No Fault Vaccine Compensation in Comparative Perspective—Lessons from International & National Systems Established during the COVID-19 Pandemic

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Background

- 2009-10 H1N1 pandemic – largely worked on liability and indemnity as obstacles to WHO-administered vaccine scheme
- 2015 and 2017 World Economic Forum-convened meetings on third-party insurance market to address pandemic vaccine risks
- Part of expert working group convened in April 2020 to address no-fault compensation as part of then-pre-licensed MRNA and viral vector vaccines
- Consult international development banks, ministries of health, and World Health Organization
- *No-Fault Vaccine Injury Compensation Systems Adopted Pursuant to the COVID-19 Pandemic*, 37 EMORY INT'L L. REV. 55 (2023).
- *Solving the Pandemic Vaccine Product Liability Problem*, 12 U.C. IRVINE L. REV. 1599 (2021)
- *The Other Side of Equitable Access to COVID-19 Vaccines – No-Fault Compensation for Vaccine Injury*, 384 NEW. ENG. J. MED. 1610 (2020) (with Heinrich and Omer)
- *A Global Vaccine Injury Compensation System*, 317(5) JAMA 471 (2017) (with Omer)

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Overview

- Differences between US VICP and CICP
- Survey of national and international no-fault vaccine compensation programs
- Featured programs and select differences (Australia, Canada, Finland, Germany, New Zealand, Sweden, United Kingdom)
- Questions

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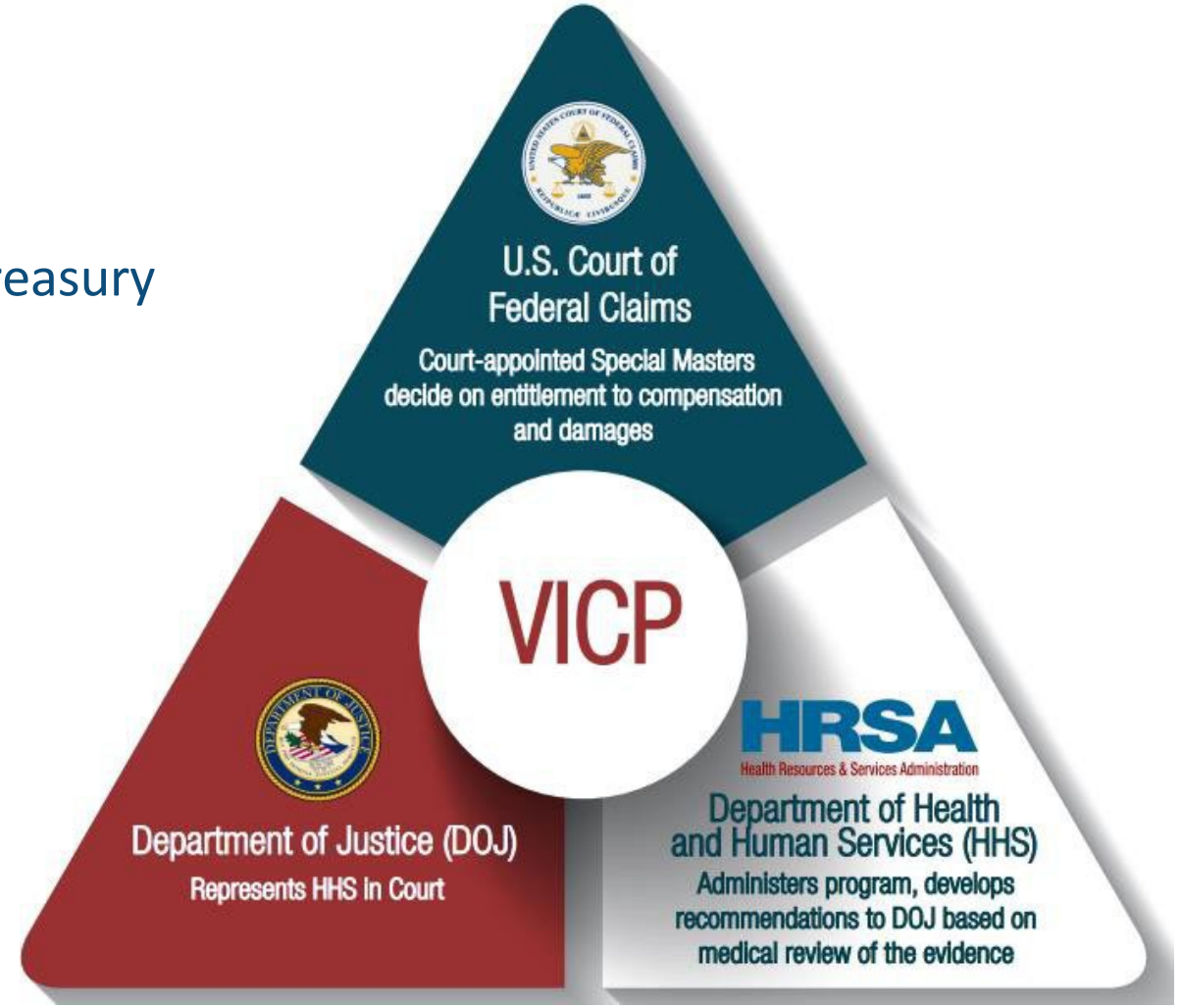
VICP Roles

Department of Treasury



Vaccine Injury Compensation Trust Fund

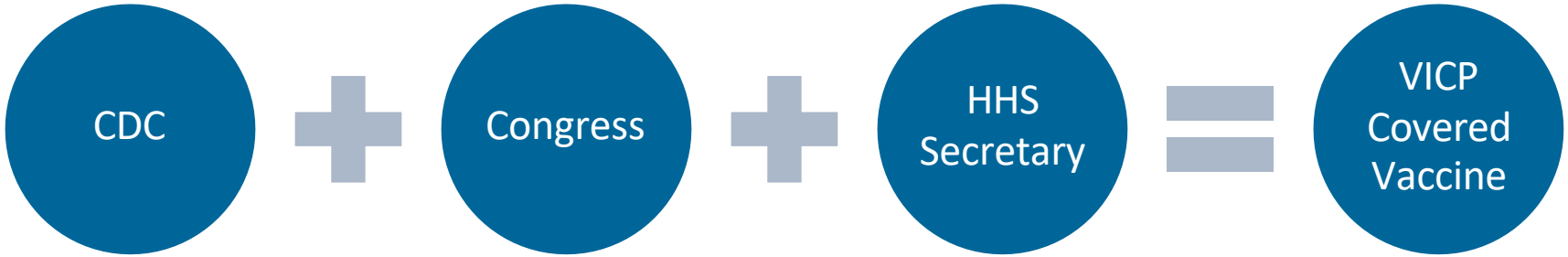
- Vaccine Injury Compensation Trust Fund provides the funding
  - To compensate eligible petitions filed (mandatory funding)
  - To administer the Program (discretionary funding)

- Funded by a $0.75 excise tax imposed on each dose of a vaccine, meaning each disease presented (so e.g. MMR = $2.25)

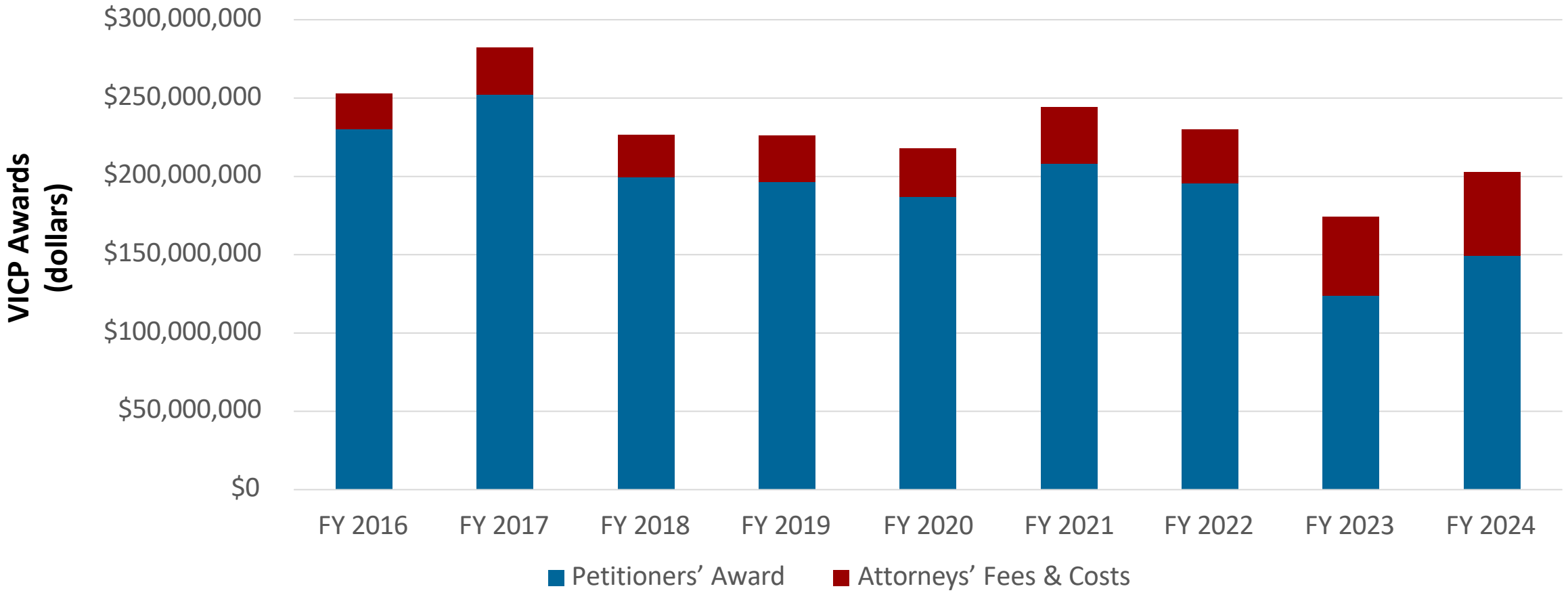
- Internal Revenue Code language defines vaccine and specifies the specific categories of vaccine for taxation

Criteria to be a Covered Vaccine in VICP

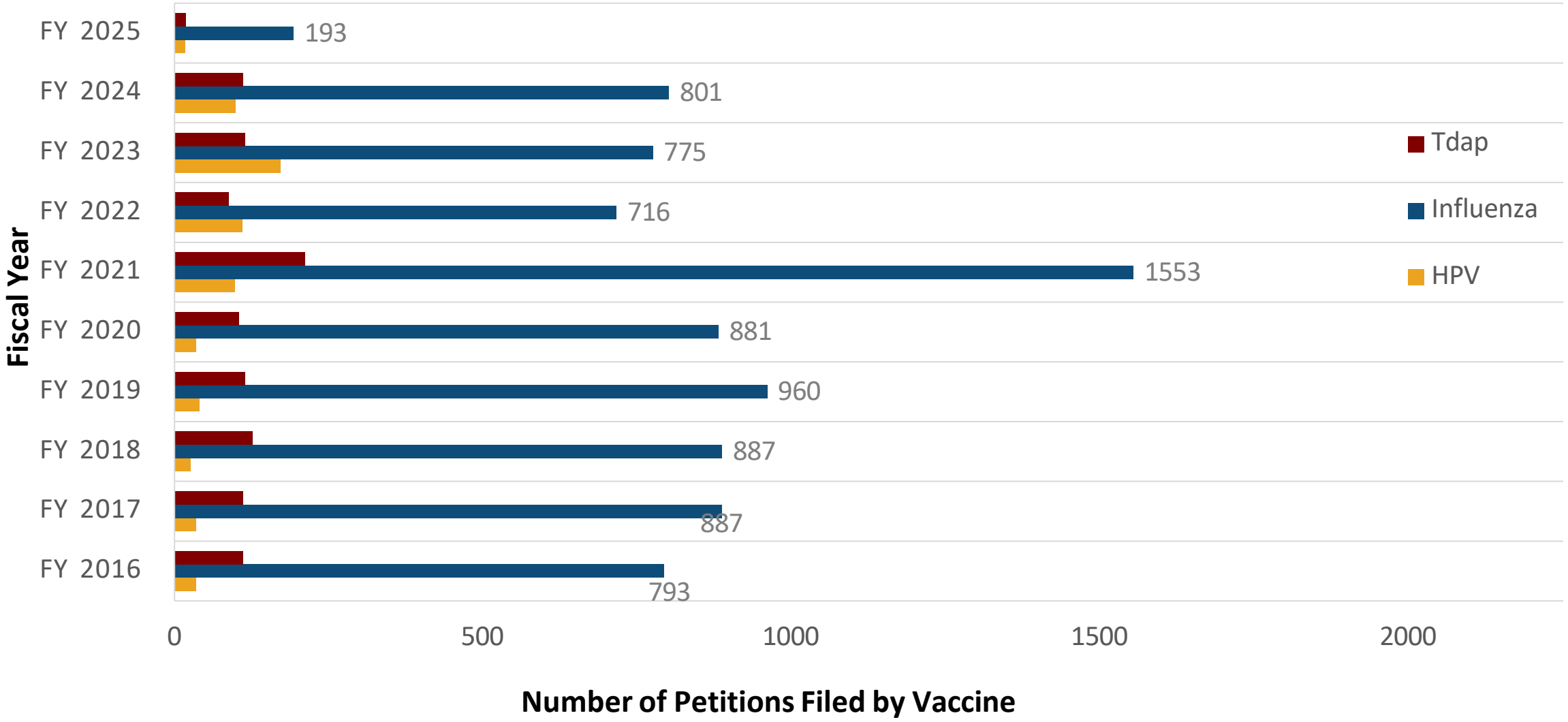
- Centers for Disease Control and Prevention (CDC) must recommend the vaccine for routine administration to children or pregnant people;
- Congress must approve an excise tax on the vaccine, which funds the administration of the VICP; and
- HHS Secretary must add the vaccine by regulation.



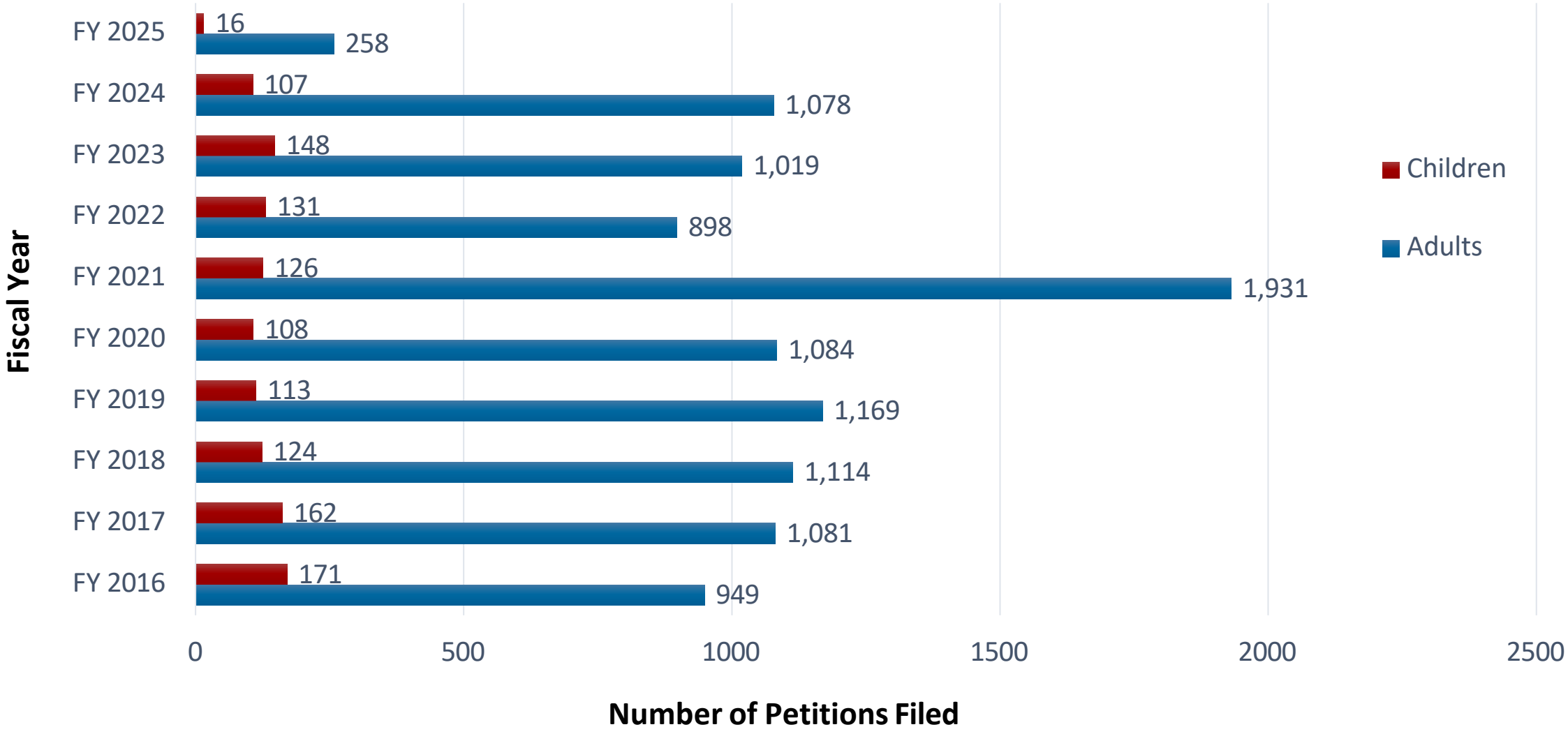
VICP Award Amounts for Petitioners' and Attorneys, FY 2016 – FY 2024



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



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



CICP and the PREP Act

PREPAct Overview

- Authorizes the Secretary of 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

PREPAct Compensation Requirements

- Allows for compensation for serious physical injuries or deaths directly caused by the administration/use of countermeasures covered by declarations.
  - Authorized a Covered Countermeasures Process Fund (i.e., CICP)
- If one of the following occurs, then an individual may pursue a tort claim in the United States District Court for the District of Columbia, but only if the claim involves willful misconduct and meets the other requirements for suit under the PREP Act:
  - ✓ funding has not been appropriated for the program;
  - ✓ the program fails to make a final determination within 240 days after a request was filed; or
  - ✓ the program determines that a covered individual qualifies for compensation, but the individual decides not to accept the compensation

CICP Compensation Requirements

- Provides compensation to eligible individuals who sustain a serious injury or death directly caused from administration/use of covered countermeasure
  - Based on *"compelling, reliable, valid, medical and scientific evidence"*

- Serious injuries are defined as those
  - warranting hospitalization (whether the individual was hospitalized or not), or
  - leading to a significant loss of function or disability.

- Requests for benefits (RFB) must be filed within 1 year of administration/use of covered countermeasure

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

CICP Eligible Requesters

- 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

1. An individual submits an RFB Package.

2. Once all expected medical records are received, the case is put in queue for review

3. 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.

4. 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.

5. The requester is notified in writing either if they were found entitled to program benefits, or if they were found ineligible for benefits.

CICP Resources

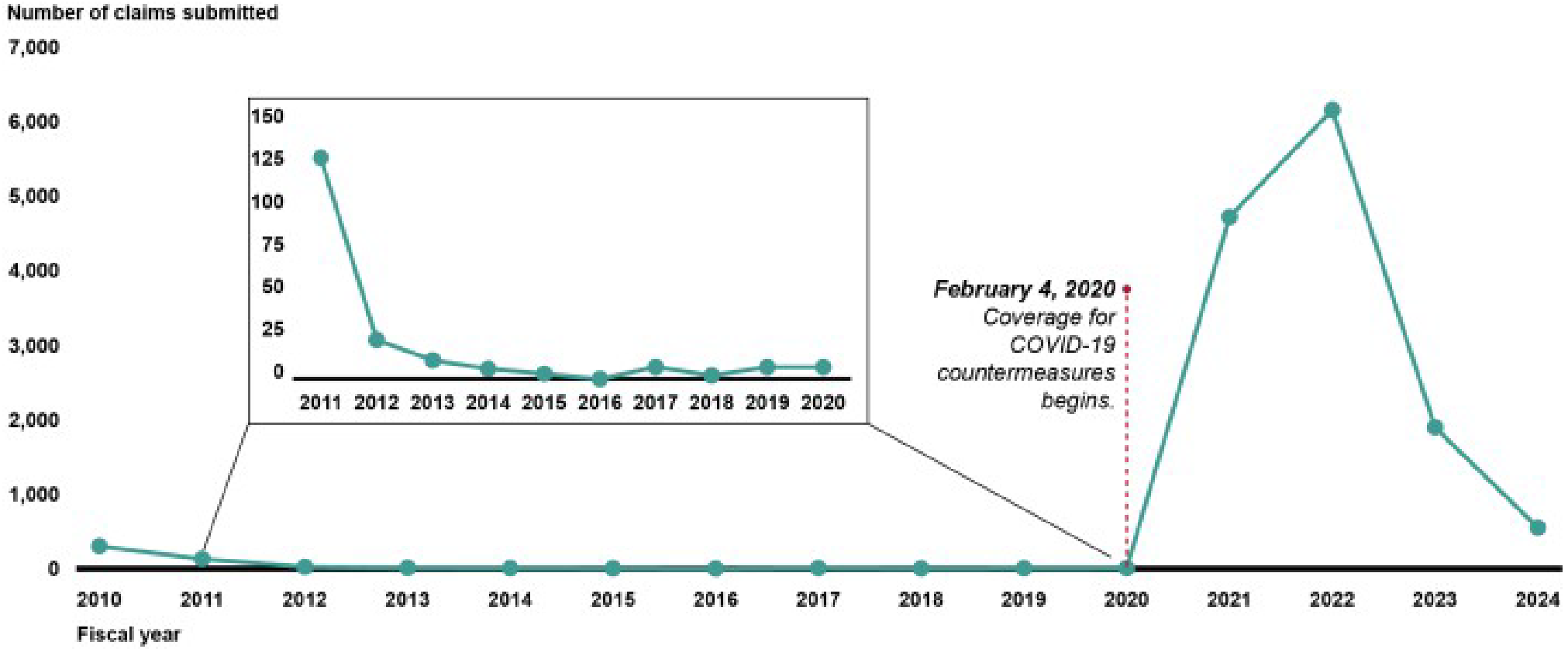
- At the beginning of the COVID-19 pandemic, CICP had four (4) staff supporting CICP operations

- 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 (11) as of 2025 year end and expedite claim review throughout

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



Source: GAO analysis of Health Resources and Services Administration data. | GAO-25-107368

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 Data as of September 1, 2025 (2026)

- Total CICP Claims Filed: **14,480 (14, 760)**
  - Total COVID Claims: **13,898 (14,152)**
- Decisions: **5,719 (8,004)** (**5,150) (7,407)** COVID-19 decisions rendered)
  - Eligible for Compensation: **122 (149)**
    - ✓ Compensated: **71 (90)**
    - ✓ Pending Benefits Determination: **40 (45)**
    - ✓ No Eligible Reported Expenses: **11 (14)**
  - Pending Review or In Review: **8,761 (6,756)**
  - Denied: **5,597 (7,855)**
    - ✓ Requested Medical Records not Submitted: **1,629 (3,081)**
    - ✓ Standard of Proof Not Met and/or Covered Injury not Sustained: **1,184 (1,682)**
    - ✓ Missed Filing Deadline: **2,403 (2,673)**
    - ✓ Not CICP Covered Product/Not Specified: **381 (419)**

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 (status in flux) historically played 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 thousands are still open

Secondary Analyses

Review	Description
Chu et. al. (2025)	This study examines the structure and effectiveness of 14 no-fault vaccine injury compensation schemes, analyzing data on approval rates for COVID-19 vaccine injury claims. Data sources include government reports and academic studies to compare diverse operational models and funding sources.
Kang et. al. (2024)	Analysis of Vaccine Injury Compensation Programs in 10 countries to present implications for improving the Korean system.
Fairgrieve et al. (2023)	Comparative analysis of the global landscape of vaccine injury compensation schemes given the near exponential growth of schemes as a result of the rapid development of the COVID-19 vaccines.
Halabi et al. (2022)	An analysis of no-fault compensation schemes established in the emergency context as well as the avenues that established no-fault compensation schemes to low- or middle-income countries after COVID-19.
Crum et. al. (2021)	Analyzed 25 published articles relating to vaccine compensation injury programs, vaccines, injuries, disabilities, illnesses, and deaths resulting from vaccination.

Chu CF, Chang TH, Ho JJ**. Comparative analysis of fourteen COVID-19 vaccine injury compensation systems and claim approval rates**. Vaccine. 2025 Apr 11;52:126830. doi: 10.1016/j.vaccine.2025.126830. Epub 2025 Mar 3. PMID: 40037238.

Kang CR, Choe YJ, Yoon SJ. **COVID-19 Vaccine Injury Compensation Program: Lessons Learned From a Review of 10 Implementing Countries**. J Korean Med Sci. 2024 Apr 8;39(13):e121. doi: 10.3346/jkms.2024.39.e121. PMID: 38599598; PMCID: PMC11004775.

Fairgrieve D, Rizzi M, Kirchhelle C, Halabi S, Howells G, Witzleb N. **Comparing No-Fault Compensation Systems for Vaccine Injury.** Tulane International and Comparative Law Journal (2022)

Halabi S, Arora N, Durran A, Qian Q, Ummer S, Ginsbach K, Aneja K**. No fault vaccine injury compensation after COVID-19: A systematic literature review and proposed typology.** Hum Vaccin Immunother. 2026 Dec;22(1):2620849. doi: 10.1080/21645515.2026.2620849. Epub 2026 Feb 2. PMID: 41630128; PMCID: PMC12885411.

Crum T., Mooney K., Tiwari B.R. **Current situation of vaccine injury compensation program and a future perspective in light of COVID-19 and emerging viral diseases.** F1000Research. 2021;10:652. doi: 10.12688/f1000research.51160.2

National and International No-Fault Vaccine Injury Compensation Systems

Number of NFCs	International/Regional NFCs	Median Age of National NFCs	Number of NFCs administered by subnational governments	Number of NFCs 100% publicly funded
28	3	6 years	3	24

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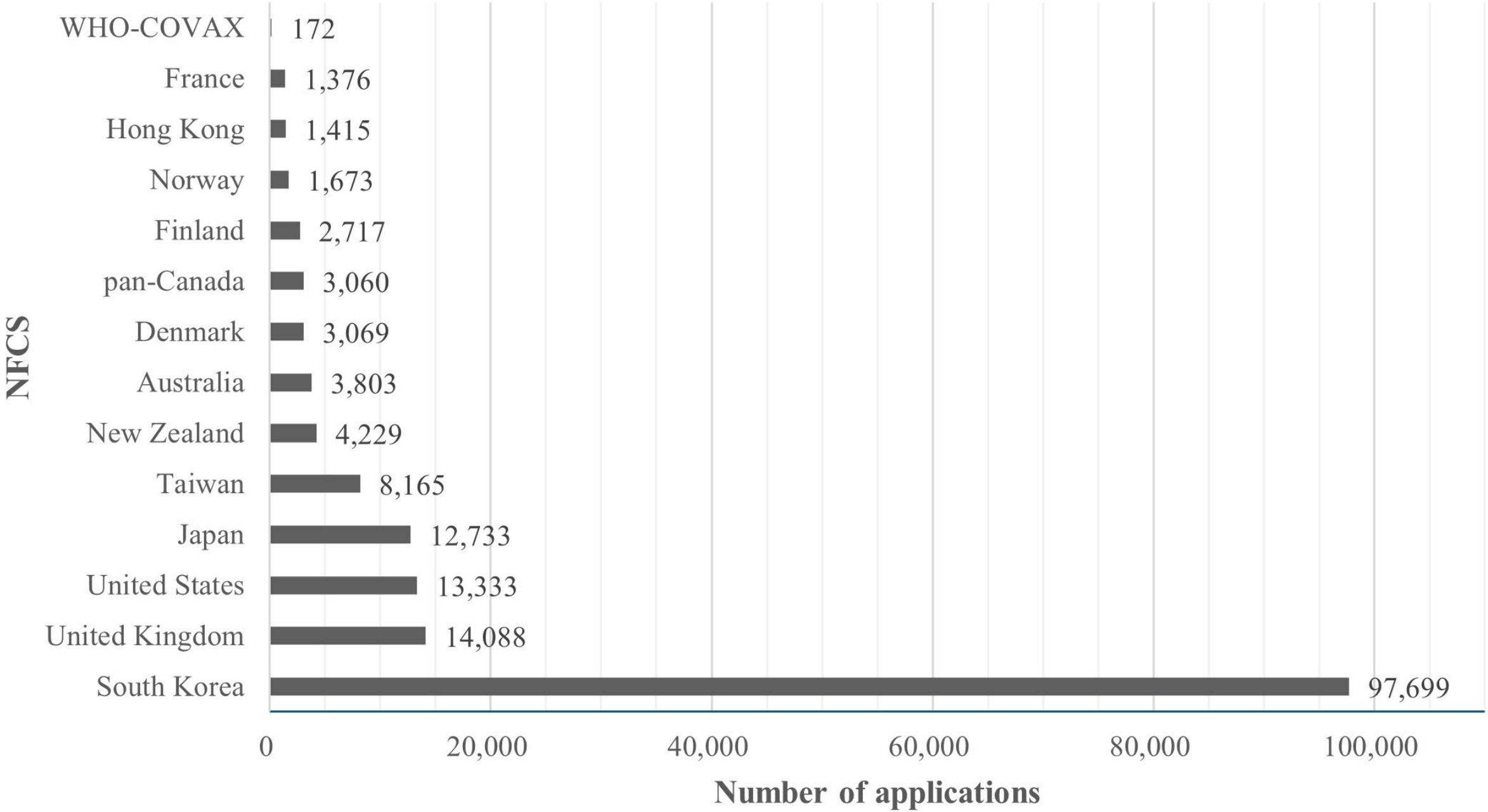
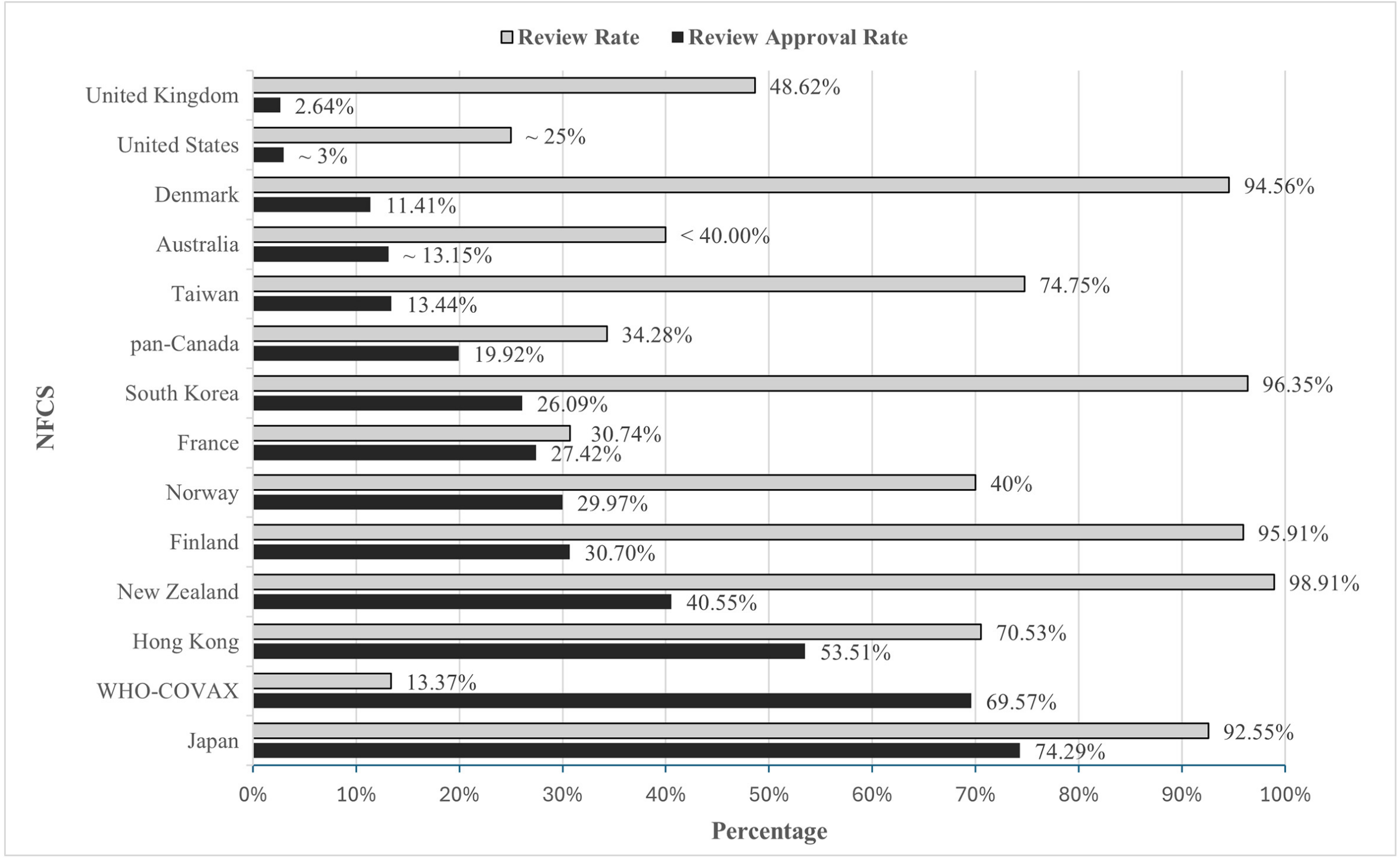

WHO-COVAX
172
France
1,376
Hong Kong
1,415
Norway
1,673
Finland
2,717
pan-Canada
3,060
Denmark
3,069
Australia
3,803
New Zealand
4,229
Taiwan
8,165
Japan
12,733
United States
13,333
United Kingdom
14,088
South Korea
97,699
NFCS
0
20,000
40,000
60,000
80,000
100,000
Number of applications


Review Rate
Review Approval Rate
United Kingdom
48.62%
2.64%
United States
~ 25%
~ 3%
Denmark
94.56%
11.41%
Australia
< 40.00%
~ 13.15%
Taiwan
74.75%
13.44%
pan-Canada
34.28%
19.92%
South Korea
96.35%
26.09%
France
30.74%
27.42%
Norway
40%
29.97%
Finland
95.91%
30.70%
New Zealand
98.91%
40.55%
Hong Kong
70.53%
53.51%
WHO-COVAX
13.37%
69.57%
Japan
92.55%
74.29%
NFCS
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Percentage

Australia

- **Australia**: Australia created a no fault compensation system pursuant to the Covid-19 pandemic. Its system was created on 22 February 2021 and closed to new claims on September 30, 2024. This scheme was created under federal legislation, the Financial Framework (Supplementary Powers) Regulations 1997 (Cth), Schedule 1AB, Part 4, Item 506. Australia is geographically large like the US and also maintains a robust system of federalism that divides responsibility for health-related policies and authority between state and federal governments. Unlike the US, Australia processes, adjudicates, and pays claims through Services Australia, with close cooperation with the Department of Health and Aged Care and its Therapeutics Goods Administration (the equivalent of FDA). Australia's system maintains a lower standard for compensable injury and does so according to an injury table that divides injuries into three tiers. Only Tiers 2 and 3 are reviewed and adjudicated and there is a minimum threshold of injury of AUD 1,000.

Germany

Germany: Only China, Italy, and Germany administer their no-fault compensation systems at the provincial level. Switzerland did before 2016. The 'Infektionsschutzgesetz' ('IfSG'), ('German Infection Protection Act') in conjunction with the Federal Law on War Pensions ('Versorgung nach dem Bundesversorgungsgesetz'/'BVG'), regulates the current no-fault compensation scheme for vaccine injuries in Germany.

Claims for compensation are filed with the Social Affairs Offices (Versorgungsämter). The Public Health Departments of the respective Federal States (Länder) are responsible for producing reports assessing potential causal links between vaccination and damage to health, and can offer assistance with the initiation of compensation claims. The funding for the scheme comes from the relevant federal state (Land). Germany's system also covers both temporary and permanent injuries. Eligible injuries are defined as '…the health-related and economic consequences of a health impairment due to vaccination the degree of which exceeds that of a normal post-vaccinal reaction' – Section 2, 11 IfSG.

Sweden

Sweden: Only Canada (2021), Finland (2012), Norway (2004), and Sweden (1978) governments comprehensively use third-party administrators for their schemes and only Canada uses a for-profit third party. Finland and Sweden use non-profit entities whose members are health product manufacturers who pay premium in proportion to their turnover in sales in-country and are also shareholders of the non-profit entity. Under the Finnish and Swedish schemes, all medicines producers contribute to an insurance scheme covering injuries from adverse events. Sweden's is administered by the Swedish Pharmaceutical Insurer (Svenska Läkemedelsförsäkringen or LFF). Companies and organizations that take out pharmaceutical insurance become a partner in the jointly owned company LFF Service AB. Each policyholder owns a share each in LFF Service AB. This company in turn owns Svenska Läkemedelsförsäkringen AB or LFF, a captive insurance company that handles the damage claims processing. The Scheme rules are set out in an Undertaking.

Norway operates under a combined system where it is administered by the central government but funded via a combination of national treasury funds and contributions from the pharmaceutical industry. Finland's system operates similarly to Sweden, but does so with the national government as a reinsurer.

United Kingdom

United Kingdom: The UK scheme was created under national legislation, the Vaccine Damage Payments Act 1979 and the Vaccine Damage Payments (Specified Disease) Order 2020. Since 1 November 2020 it has been administered by the NHS Business Services Authority (NHSBSA), a public body. Like Canada, the UK's system only covers permanent injuries although any injury is potentially covered. Compensation only issues where there is a finding of 60% or greater disablement. When there is such a finding, a single lump sum payment of £120,000 issues.

Post-COVID Observations

- Large increases in claims related to COVID-19 as well as complex cases and/or cases submitted with insufficient information have created backlogs and have made claims processing resource intensive for all jurisdictions.
- In Canada, the portion of no-fault compensation budget dedicated to payouts versus non-payout costs is among the highest among all countries. As of December 2024, OXARO had received $56.2 million and paid out $16,574,972 in compensation, or approximately 77% of costs went to program administration. For Sweden, that proportion is 12-14% and for Quebec 10-20%. With respect to the US, it is currently 70%, although the portion is likely to decline as a $10M appropriation is further paid to claimants.
- Use of tables of allowances and/or pre-determined structure for compensation has been credited with facilitating efficient and appropriate assessment and payment. Australia, Quebec, and the US use such tables (though the US has not done so for COVID-19 vaccines). Sweden does not use tables but does use claims adjusters with extensive (10 years) experience.

Sweden's LFF System

Funding Structure

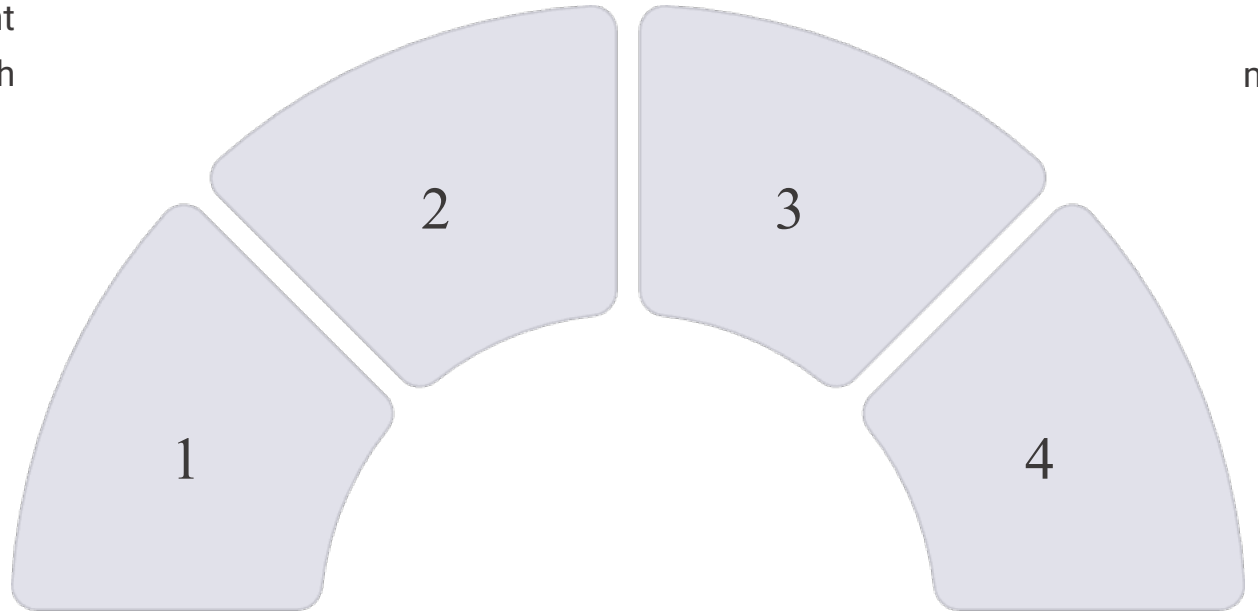
Insurance contributions from LFF members form the primary funding mechanism. Government provides statutory top-up through provision 2020/21:221.

Administrative Efficiency

14% administrative costs position Sweden between Finland and Canada in operational efficiency.

Payout Allocation

86% of budget directed to claimant compensation demonstrates strong financial prioritization.



Government Intervention

Swedish government indemnifies when manufacturers aren't LFF members or when claims exceed 20M SEK cap.

Finland's Compensation Framework*

€ 7M

Annual Funding

Insurance premiums from pharmaceutical companies

500

Claims Processed

Lowest volume among compared nations

12%

Administrative Costs

Moderate efficiency level

88%

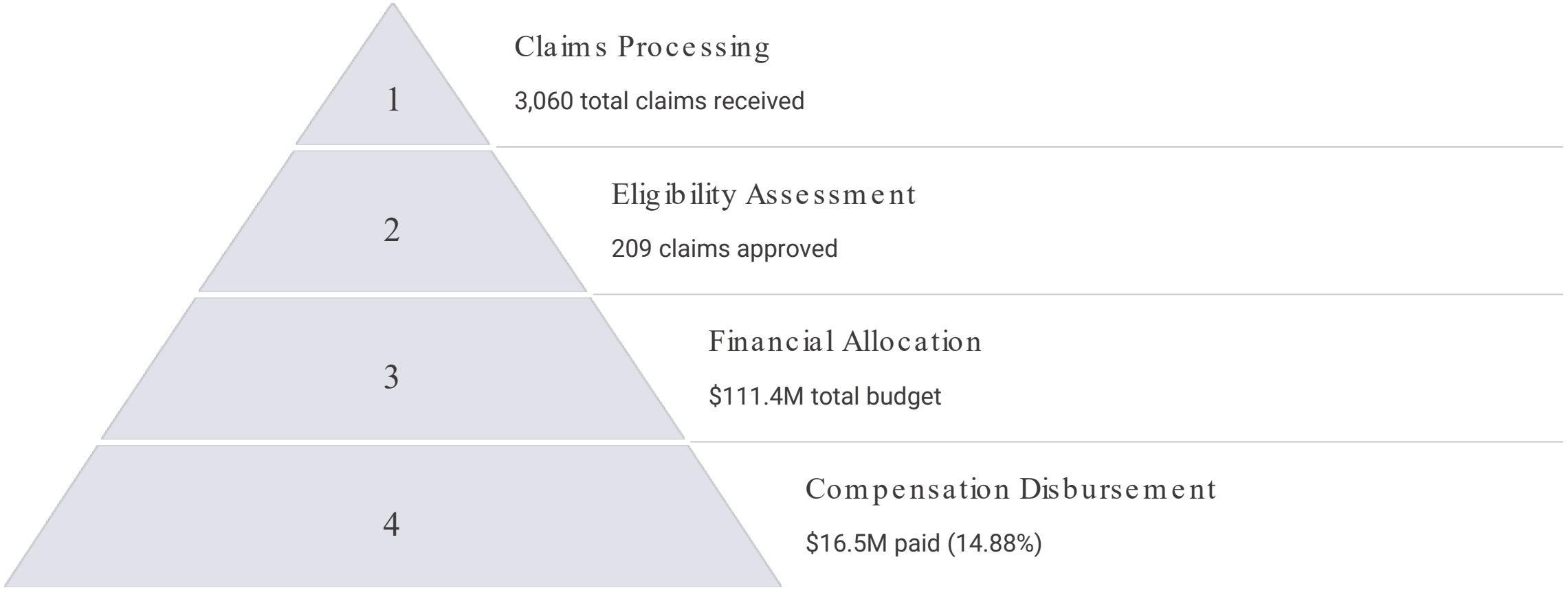
Payout Allocation

High percentage to claimants

The Finnish system utilizes government guarantees for COVID-19 claims since reinsurance was unavailable. Investment income supplements funding through bonds, real estate, and equity funds.

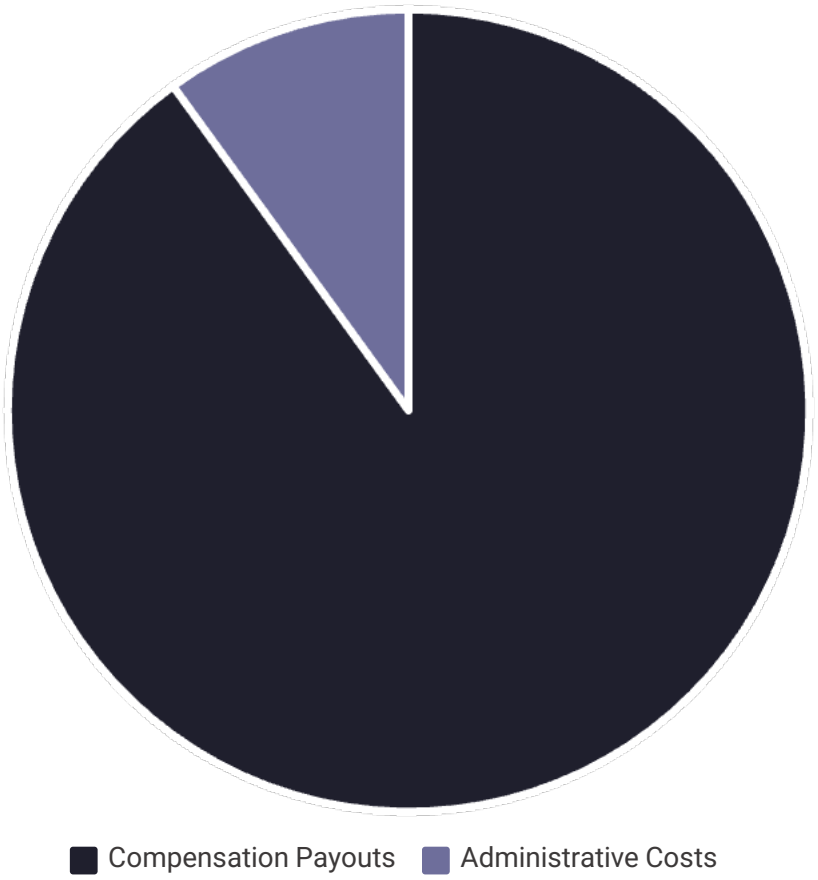
*These figures are taken from the financial statements for Finnish Mutual Insurance Company in 2023

Canada's VISP Program



Canada's federally funded program has expanded its budget allocation from an initial $75M to $111.4M by 2024. In 2026, announced transition from third-party processor to government-run system.

New Zealand's ACC System



- ACC's vaccine compensation comes from central government funding, employer contributions, and motor vehicle levy.
- With 4,229 total COVID-19 vaccine claims lodged, 1,696 were accepted and 2,487 declined.
- The system disbursed NZD 10.66 million between February 2021 and January 2024, demonstrating high financial efficiency with 90% allocation to payouts.