National Vaccine Injury Compensation Program Needs Modernizing

Renée J. Gentry
The George Washington University Law School

Testimony before the Select Subcommittee on the Coronavirus Pandemic

March 21, 2024

Good afternoon. Thank you to Chairman Wenstrup, Cong. Ruiz and members of the Committee for this opportunity to discuss a critical national public health issue. My name is Renée Gentry and I am a vaccine injury attorney that has practiced in the National Vaccine Injury Compensation Program for over 20 years. In addition to my private practice in the NVICP, I am the Director of the George Washington University Law School's Vaccine Injury Litigation Clinic, which this year will celebrate its 30th Anniversary representing vaccine-injured children and adults. I've had the great privilege of working with the Clinic for the last ten years.

My role this afternoon is to give you an overview of the evolution of the Vaccine Injury Compensation and Countermeasures Programs and how the VICP needs modernizing to shift from the aspirations of 1986 to reflect the reality of 2024. A lot has changed in the nearly 40 years this program has existed.

Following the 1976 Swine flu pandemic and injuries stemming from the nation's mass vaccination campaign, the number of vaccine manufacturers dwindled dramatically. Recognizing the potential erosion of the nation's vaccine supply, Congress enacted the National Childhood Vaccine Injury Act of 1986 (NCVIA). In a post-9/11 world, after President Bush recognized similar concerns should the nation face a SARS or influenza threat, Congress passed the Public

Readiness and Emergency Preparedness (PREP Act) in 2005. Born out of two laws enacted two decades apart, the Vaccine Injury Compensation Program (VICP) and Countermeasures Injury Compensation Program (CICP) were intended to preserve vaccine manufacturer participation in the market by insulating them from legal liability in exchange for compensating vaccine-related injuries, as well as encourage the development of new life-saving vaccines.

Distinguishing the VICP and CICP

Injury claims under either program are not lawsuits. Rather they are no-fault claims for compensation. Both programs are supported administratively by the Health Resources and Services Administration (HRSA), which pays compensation to claimants. Otherwise, the programs differ greatly in terms of persons, injuries and products covered, as well as compensation level, processes and appeal rights.

Under the Act, the Vaccine Injury Compensation Program compensates injuries from vaccines on the childhood vaccination schedule with funding through a voluntary manufacturer contribution via excise tax. Although called the *Childhood* Vaccine Injury Compensation Program, adults who were injured by covered vaccines could also file for compensation, but vaccines recommended only for adults (e.g. the shingles vaccine) are not yet covered by the VICP.

Under the PREP Act, the CICP provides broad immunity from liability and compensation for injuries related to virtually the entire medical countermeasures enterprise during a public health emergency. The Secretary of HHS determines the scope of "Covered Countermeasures" and "Covered Persons." As you are aware, COVID-19 vaccines are covered under the CICP and not the VICP.

Under the CICP, claims are filed directly with HRSA, while VICP claims are filed in the US Court of Federal Claims in Washington DC. Within the Court of Federal Claims is the Office of Special Masters, the Vaccine Court, consisting of 8 special masters who adjudicate cases. This is

a critical distinction. Like trial judges, the special masters hear the evidence and make determinations as to whether or not the individual was injured by the vaccine and if they were, they make a determination of damages. Injury claimants are barred from bringing suit against a vaccine manufacturer until they have exhausted their claims in the VICP.

Under the VICP, approved claims and some expenses for administering the program are paid from a manufacturer excise tax (75 cents per disease prevented) held in a Vaccine Injury Fund. Vaccine injured children and adults are compensated out of the same currently $4 billion fund. Funds to support operation of the program are subject to annual congressional appropriations. Unlike the VICP, the CICP's compensation is funded through separate Congressional appropriations that must occur each time a new countermeasure is designated.

The National Childhood Vaccine Injury Act of 1986 established the VICP—a no-fault compensation program where vaccine-injured parties may file a claim for compensation for suffering injury or death as a result of the administration of certain vaccines. Congress intended that the VICP provide individuals (petitioners) a swift, flexible, and non-adversarial alternative to the often costly and lengthy traditional civil tort litigation. You cannot file a lawsuit against a manufacturer or administrator of a covered vaccine without going through this program first.

While imperfect, the NVICP was tremendously successful in its first 30+ years. New vaccines were developed at a rate that the Program grew from 6 covered vaccines to 16. Very few petitioners rejected the decision of the Vaccine Court and filed suit against a manufacturer. Fewer still, opted-out of the Program at the 240-day mark when they are permitted to pursue civil litigation if their claim has not been processed. This perfectly reflected Congress' intent that Petitioners be compensated quickly and generously by making the VICP a reasonable and meaningful alternative to civil litigation.

The CICP faces its own challenges. As a purely administrative program outside of the courts, it is overwhelmed in its ability to process claims for the COVID-19 vaccine and the very legality of its legal liability shield has been called into question in the courts.

Unlike, the VICP, the CICP is not a court process. Those injured by the Covid-19 vaccines are not entitled to counsel. They have no right of appeal. There are no pain and suffering damages, substantial limits exist on actual economic damages, and a drastic one-year (from the date of vaccination) statute of limitations applies by which a claim must be filed.

As of January. 1, 2024[1], of the 12,854 Covid-19 claims submitted to the CICP, only 40 claims have been found eligible for compensation while only 11 were actually compensated. There were 9,682 claims filed alleging injury or death from Covid-19 vaccines.

Based on its history (in the entirety of its existence the CICP has only compensated 41 individuals), compensation for these claims will be few and far between.

The slow pace of the program and relatively low rates of compensation has generated public frustration and media coverage that does no favors for vaccine confidence. In essence, the CICP gives the vaccine-injured "little more than the right to file and lose."

This has only been exacerbated by the recent announcement of the paltry CICP settlements in the first 11 compensated COVID-19 vaccine injury claims – the highest was for myocarditis: $8,961. Five others for were compensated at roughly half that amount, the remaining claims for even less. This has enflamed anger and frustration and that will further drive vaccine hesitancy.

[1] As of March 18, 2024, the most recent data available is through January 1, 2024. https://www.hrsa.gov/cicp/cicp-data

The Countermeasures Program remains ill-equipped to handle the Covid-19 vaccine claims, and piecemeal efforts to improve it are likely inadequate and, more importantly, unnecessary, because a reasonable alternative exists, albeit in need of modernization. The VICP.

For most of its first three decades, most cases moved through the VICP at a reasonable pace, and most conceded cases and settled cases, resolved damages quickly for reasonable amounts consistent with previously decided cases (accounting for new treatments and health care growth rates, though some elements of compensation remain at 1986-dollar values). Since its inception the VICP has awarded some $4 Billion in compensation to vaccine-injured children and adults.

A perfect storm of three events has now pushed the VICP to the point of collapse –

An Influx of Claims – With the addition of the influenza vaccination in 2005, which is recommended for adults and children every year (rather than to just children for a limited time-period in their life like most vaccines) the pool of potential petitioners increased exponentially and filed cases tripled to today's numbers. Despite this, the Program may well have been able to survive this addition, as the bulk of the injuries coming from the influenza vaccination are Table injuries, which should be processed rapidly and prior to 2015, Table cases were being resolved in approximately 1 year.

Addition of HPV & Meningitis Vaccination - In 2015, two additional vaccines were added.

Finally...

Table Injuries Added - Then, in 2017, two Table injuries were added, SIRVA (shoulder injury related to vaccine administration) added to most of the covered vaccines and Guillain-Barré Syndrome following influenza vaccination).

In fiscal year 2011, just 386 petitions were filed. The numbers increased to 1,120 in FY 2016, in FY 2021 the number of cases filed was 2,060, in 2022 another 1027 cases were filed, and

just this past 2023 fiscal year, 1,161 claims were filed in the VICP. As of last Friday, March 15, 2024, there were approximately 3,618 open cases in the vaccine court.

The collective effect of the above was to triple the workload of the Special Masters, the number of which remains statutorily restricted to 8. In addition, underfunding of HHS and the DOJ who represent the Secretary in VICP claims, contributes to this problem. Typical wait times for vaccine-injured Petitioners in 2023: HHS' Initial Review (12-16 months), Trial Dates (18-24 months-after however many years Petitioners have waited to get the record ripe for trial), Decisions of Special Masters on Entitlement (12-18 months to multiple years after post-trial briefing).

In this case, Justice delayed is Justice denied.

While the Office of Special Masters has been operating valiantly under these circumstances, the VICP has reached a critical point. Congress has acted to promote a strong universal immunization program. Essential to supporting a strong universal immunization program is maintaining a vibrant safety net for those individuals who are harmed by immunizations. That safety net is in danger of failing. Not because vaccines are less safe, but because Congress has failed to update the VICP's infrastructure while allowing caseloads to increase.

And we haven't even address Covid-19 vaccines yet.

In an effort to modernize the critically endangered National Vaccine Injury Compensation Program (VICP) so that it reflects the national public health policy regarding immunizations today and not 40 years ago, the Vaccine Injury Modernization Act of 2023 (H.R. 5142) and the Vaccine Access Improvement Act (H.R. 5143), were introduced by the bipartisan team of Rep. Lloyd Doggett (D-Texas) and Rep. Lloyd Smucker (R-PA), alongside Cong. Blumenauer (D-OR), on August 4, 2023.

These two bills - introduced simultaneously in an effort to streamline the cumbersome process by which new vaccines are added to the VICP— seek to modernize the program to reflect today's realities.

The single most important part of these legislative efforts is reducing delay by increasing the number of special masters. H.R. 5142 also seeks to bring compensation caps in line with inflation, as well as increasing the statute of limitations by two years and reducing the bureaucratic delay for allowing compensation to those who receive new vaccines. H.R. 5143 streamlines the application of the excise tax -the manufacturers' voluntary contribution to ensure a self-funded program, for all new vaccines added.

Which brings us to Covid-19 vaccines.

Congress Must Include Covid-19 Vaccines in the Vaccine Injury Program

Covid-19 vaccines were produced in response to a pandemic. As such, they are covered exclusively under the CICP. This means a person cannot sue a Covid-19 vaccine manufacturer and must go through the CICP.

Congress must act quickly to include the Covid-19 vaccines – and those currently filed in the CICP - in the VICP so those people who did the right thing to protect themselves, their families, and their communities by getting vaccinated have a reasonable and fair opportunity for compensation for their vaccine injuries.

Further, Congress must ensure that the participants in the VICP, including the Office of Special Masters, the Department of Health & Human Services, and the Justice Department have the resources, staff, and infrastructure to properly administer this critical public health program.

It is well past time to bring this nearly 40-year-old program up to date and for Congress to keep the promise of the VICP. The assurance of adequate and timely compensation of vaccine-related injuries in exchange for legal liability protection for vaccine manufacturers is a cornerstone of routine and pandemic immunization programs. The success of these programs relies on public confidence in vaccines, which can be bolstered by addressing the above programmatic deficiencies.

Thank you.

Author Information

Renée J. Gentry is the director of the Vaccine Injury Litigation Clinic at the George Washington University Law School where she is a Distinguished Professorial Lecturer in Law. She is a leading expert on vaccine injury litigation in the VICP.