



Restoring  
Remedies  
for Serious

# VACCINE INJURIES

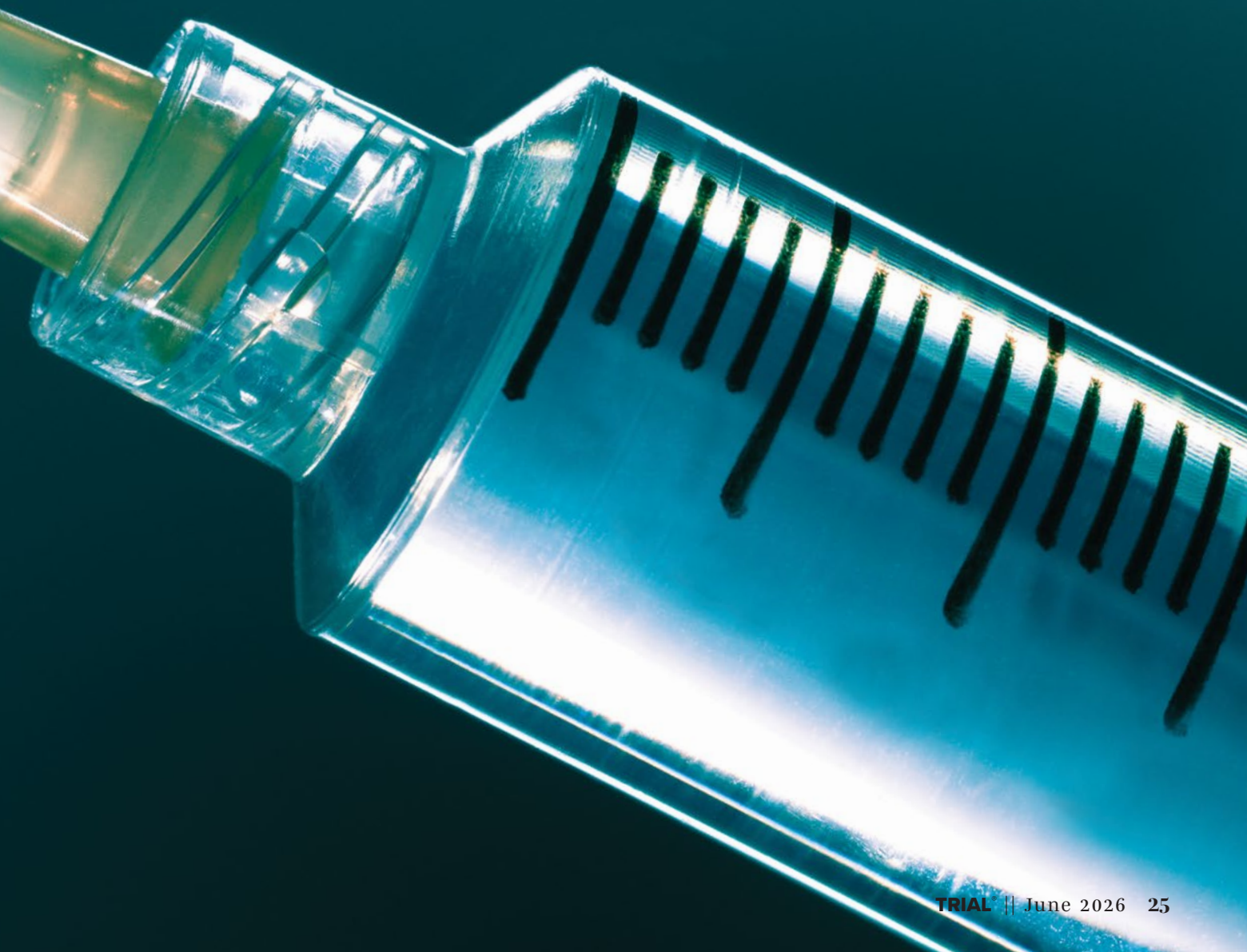
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The PREP Act grants sweeping legal immunity while providing no real remedy to those the countermeasures injure.

**A**s trial lawyers, we fight to uphold the rule of law. Passed in 2005, the Public Readiness and Emergency Preparedness (PREP) Act challenges that commitment. Although the PREP Act is intended to encourage the rapid development and deployment of medical countermeasures (vaccines, drugs, devices) during public health emergencies, it grants sweeping legal immunity to manufacturers, administrators, and sellers of covered countermeasures—while providing no real remedy to those the countermeasures injure.<sup>1</sup>

The act provides a single exception: an exclusive federal cause of action for death or serious physical injury proximately caused by willful misconduct.<sup>2</sup> That claim must be filed in the U.S. District Court for the District of Columbia, pleaded with particularity under oath, supported by a physician's affidavit, and proven by clear and convincing evidence before a three-judge panel.<sup>3</sup>

In February 2020, the Secretary of Health and Human Services (HHS) invoked the PREP Act and declared COVID-19 a public health emergency, triggering legal immunity for covered



countermeasures.<sup>4</sup> That immunity remains in effect.

In December 2024, the secretary issued an amendment to the declaration under the Public Readiness and Emergency Preparedness Act for medical countermeasures against COVID-19, extending legal immunity for COVID-19 countermeasures, including vaccines, through Dec. 31, 2029.<sup>5</sup> As a result, a COVID-19 vaccination negligently administered in December 2029 would still be shielded from liability.

The PREP Act does theoretically provide compensation through the Countermeasures Injury Compensation Program (CICP).<sup>6</sup> But CICP claims must be filed within one year of injury. Additionally, no damages are available for pain and suffering. HHS makes all determinations internally regarding whether to deny or award compensation and in what amount, and the act explicitly bars judicial review.<sup>7</sup>

Several courts of appeal have questioned whether the CICP provides an adequate substitute for a state civil action,<sup>8</sup> and constitutional challenges to the PREP Act's immunity provisions are pending.<sup>9</sup> Even if immunity were deemed unconstitutional, litigation would remain difficult.<sup>10</sup> The role of the federal government and manufacturers in developing and distributing COVID-19 countermeasures raises significant preemption issues, and the emergency context of the pandemic would invite formidable legal defenses.

A more workable compensation system already exists. Congress created the National Vaccine Injury Compensation Program (VICP) in the 1980s as an insurance-like system for people injured by covered vaccines, including influenza, tetanus, and childhood immunizations.<sup>11</sup> Claims are filed in the U.S. Court of Federal Claims, defended by the Department of Justice, heard by specialized judges, and paid via a dedicated excise tax on each covered vaccine dose sold.<sup>12</sup> Over the past four decades, the VICP has compensated 12,588 vaccine injury claims, awarding approximately \$5.5 billion.<sup>13</sup>

Two steps would allow people injured by COVID-19 vaccines to bring claims under the VICP. First, the HHS Secretary must add the COVID-19 vaccine to the Vaccine Injury Table.<sup>14</sup> Second, Congress must authorize an excise tax on future COVID-19 vaccine doses to fund the Vaccine Injury

Compensation Trust Fund.<sup>15</sup> Once those steps occur, the Court of Federal Claims will have jurisdiction over COVID-19 vaccine injury claims.<sup>16</sup>

The VICP is not perfect. For 40 years, the program has been limited to eight judges, and pain and suffering damages remain capped at \$250,000. Adjusted for inflation, that cap would approach \$750,000 today.<sup>17</sup> Expanding the bench and aligning the damages cap with inflation are overdue reforms. With those fixes—and with jurisdiction extended to serious COVID-19 vaccine injuries—the system could finally provide a meaningful remedy to those harmed. ▣



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#### NOTES

1. 42 U.S.C. §247d-6d(a)(1).
2. *Id.* §247d-6d(d).
3. *Id.* §§247d-6d-247d-6e.
4. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020).
5. 12th Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 89 Fed. Reg. 99875 (Dec. 11, 2024).
6. 42 U.S.C. §247d-6e.
7. *Id.*
8. See Richard Hughs IV et al., *COVID-19 PREP Act Litigation: The Tip of the Liability Iceberg*, Health Affairs, Nov. 30, 2022, [www.healthaffairs.org/content/forefront/covid-19-prep-act-litigation-tip-liability-iceberg](http://www.healthaffairs.org/content/forefront/covid-19-prep-act-litigation-tip-liability-iceberg).
9. *E.g.*, *Moms for America v. Dept. Health & Human Servs.*, No. 3:24-cv-00650 (M.D. Fla. June 25, 2024); *Kevin Searcy v. Pfizer, Inc.*, No. 25-14198 (11th Cir. Dec. 1, 2025).
10. 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); Nora Freeman Engstrom, *A Dose of Reality for Specialized Courts: Lessons from the VICP*, 163 U. Pa. L. Rev. 1631, 1673 (2015).
11. Pub. L. No. 99-660, §311, 100 Stat. 3743 (1986).
12. 42 U.S.C. §§300aa-10–300aa-44.
13. *HRSA Data & Statistics January 2026*, Health Res. & Servs. Admin., Jan. 1, 2026, [www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-01-01-26.pdf](http://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-01-01-26.pdf); see also 42 U.S.C. §300aa-15(i)(2) (establishing that all payments for compensation from vaccine-related injury or death after Oct. 1, 1988, shall be made from the VICP).
14. 42 U.S.C. §300aa-14(e)(2).
15. 26 U.S.C. §4132.
16. 42 U.S.C. §300aa-12(a).
17. *Id.* §§300aa-12(c), 300aa-15(a)(4).