"Assessing America's Vaccine Safety Systems, Part 1"
February 15, 2024

Responses to Questions for the Record
Select Subcommittee on the Coronavirus Pandemic
Committee on Oversight and Accountability
U.S. House of Representatives

Questions for the Record from Rep. Mariannette Miller-Meeks

1. **What is the rate of denial for compensation for claims for COVID-19 vaccines in CICP?**
2. **What is the current backlog of claims in CICP? (answer should be more than 10,000)**
3. **Why is there such a backlog of claims at CICP for COVID-19 vaccines?**
4. **Can you highlight some of the differences between how COVID-19 claims are adjudicated, versus vaccines in VICP?**
5. **Is it harder to win in CICP?**
6. **Is there a shorter deadline to file in CICP?**
7. **Are the payouts smaller in CICP?**
8. **Are the eligible injuries fewer in CICP?**
9. **Can petitioners appeal decisions in CICP?**
10. **According to Renee Gentry, the Director of George Washington University's Vaccine Injury Litigation Clinic, the cost of [CICP's] failing will be like throwing kerosene on the antivax fire."**
    a. **Do you believe properly compensating those injured by vaccines, no matter how many or how few, is necessary in the preservation of trust in vaccines?**

11. **HHS and HRSA have paid billions in promoting and distributing Covid vaccines but has only paid out $41,000 total for Covid vaccine injuries.**
    a. **Do you believe this is sufficient in preserving the public's trust in vaccines?**

Response: The Countermeasures Injury Compensation Program (CICP) and the National Vaccine Injury Compensation Program (VICP) are distinct programs and have different statutory requirements, eligibility standards, and adjudication processes. In 2020, the PREP Act declaration for medical countermeasures against COVID-19 was issued by the then-HHS Secretary, which allowed for claims of injury from COVID-19 covered countermeasures, including COVID-19 vaccines, to be considered by the CICP. COVID-19 vaccines will not be eligible for VICP unless certain steps are taken, including that Congress takes action to make them eligible through the enactment of an excise tax on the vaccines.

Overview of the CICP Program

The PREP Act established the CICP as a compensation program for serious physical injuries or death ("covered injury") determined to be directly caused by the administration or use of a countermeasure covered under a PREP Act declaration. A covered countermeasure can include a

vaccine, medication, device, or other item used to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic. In establishing the CICP, Congress defined the threshold that must be met for an individual to be eligible for compensation. Specifically, Congress required that, to be eligible for compensation, the covered countermeasure must have directly caused the covered injury – not just be temporally associated with receipt or use of the countermeasure – and that such determinations can only be based on "compelling, reliable, valid, medical, and scientific evidence."

Congress also required that the CICP can pay only reasonable and necessary unreimbursed medical expenses, a portion of lost employment income, or a death benefit. The CICP is a secondary payer to other government and third-party payers. Generally, this means CICP compensation is reduced by the amount paid or owed to a requester by other government benefits programs, workers' compensation, or private insurance like health insurance. By statute, neither damages for pain and suffering nor attorneys' fees are payable under the CICP.

The CICP is required by law to compensate claims only after a requester establishes that a covered countermeasure directly caused a covered injury. A CICP requester must submit a Request for Benefits Form or Letter of Intent within one year of receipt of a countermeasure. A requester must also provide documentation, including comprehensive medical records, showing that the covered injury was directly caused by the administration or use of a covered countermeasure. The CICP then conducts an individualized medical review to determine if there is compelling, reliable, valid, medical, and scientific evidence that the covered injury was directly caused by the administration or use of a covered countermeasure under the PREP Act declaration. The CICP conducts these detailed medical reviews, which include closely reviewing and monitoring the medical literature and regularly engaging with requesters to obtain additional medical documentation as needed, to ensure that requesters have a robust opportunity to demonstrate whether the injury meets the statutory evidence standard.

Pursuant to 42 CFR § 110.90, requesters have the right to seek reconsideration of a decision that they are not eligible for program benefits, which includes missing the filing deadline, or as to the amount of benefits. Reconsideration requests must be postmarked within 60 calendar days of the date of the determination letter. Reconsideration requests are reviewed by a panel independent of the CICP and are decided by the Associate Administrator. This determination is the agency's final determination on the issue for which the reconsideration was sought. No new documentation may be considered during the reconsideration process that was not previously provided to the CICP at the time of determination. The reconsideration panel bases its recommendation on the documentation before the CICP when the original determination(s) was made.

Overview of the VICP Program

The VICP was established as part of the National Childhood Vaccine Injury Act of 1986. Serving as an alternative to the traditional tort system, the VICP compensates individuals who have been found to be injured by (or to have died from) certain vaccines. HRSA administers the VICP, and the Department of Justice (DOJ) represents HHS in the U.S. Court of Federal Claims (Court), which ultimately decides whether to provide compensation or to dismiss claims. For a

vaccine to be covered under the VICP, three conditions must be met: (1) the Centers for Disease Control and Prevention (CDC) must recommend the vaccine for routine administration to children or individuals who are pregnant; (2) Congress must enact an excise tax on the vaccine, which funds the administration of the VICP; and (3) the HHS Secretary must add the vaccine to the VICP.

Determination for VICP compensation follows a judicial process, under which claimants (petitioners) file a petition for vaccine injury compensation with the Court. HHS makes a preliminary recommendation on eligibility for compensation that is incorporated into a response to the petition filed by DOJ, which is submitted to a court-appointed special master. After considering the evidence, the special master makes a determination related to eligibility and compensation. The Vaccine Injury Compensation Trust Fund is supported through a $0.75 excise tax enacted by Congress on each dose of vaccine recommended by the CDC for routine administration to children or individuals who are pregnant.

Overview of CICP Claim Reviews After COVID-19

HRSA has received approximately 13,000 CICP claims alleging a COVID-19 countermeasure injury (roughly 9,600 allege COVID-19 vaccines as the covered countermeasure) since the PREP Act declaration for medical countermeasures against COVID-19 was issued in 2020. For context, over its 10-year history prior to the COVID-19 pandemic, the Program received about 500 claims in total. While injuries are rare and the claims received for COVID-19 vaccines represent less than .001 percent of all COVID-19 vaccine administrations in this country, the current caseload is of a different order than the previous volume of claims in the CICP given the scale of the utilization of COVID-19 covered countermeasures.

At the time the PREP Act declaration for COVID-19 was issued in 2020, the CICP had no direct appropriation and only four staff. HRSA received a direct appropriation for the first time in the history of the Program in fiscal year 2022 – although less than the amount requested in the President's Budget. HRSA has worked to increase staff to process claims. HRSA also implemented other key process improvements to resolve claims at a faster rate. Additionally, the Agency is improving information technology and other communication with CICP requesters.

Questions for the Record from Rep. Debbie Lesko

1. Have you investigated the case I mentioned in my question and my staff followed up with you about my former constituent Steve Wenger? If so, what have you found out?

Response: We attempted to contact the requester to update them regarding the status of their claim. At this time, we have received the medical records submitted by the requester and will continue to work as expeditiously as possible to process all claims.

2. What steps are you taking to remedy the situation with Steve Wenger?

Response: We appreciate how important this claim is to your constituent. As a reminder, HRSA medical staff conduct a thorough, individualized review of a requester's medical records to determine whether a COVID-19 countermeasure directly caused the requester's injury based on the standard set out in the PREP Act. We continue to work as expeditiously as possible to process all claims.

Questions for the Record from Rep. Michael Cloud

1. Do you own individual stocks in any of the following companies?
    a. Pfizer
    b. Moderna
    c. BioNTech
    d. Novavax

Response: All federal employees are responsible for preventing conflicts of interest, including financial interests that conflict with official Government duties and responsibilities. General Schedule employees whose duties require them to participate personally and substantially through the decision-making or the exercise of significant judgment in a matter which could have an economic impact on a non-Federal entity are required to file a confidential financial disclosure report. The confidential financial disclosure system assists employees and their agencies in avoiding conflicts between official duties and private financial interests or affiliations. Only authorized personnel within a filer's agency have access to these reports. Section 13109 of Title 5, United States Code (commonly referred to as part of the Ethics in Government Act), provides that confidential financial disclosure reports shall be confidential and shall not be disclosed to the public.

2. Several of the COVID-19 vaccines have received full FDA approval and are no longer being used under emergency authorization. Is it standard practice for the countermeasures that have received such approval to continue receiving liability protection under the PREP Act and for injury claims regarding these countermeasures to be compensated via the Countermeasures Injury Compensation Program?

Response: Yes, there are several vaccines with Food and Drug Administration (FDA) approval that are covered under PREP Act declarations and thus maintain PREP Act liability protection and eligibility for injury compensation through the CICP, including Anthrax vaccines to protect against the bacterium *Bacillus anthracis*, the JYNNEOS vaccines for protection against smallpox and mpox, and ACAM2000 vaccines for smallpox protection. COVID-19 vaccines will not be eligible for VICP unless certain steps are taken, including that Congress takes action to make them eligible through the enactment of an excise tax on the vaccines.

3. What criteria would need to be satisfied to rescind the current PREP Act declaration and remove the covid vaccines from the CICP before its October 2024 expiration date?
    a. How are these criteria decided upon and who is responsible for making such a decision?

Response: The current PREP Act declaration for medical countermeasures against COVID-19 is in effect through December 2024. The decision to enact, amend, renew, or terminate a PREP Act declaration is under the purview of the Secretary of Health and Human Services. However, no amendments can retroactively limit the applicability of a PREP Act declaration with respect to the administration or use of a covered countermeasure. COVID-19 vaccines are not eligible for VICP unless certain steps are taken, including that Congress takes action to make them eligible through the enactment of an excise tax on the vaccines.