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on

"Assessing America's Vaccine Safety Systems, Part 1"

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Chairman Wenstrup, Ranking Member Ruiz, and Members of the Subcommittee, thank you for the opportunity to speak with you today about the work of the Health Resources and Services Administration's (HRSA) injury compensation programs. My name is Commander Reed Grimes, and I am the Director of the Division of Injury Compensation Programs for HRSA, the agency of the Department of Health and Human Services (HHS) that oversees both the Countermeasures Injury Compensation Program (CICP or "the Program") and the National Vaccine Injury Compensation Program (VICP). I am a physician double-board certified in Occupational Medicine and General Preventive Medicine and Public Health, having proudly served in uniform with the Commissioned Corps of the United States Public Health Service and the United States Navy for nearly 15 years of active-duty status. Prior to coming to HRSA, I led in several roles advancing our Nation's emergency preparedness and response efforts. I became the Director of Injury Compensation Programs in 2021, where I lead a team dedicated to supporting the Nation's public health through the implementation of these critical injury compensation programs created by Congress. Our team ensures that people who are injured by certain vaccines or other medical countermeasures have an avenue to seek compensation for their injuries.

The Countermeasures Injury Compensation Program

The CICP was authorized by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act) and began operation in Fiscal Year (FY) 2010. Under the PREP Act, the HHS Secretary can issue a PREP Act declaration when he or she determines that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency. 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, or treat 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."[1] Congress also required that the CICP can pay only unreimbursed medical expenses, a portion of lost employment income, and a death benefit. The CICP must be a secondary payer to other government and third-party payers, meaning the CICP must subtract from the compensation payment the value of other government benefits, workers' compensation, or private insurance like health insurance that are paid or owed to a requester. 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 documentation, including comprehensive medical records, showing that the covered injury was directly caused by the administration or use of a covered countermeasure.[2] The CICP then conducts an individualized medical review to determine if there is compelling, reliable, valid, medical and scientific evidence that the serious physical injury or death was directly caused by

[1] Section 319F-4(b)(4) and (5)(A) of the Public Health Service (PHS) Act (42 U.S.C. 247d-6e(b)(4) and (5)(A)).
[2] Parts 110.20, 110.50-110.53 of the Title 42 of the Code of Federal Regulations (42 CFR 110.20(a), 110.50-110.53)

the administration or use of a covered countermeasure under the PREP declaration. The CICP conducts these detailed medical reviews, including closely reviewing and monitoring the medical literature and regularly engaging with applicants to obtain additional medical documentation as needed to ensure that applicants have a robust opportunity to demonstrate whether the injury meets the statutory evidence standard. In addition, when there is sufficient evidence to meet the statutory standard for identifying serious physical injuries that are shown to be directly caused by the administration or use of a certain covered countermeasure, the HHS Secretary can establish a Covered Countermeasures Injury Table. Such Tables list and explain injuries that, based on compelling, reliable, valid, medical, and scientific evidence, are presumed to be caused by a covered countermeasure, and the time periods in which the onset (i.e., first sign or symptom) of these injuries must occur after administration or use of the covered countermeasure to be covered by the Table. If an injury identified on a Table occurred within the listed time periods, and at the level of severity required (i.e., a serious physical injury or death), there is a rebuttable presumption that the covered countermeasure was the cause of the injury.

If the requester is eligible for compensation, the PREP Act authorizes the CICP to provide compensation, minus the paid or owed amounts from other third-party payers, for limited statutorily specified benefits including unreimbursed medical expenses and lost employment income to the requester or the requester's estate, as well as death benefits to requesters' survivors. By statute, the Program is limited in the types of compensation it can provide.[3] CICP benefits are also subject to various annual and lifetime limits. For example, annual lost employment income awards are capped at $50,000 per year; the standard maximum death benefit

[3] Section 319F-4(b)(2) of the PHS Act (42 U.S.C. 247d-6e(b)(2), referencing sections 264-266 of the PHS Act (42 U.S.C 239c-239e).

is the same as that under the Public Safety Officers' Benefits program (currently $422,035). To comply with the law's requirement that the CICP function as a secondary payer after other public and private payers (including insurance and public benefits), the CICP must also request detailed benefit and reimbursement information from applicants to document what health insurance, life insurance, Veterans benefits, workers' compensation, and other third-party payers may have an obligation to pay for the eligible injury before the CICP compensation amount is calculated.

Since the CICP began operating, PREP Act declarations have authorized compensation for covered injuries directly caused by medical countermeasures against multiple different public health threats, although the vast majority of CICP claims that have been compensated prior to COVID-19 were for H1N1 influenza and totaled less than 35 claims. In fact, prior to COVID-19, the CICP received only about 500 claims over its 10-year history.

COVID-19

HHS Secretary Azar issued a PREP Act declaration for medical countermeasures against COVID-19, effective February 4, 2020. COVID-19 vaccines authorized under the Food and Drug Administration's (FDA) emergency use authorization authority are included in the countermeasures covered by the COVID-19 PREP Act declaration, as are FDA-approved COVID-19 vaccines. The PREP Act declaration was amended several times and is currently in effect through December 31, 2024. To date, approximately 13,000 claims alleging a COVID-19 countermeasure injury have been filed with the CICP for various countermeasures, including not only vaccines but also medications, ventilators, or other equipment. Of these, 9,682 claims allege COVID-19 vaccines as the covered countermeasure, which is equivalent to approximately 0.001

percent of all COVID-19 vaccine administrations in the United States.[4] While injuries are rare and these claims represent a small fraction of the approximately 676 million total COVID-19 vaccines that have been administered in the United States, the current caseload is of a different order than the previous volume of claims in the Program given the scale of the utilization of COVID-19 covered countermeasures.

At the time of the issuance of the PREP Act declaration in 2020, the CICP had no direct appropriation and only four staff. When I became Director, I immediately focused on the need to increase the Program's capacity to conduct medical reviews of applications. To support this goal, in FY 2022, the CICP sought a direct appropriation for the first time in the history of the Program. The President's FY 2024 Budget proposes $15 million to operate the CICP to support: (1) the Program's capacity to analyze claims and make determinations – including through increased medical claims review staffing, (2) the CICP information technology infrastructure to better facilitate claims processing; (3) process efficiencies in the review and management of claims; and (4) improved communication with requesters. Resources are necessary for the Program to conduct reviews.

Notwithstanding the ongoing resource constraints, securing initial modest appropriations has allowed the Program to make some targeted improvements in increasing hiring, implementing key process improvements, and beginning to augment capacity to conduct medical reviews, leading to progress in reviewing claims. The CICP now has over 35 full-time staff members

[4] Data on COVID-19 vaccines administered as of May 2023, when tracking of this statistic concluded at the end of the COVID-19 Public Health Emergency.

working to process claims. Additionally, due to other improvements, the CICP is now processing claims at a faster rate. For example, in 2020, the CICP averaged zero claims resolved per month; in 2023, the CICP resolved more than 90 claims per month – that average would be expected to increase even more significantly under the President's FY 2024 Budget. The Program is also working to improve information technology and other communication with claimants. In 2023, the CICP launched a new feature in its document submission portal that allows claimants to check the status of their claims online, even if they submitted claims by physical mail. The Program also launched a chat function on its website to assist requesters and the public with information about the CICP and the claim review process. The CICP has also undertaken the process of establishing an Injury Table for COVID-19 vaccine injuries. The Table is another tool that will allow HRSA to streamline the claims review process and more expeditiously address requests.

HRSA is committed to working with Congress to ensure that the resources and staffing are available to increase CICP claim reviews and processing. Furthermore, without Congressional action, HHS does not have the administrative authority on its own to move claims from the CICP to VICP.

The National Vaccine Injury Compensation 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 or families of individuals who have been injured by 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 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. Currently, these conditions have not been met for COVID-19 vaccines as no excise tax has been enacted and thus the HHS Secretary cannot add the vaccine to the VICP.

Determination for VICP eligibility follows a judicial process, under which claimants (petitioners) file a petition with the Court. These petitions are reviewed by HHS, which makes a preliminary recommendation on the eligibility for compensation. This recommendation becomes part of a report that is submitted to a court-appointed special master, who reviews the report and may hold a hearing for the government and the petitioner to present evidence. After considering the evidence submitted on the petition, the special master makes a determination related to compensation. Congress annually appropriates funding from the existing Vaccine Injury Compensation Trust Fund (Trust Fund) for VICP administration and compensation for vaccine-related injury or death claims for covered vaccines administered on or after October 1, 1988. The Department of Treasury maintains the Trust Fund 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.

The Vaccine Injury Table currently lists 14 specific injuries following receipt of 16 categories of vaccines covered under the Table. 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 legally presumed that the vaccine caused the injury or condition unless another cause is proven. Petitions may also be filed for injuries or conditions that are not listed on the Table, but the presumption of causation does not apply in those circumstances.

Conclusion

Thank you for the opportunity to discuss HRSA's injury compensation programs. We look forward to continuing to work with Congress on these critical issues.