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A New Way Forward For COVID Vaccine Lawsuit Immunity

By **Altom Maglio** (August 20, 2024, 2:41 PM EDT)

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Since the pandemic, those that make and give COVID-19 shots have benefited from unprecedented legal immunity. That immunity is ending.

Attorneys advising hospitals, pharmacies, medical professions and manufacturers are facing the question from their clients: What now? Likewise, attorneys counseling those injured by adverse reactions to COVID-19 vaccines dispense grim news of no compensation.

This article explores the source of the lawsuit protections, the status of that immunity, the possibility of continued lawsuit protection for COVID-19 vaccine manufacturers and administrators, and a path for real compensation for those injured.

During the pandemic, the PREP Act provided almost complete legal protection for COVID-19 vaccine administrators and manufacturers.

The Public Readiness and Emergency Preparedness Act provides unprecedented immunity to COVID-19 vaccine manufacturers and administrators for vaccines sold and administered during the pandemic.

The U.S. Department of Health and Human Services secretary invoked the PREP Act, declared COVID-19 to be a public health emergency, and triggered the immunity provision for manufacturers and administrators of COVID-19 vaccines effective Feb. 4, 2020.[1]

Title 42 of the U.S. Code, Section 247d-6d(a)(1), of the PREP Act states, "a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure."

The sole exception to the conferred immunity is an "exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct."

Further, it requires lawsuits to be filed in the U.S. District Court for the District of Columbia. It also requires the complaint be pled with particularity, under oath, with a doctor's affidavit, and proof of willful misconduct by clear and convincing evidence. The complaint must be heard by a three-judge panel.[2]

The PREP Act provides for limited compensation for vaccine adverse reactions under the Countermeasures Injury Compensation Program.

The PREP Act provides extremely limited compensation under strict, undisclosed and unreviewable criteria for COVID-19 vaccine adverse reactions. The means to access that limited compensation is the Countermeasures Injury Compensation Program.[3]

CICP claims must be brought within one year of injury, no compensation is made for pain and suffering, all determinations are made internally by HHS, and the PREP Act prohibits judicial review.[4]

Only 1 in 1,000 COVID-19 vaccine claims have been compensated by the CICP as of June 1.

Pursuant to data from the CICP, as of July 1, there were 13,309 COVID-19 vaccine injury claims that had been filed in the CICP.[5] Of those claims, 2,855 have been denied and only 13 have been compensated.[6]

The 13 COVID-19 vaccine-injured people compensated received an average of $3,721 from the CICP.

The CICP only provides compensation for death or serious physical injuries.[7] According to the CICP, the 13 COVID-19 vaccine injury claims that have been compensated were for myocarditis, myopericarditis, anaphylaxis or syncope.[8]

Compensation for the 13 claims ranged from a high of $8,962 to a low of $1,033.[9] The grand total of compensation paid out by the CICP of $48,378 for COVID-19 vaccine injuries averages to $3,721.23 per death or serious physical injury.[10]

PREP Act immunity is so complete and remedies so limited that its unprecedented scope is being used to challenge its constitutionality.

Multiple U.S. courts of appeal have called into question whether the CICP provides an adequate alternative to a state court civil suit.[11] Direct challenges are currently underway to the constitutionality of the immunity provisions of the PREP Act for COVID-19 vaccine injuries in multiple courts.[12]

The lawsuits directly challenge the constitutionality of the PREP Act immunity for vaccine manufacturers, stating for example, in Moms for America v. HHS in the U.S. District Court for the Middle District of Florida in June: "Indeed, the PREP Act unconstitutionally created an opaque, unappealable, quasi-judicial tribunal to adjudicate claims lacking even a fig leaf of due process and explicitly disclaimed judicial oversight."[13]

PREP Act immunity for COVID-19 vaccines is in the process of expiring or has expired.

Under the PREP Act, the HHS secretary identifies the duration of the grant of immunity for a covered countermeasure such as the COVID-19 vaccine.[14] The secretary dictated the immunity dates for COVID-19 vaccines under the initial declaration and the 11 amendments to the declaration.[15]

The 11th amendment to the declaration set the expiration of most COVID-19 vaccine immunity for Dec. 31 this year, with both earlier and later dates of expiration.[16] As a result, the immunity conferred by the PREP Act for COVID-19 vaccine administrators and manufacturers is in the process of expiring or has expired.[17]

The addition of COVID-19 vaccine injuries to the VICP would provide real compensation for those injured by adverse reactions.

The National Vaccine Injury Compensation Program is a tort reform insurance-like system devised by Congress in the 1980s to provide compensation to people suffering injuries from adverse reactions to covered vaccines.[18]

Claims are brought in the U.S. Court of Federal Claims in Washington, D.C.; defended by the U.S. Department of Justice; heard by specialized judges; and awards taken from a dedicated excise tax-funded trust.[19]

During the past three-plus decades, 11,044 vaccine injury claims have been compensated by the VICP, with compensation totaling over $4.7 billion for an average of $425,570 per claim.[20]

Compensation is paid from the vaccine injury compensation trust fund, which is funded by an excise tax on each dose of covered vaccine sold.[21] As of May 31, the vaccine injury compensation trust fund contained over $4.5 billion.[22]

The PREP Act does not bar coverage of COVID-19 vaccines by the VICP.

None of the provisions of the PREP Act restricts the addition of COVID-19 vaccines to the VICP. In fact, Congress specifically provided in the PREP Act that vaccines subject to the PREP Act could also be covered by the VICP. Title 42 of the U.S. Code, Section 247d-6d(h), of the PREP Act states:

> RULE OF CONSTRUCTION CONCERNING NATIONAL VACCINE INJURY COMPENSATION PROGRAM.--Nothing in this section, or any amendment made by the Public Readiness and Emergency Preparedness Act, shall be construed to affect the National Vaccine Injury Compensation Program under title XXI of this Act.

The VICP provides a rarely used opt-out provision to allow an injured individual to file a civil lawsuit.

The VICP provides an opt-out provision for injured persons to reject a judgment for compensation or exit the VICP if a decision is not rendered timely.[23]

All covered claims must initially be brought and pursued in the Court of Federal Claims.[24]

At the conclusion of the claim, the claimant has the option of accepting an award from the CFC, or rejecting the award and pursuing civil litigation.[25] Additionally, at a certain point after filing in the CFC, if a judgment has not been entered, a claimant is able to make the decision to opt out and pursue civil litigation.[26]

The purpose of the opt-out deadline is to protect the vaccine-injured person from delayed proceedings. In a 1986 House Energy and Commerce Committee report discussing the Vaccine Act, the committee stated:

> The entire proceeding — from date of filing through Special Master proceedings and court review — is to take place as expeditiously as possible and, in no case, should take more than one year. The Committee notes that much of the equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the petitioner can expect judgment; without such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner.[27]

However, despite current delays, very few cases opt out of the VICP.[28] In the almost 40 years since the VICP was created, only a tiny number of cases have opted out of the VICP and then successfully brought a lawsuit against a vaccine administrator or manufacturer.[29]

The VICP bars design defect and failure to warn claims against vaccine manufacturers.

The VICP opt-out still eliminates liability for vaccine manufacturers for design defect claims and failure to warn claims.[30]

As explained by the U.S. Supreme Court in its 2011 decision in Bruesewitz v. Wyeth, Congress enacted the VICP to "[t]o stabilize the vaccine market and facilitate compensation" to those suffering adverse reactions by establishing a no-fault compensation program "designed to work faster and with greater ease than the civil tort system."[31]

According to the court in Bruesewitz, the quid pro quo for this no-fault compensation system funded by vaccine manufacturers is "the provision of significant tort-liability protections for vaccine manufacturers," which was "designed to stabilize the vaccine market."[32]

Pursuant to the Vaccine Act, (1) all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects are preempted, [33] and (2) claims alleging liability for failure to properly warn injured plaintiffs or their parents are expressly barred.[34]

Adding COVID-19 vaccines to coverage by the VICP would not eliminate or decrease the immunity provided by the PREP Act.

Immunity for COVID-19 vaccine manufacturers and administrators conferred by the PREP Act would not be eliminated or decreased by the addition of COVID-19 vaccines to the VICP. Nothing in the opt-out provisions of the VICP alters the immunity provisions of the PREP Act.[35]

Assuming an injured person made the decision to opt out of the VICP, and instead embark on the rarely successful endeavor of directly suing a vaccine manufacturer, they would still face all the limitations of the PREP Act.

Their suit would be limited to physical injury proximately caused by willful misconduct shown by clear and convincing evidence in the D.C. district court before a special three-judge panel.[36] This would be no different than if COVID-19 vaccine were never added to the VICP.

Liability protections for vaccine manufacturers and administrators would increase with the addition of COVID-19 to the VICP.

What would change if COVID-19 vaccine injuries were added to the VICP is an increase in liability protections over those afforded by the PREP Act alone. The PREP Act immunity is so sweeping, and the remedies afforded by the CICP so scant, that it may well be found unconstitutional.

Adding COVID-19 vaccine injuries to the VICP would serve as a real remedy for those injured by adverse vaccine reactions and decrease the pressure to challenge the constitutionality of PREP Act immunity.

Further, adding COVID-19 vaccines to the VICP would afford those injured by an adverse vaccine reaction the possibility of an adequate remedy. This adequate remedy might even serve to decrease the likelihood of the PREP Act being found unconstitutional.

In conclusion, immunity for COVID-19 vaccine manufacturers and administrators conferred by the PREP Act is ending. However, the addition of COVID-19 vaccines to the VICP would serve to provide additional protection for administrators and manufacturers of COVID-19 vaccines and a real remedy for those injured.

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[1] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198.

[2] 42 U.S.C. §§ 247d-6d & 247d-6e.

[3] 42 U.S.C. § 247d-6e.

[4] Id.

[5] See CICP Data, https://www.hrsa.gov/cicp/cicp-data (last visited July 18, 2024).

[6] Id.

[7] 42 U.S.C. § 247d.

[8] See CICP Data, https://www.hrsa.gov/cicp/cicp-data/table-4 (last visited July 18, 2024).

[9] Id.

[10] Id.

[11] See Insult to The Injured: The Case for Modernizing Vaccine Injury Compensation, Health Affairs Forefront, July 19, 2023.

[12] E.g., Moms for America v. HHS, No. 3:24-cv-00650 (M.D. Fla.) and Smith v. US, No. 3:23-cv-01425 (W.D. La.).

[13] Moms for America v. HHS, No. 3:24-cv-00650, ECF No. 1, at 8.

[14] 42 U.S.C. 247d-6d(b)(2)(B).

[15] See Kevin J. Hickey, Cong. Rsch. Serv., LSB10730, The PREP Act and COVID-19, Part 2: The PREP Act Declaration for COVID-19 Countermeasures (2023).

[16] Eleventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 88 Fed. Reg. 30,769 (May 12, 2023).

[17] Id.

[18] Pub. L. No. 99-660, § 311,100 Stat. 3743 (1986).

[19] 42 U.S.C. §§ 300aa-10–300aa-44.

[20] See HRSA Data & Statistics, https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-07-01-24.pdf (last visited July 18, 2024).

[21] 42 U.S.C. § 300aa-15(i)(2).

[22] See Advisory Commission on Childhood Vaccines (ACCV), Welcome and Introduction, 130th ACCV Meeting, https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/accv-07112024-cdr-grimes.pdf (last visited July 18, 2024).

[23] 42 U.S.C. 300aa-21(a)(b).

[24] 42 U.S.C. §§ 300aa-11.

[25] 42 U.S.C. 300aa-21(a).

[26] 42 U.S.C. 300aa-21(b).

[27] H.R. Rep. No. 99-908, at 17.

[28] See Mary S. Holland, Liability for Vaccine Injury: The United States, the European Union, and the Developing World, 67 Emory L. J. 415, 424 (2018) and Nora Freeman Engstrom, A Dose of Reality for Specialized Courts: Lessons from the VICP, 163 U. Pa. L. Rev. 1631, 1673 (2015).

[29] Id.

[30] 42 U.S.C. § 300aa-22.

[31] Bruesewitz v. Wyeth LLC, 562 U.S. 223, 228–30 (2011).

[32] Bruesewitz, 562 U.S. at 229.

[33] Bruesewitz, 562 U.S. at 243.

[34] G.M. v. Sanofi Pasteur Inc., No. CV 14-9549 FMO (ASX), 2016 WL 7638186, at *4 (C.D. Cal. Mar. 22, 2016) ("To the extent plaintiff alleges that defendant failed to warn her or the public of the risks that the Fluzone vaccine could cause transverse myelitis, such claims are expressly preempted by the Vaccine Act."); accord In re Gardasil Prod. Liab. Litig., No. 3:22-CV-00117, 2024 WL 1197919, at *9 (W.D.N.C. Mar. 20, 2024), Stratton v. Merck & Co., No. CV 2:21-02211-RMG, 2021 WL 5416705, at *5 (D.S.C. Nov. 17, 2021); Flores v. Merck & Co., No. 321CV00166MMDCLB, 2022

WL 798374, at *4 (D. Nev. Mar. 16, 2022); Colbath v. Merck & Co. , No. 3:21-CV-120-W (DEB), 2022 WL 935195, at *3 (S.D. Cal. Mar. 29, 2022).

[35] 42 U.S.C. §§ 300aa-10-300aa-44.

[36] 42 U.S.C. §§ 247d-6d & 247d-6e.