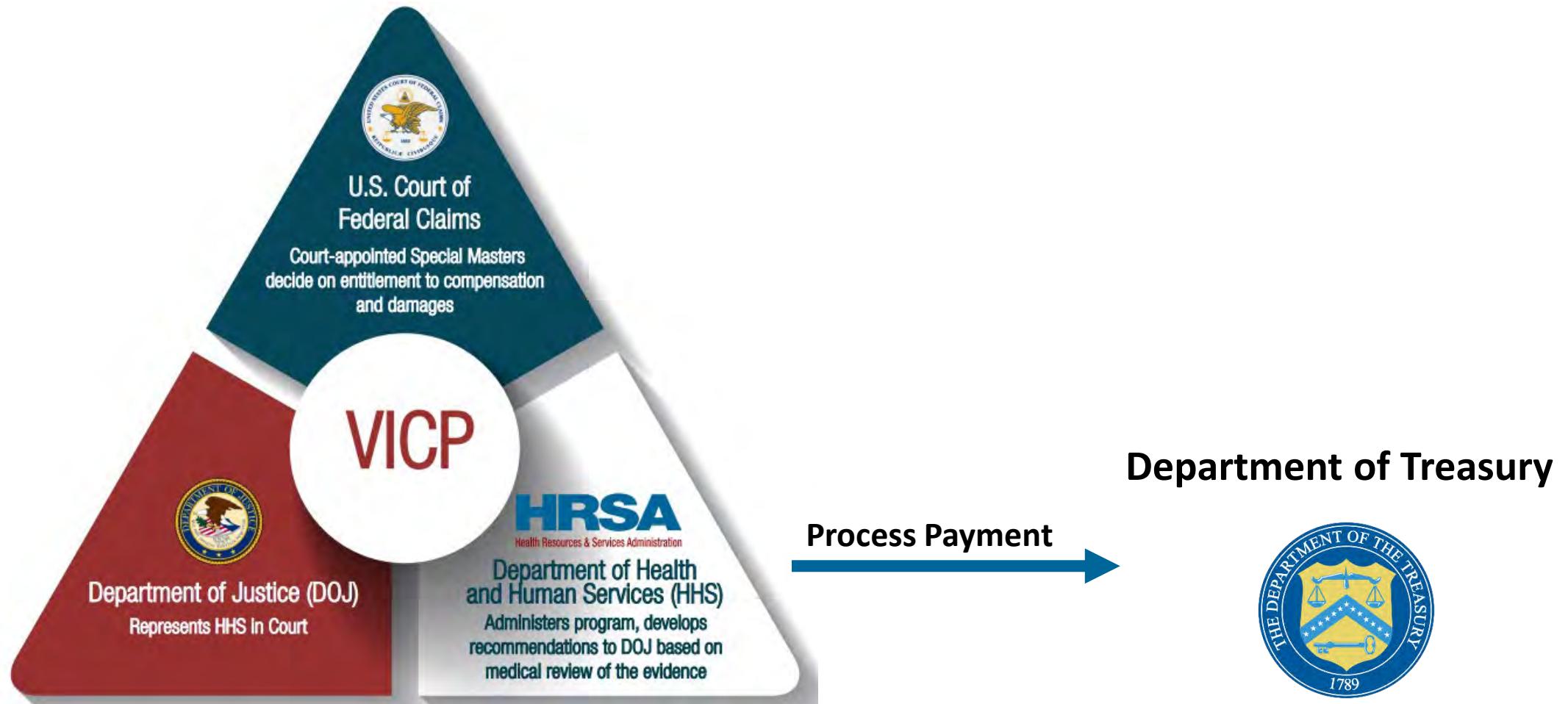
VICP Roles – Awaiting Adjudication



VICP Roles – Judgment for Payment



VICP Roles – Processing Payment



VICP Roles – Processing Payment



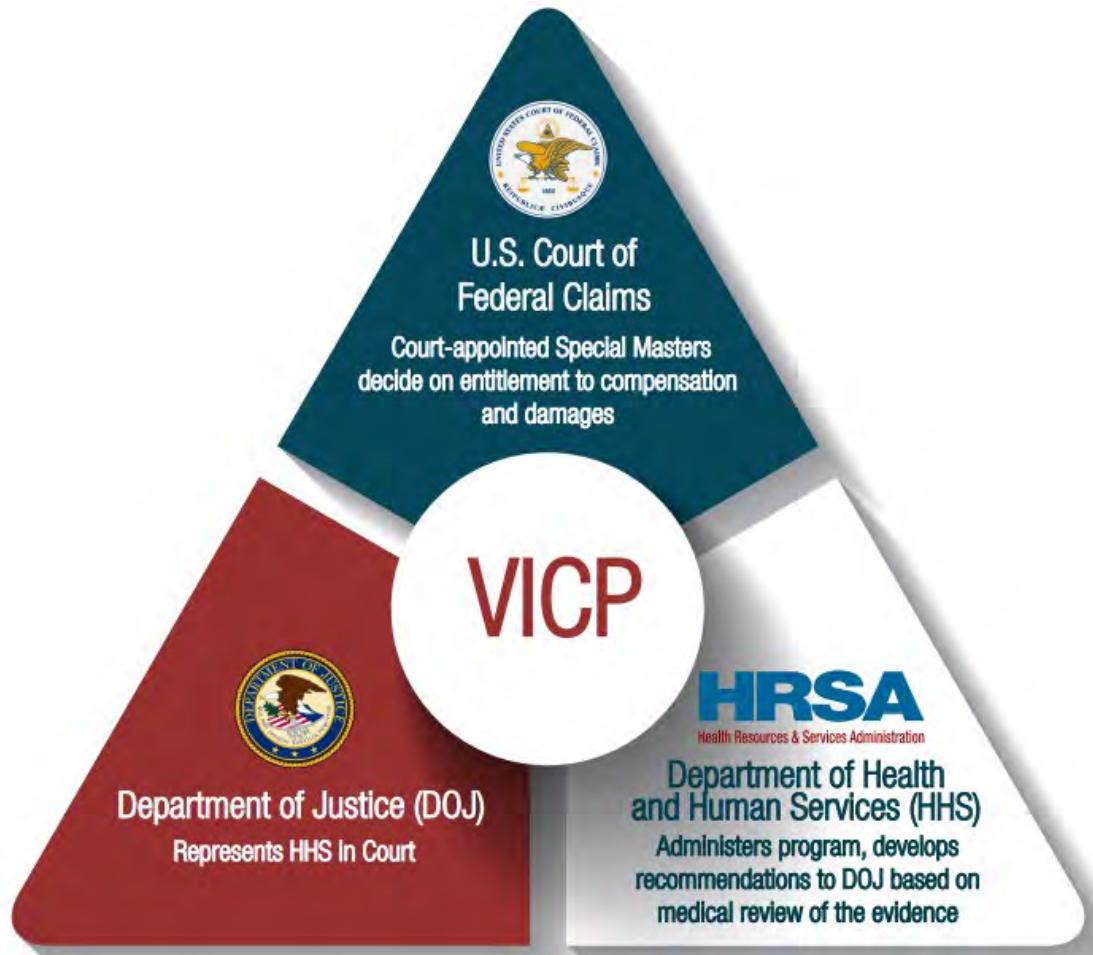
Vaccine Injury Compensation Trust Fund

- Vaccine Injury Compensation Trust Fund provides funding for the VICP to compensate eligible petitions filed
- Balance as of November 30, 2025
 - \$ 4,703,966,516
- Activity from FY 2026
 - Excise Tax Revenue: \$18,334,000
 - Investments: \$30,495,912
 - Total Income: \$48,829,912

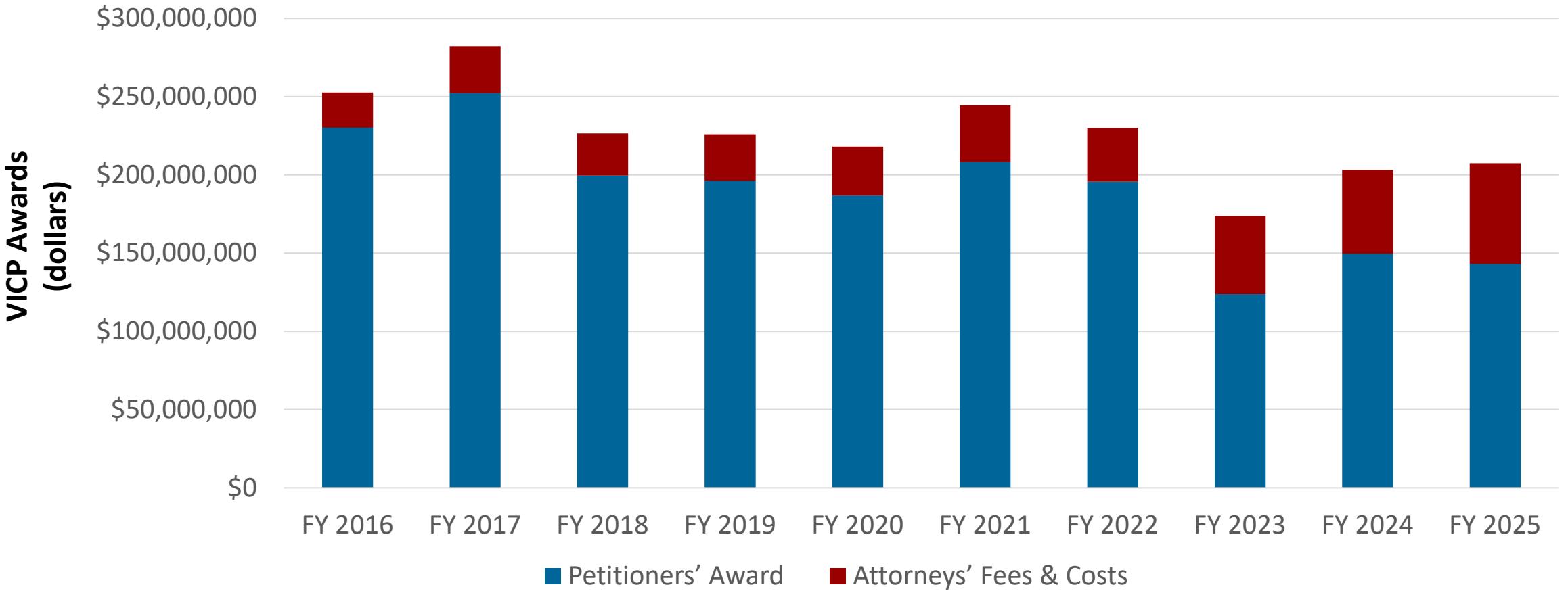
[Source: U.S. Treasury, Bureau of the Fiscal Service](#)



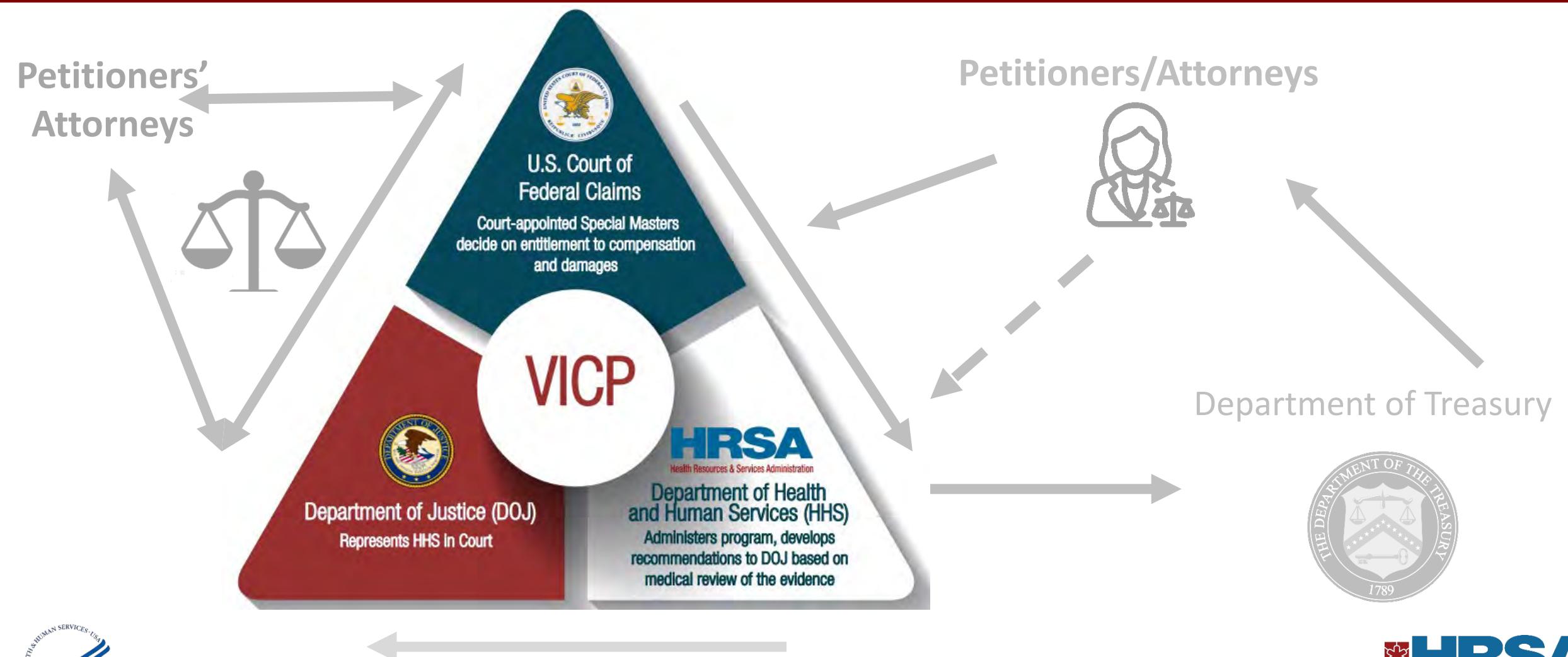
VICP Roles – Processing Payment



VICP Award Amounts for Petitioners' and Attorneys, FY 2016 – FY 2025



VICP Roles



VICP Timeline



Generally, 2 – 3 years



Summary of VICP Updates

- Claims increased from prior FYs, with the vast majority filed for influenza vaccine
- Claims continue to be adjudicated more expeditiously than other tort claims, with claims generally averaging 2-3 years until adjudication
- HRSA has gained efficiencies at each step in the process



Contact Information

Division of Injury Compensation Programs

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Rockville, Maryland 20857

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