

DRUG, DEVICE AND BIOTECHNOLOGY

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IN THIS ISSUE

The PREP Act, a relatively unknown federal statute enacted in 2005, provides liability immunity for the manufacture, distribution, administration, and use of covered medical countermeasures. HHS invoked the PREP Act in February of 2020 in response to the COVID-19 pandemic. The scope of who is entitled to protections under the PREP Act for COVID-19 responses and how far those protections extend has been taking shape over the past eighteen months.

The Virus Mutated...Have the PREP Act's Protections Against Liability for Countermeasures Followed Suit?

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As the United States returns to a state of normalcy, it may prove difficult to remember how things looked prior to the onslaught of the novel coronavirus disease 2019 (“COVID-19”) pandemic. Companies of all sorts trudged headfirst into the COVID-19 market, producing critical treatments, vaccines, and products that the entire world required to move forward.¹ The litigation risks for those same entities that pivoted and evolved to assist in the global efforts to fight the pandemic remain uncertain.

The principal protection in the United States against COVID-19 litigation is the Public Readiness and Emergency Preparedness Act (the “PREP Act”). The PREP Act was enacted by Congress in 2005 and authorizes the Secretary of the Department of Health and Human Services (“HHS”) to deem an event a “public health emergency,” issue a Declaration to that effect, and utilize funds established by the U.S. Treasury to manage the emergency.² The HHS invoked the PREP Act for COVID-19 on February 4, 2020, which paved the way for protections for covered persons, manufacturers, and distributors engaged in lawsuits concerning the administration or use of pandemic

countermeasures.³ Of course, the devil is in the details. The scope of who is entitled to protections under the PREP Act and how far those protections extend has been changing—and thankfully expanding—over the past seventeen months.

As for the “who,” a covered person under the PREP Act includes manufacturers and distributors of covered countermeasures; the United States; program planners and other “qualified persons” who prescribe, administer, or dispense covered countermeasures.⁴ For the “how far,” a covered countermeasure essentially includes any drug, biologic, or device that has been approved or authorized by the FDA or the Occupational Safety and Health Administration to diagnose, mitigate, prevent, treat, cure, or limit the harm of COVID-19.⁵ When the PREP Act applies, injured persons must pursue injury claims via an administrative remedy—the Covered Countermeasure Process Fund.⁶ However, there is one caveat to PREP Act immunity—willful misconduct.⁷ Claims involving allegations of willful misconduct must be pursued in the United States District Court for the District of Columbia.

¹ See generally Susan Burnett & Daniel Rock, *Implied Conflict Preemption May Apply in COVID-19 Cases*, LAW360 (May 15, 2020), <https://www.law360.com/articles/1273388/implicit-conflict-preemption-may-apply-in-covid-19-cases>.

² *Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC*, 2020 WL 6140474, at *6 (W.D. Pa. Oct. 16, 2020) (citing 42 U.S.C. § 247d(a)), *appeal filed*, (3d Cir. Nov. 10, 2020).

³ Declaration Under the Public Readiness and Emergency Preparedness Act for Medical

Countermeasures Against COVID-19, 85 Fed. Reg. 15198-01 (Mar. 17, 2020).

⁴ *Id.* at 15199.

⁵ *Advisory Opinion on the PREP Act and the March 10, 2020 Declaration under the Act*, HHS (May 19, 2020), <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf>.

⁶ 42 U.S.C. § 247d-6e.

⁷ 42 U.S.C. § 247d-6d(d).

The Federal Government's Narrative

During this time of unprecedented need, the federal government has been eager to encourage businesses to increase manufacturing and distribution by expanding the scope of persons and countermeasures eligible for PREP Act protection. That eagerness and the ever-developing circumstances of the pandemic have led to eight amendments to the initial COVID-19 Declaration and six advisory opinions from the Office of the General Counsel of HHS.

The Fourth Amendment to the Declaration made perhaps the largest expansion of protection by emphasizing the “substantial federal legal and policy issues, and substantial federal legal and policy interests, in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities.” Specifically, the Secretary noted that to respond to the unprecedented pandemic, there “must be a more consistent pathway for Covered Persons to

manufacture, distribute, administer, or use Covered Countermeasures across the nation and the world.”⁸

Court of Public Opinion

In response to the federal government's broad declarations, news outlets all over the country have reported that “[v]accine makers got immunity to tackle a public health emergency.”⁹ Fact-checking internet websites also have been confirming this general perception.¹⁰ Columnists have observed that “under the federal PREP Act, lawyers have secured total immunity from liability for Big Pharma just in case something goes terribly wrong with the vaccine.”¹¹ On social media, many people continue to post that pharmaceutical companies are immune from lawsuits relating to COVID-19 vaccines.

The unanswered question is whether the narrative from the government about the need for private businesses to help defend against COVID-19 and the media narrative that vaccine manufacturers “can’t be sued” will help to minimize the litigation burden on

⁸ Fourth Amendment to the Declaration, 85 Fed. Reg. 79190 (Dec. 9, 2020), <https://www.govinfo.gov/content/pkg/FR-2020-12-09/pdf/2020-26977.pdf>.

⁹ *Victims of Rare Vaccine Injury Wait to See if U.S. Will Pay*, BLOOMBERG LAW (May 3, 2021), <https://news.bloomberglaw.com/product-liability-and-toxics-law/victims-of-rare-vaccine-injury-wait-to-see-if-u-s-fund-will-pay>.

¹⁰ Shayna Greene, *Fact Check: Are Pharmaceutical Companies Immune from COVID-19 Vaccine Lawsuits?* NEWSWEEK (Jan. 19, 2021), [https://www.newsweek.com/fact-check-are-](https://www.newsweek.com/fact-check-are-pharmaceutical-companies-immune-covid-19-vaccine-lawsuits-1562793)

[pharmaceutical-companies-immune-covid-19-vaccine-lawsuits-1562793](https://www.newsweek.com/fact-check-are-pharmaceutical-companies-immune-covid-19-vaccine-lawsuits-1562793); *Verify: Can Pharmaceutical companies be sued for complications from vaccine symptoms?* WUSA9 (Mar. 2, 2021), <https://www.wusa9.com/article/news/verify/adverse-effects-side-effects-covid-19-can-vaccine-companies-be-sued-for-complications-from-symptoms-verify-fact-check/65-ae9305ac-1193-4b7a-a90f-eb8536f06058>.

¹¹ *Big Pharma's Vaccine Immunity*, LEGALCHATNOW, <https://www.legalchatnow.com/big-pharmas-vaccine-immunity/>.

businesses. This has led some commentators to issue cautionary notes to plaintiffs:

With the prospect of COVID-19 vaccines on the immediate horizon, the thoughts of some—especially those of certain plaintiffs’ counsel—may turn to litigation opportunities. Not so fast.¹²

If you’ve suffered an injury related to Pfizer, Moderna, or Johnson & Johnson vaccines, you’re basically out of luck.¹³

Nonetheless, as time moves on, it’s a safe bet that ambitious plaintiff lawyers will ignore these narratives and attack the protections provided by the PREP Act.

Litigation Strategies to Anticipate – Muddying the Causal Connection

For PREP Act immunity to apply, there must be a causal relationship between the “administration to or use by an individual of a covered countermeasure,” and the loss claimed.¹⁴ Despite commentary on the blanket protections of the PREP Act, the

metes and bounds of the causal connection already have spurred some litigation.¹⁵

Cases filed early in the pandemic declined to extend PREP Act immunity to the *non*-use of covered countermeasures. These initial cases involved allegations that nursing homes and other healthcare facilities failed to: take preventive measures; use covered countermeasures; or implement effective infection programs. Courts found these claims outside the purview of the PREP Act because the immunity applies to claims of loss causally connected to the administration or “use” of covered countermeasures—allegations of action, as opposed to inaction.¹⁶

Following these initial cases, the HHS’s Fourth Amendment clarified that claims of *inaction* or failure to administer countermeasures are not necessarily beyond the scope of the PREP Act. However, courts have interpreted this pronouncement narrowly finding that “failures to take countermeasures, much less action not *directly linked* to countermeasures at all . . . fall outside the ambit of the PREP Act.”¹⁷ For example, the use of covered countermeasures somewhere in a facility is

¹² Eric Kraus & Jennifer Shah, *COVID-19 Vaccines Unlikely to Create Litigation Opportunities*, LAW360 (Dec. 7, 2020), <https://www.law360.com/articles/1335242/covid-19-vaccines-unlikely-to-create-litigation-opportunities>.

¹³ Jenna Greene, *A ‘black hole’ for COVID vaccine injury claims*, REUTERS (June 29, 2021), <https://www.reuters.com/legal/government/black-hole-covid-vaccine-injury-claims-2021-06-29/>.

¹⁴ 42 U.S.C. § 247d-6d(a)(2)(B).

¹⁵ *Advisory Opinion 21-01*, HHS (Jan. 8, 2021), <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf>.

¹⁶ *Sherod*, 2020 WL 6140474, at *7; see also *Eaton v. Big Blue Healthcare, Inc.*, 480 F. Supp. 3d 1184, 1195 (D. Kan. Aug. 19, 2020).

¹⁷ *Khalek v. S. Denver Rehab.*, 2021 WL 2433963 (D. Colo. June 11, 2021) (citing cases).

insufficient to invoke the PREP Act protection as to *all* claims that arise in that facility because the statute “still requires a causal connection between the injury and the use or administration of covered countermeasures.”¹⁸

Many PREP Act immunity cases will rise and fall on the existence of a close causal relationship. Plaintiffs can be expected to argue that the measure (even if a covered countermeasure) bears no causal relation to the harm.

Jurisdiction – Is the PREP Act a Complete Preemption Statute?

Another likely battleground is all too familiar in the field of product liability—preemption. The Fifth Advisory Opinion from January 2021 labels the PREP Act as a “Complete Preemption Statute.”¹⁹ On the other hand, nearly every district court to consider whether the PREP Act completely preempts similar state-law claims against nursing homes has concluded it is not a complete preemption statute.²⁰ Questions of this nature are on appeal to multiple Courts of Appeals across the country.²¹

In remanding a case premised on state-law claims and a nursing home’s allegedly inadequate response to the pandemic, the

United States District Court for the Middle District of Tennessee noted:

The Court is mindful of the United States’ policy arguments that reasonably emphasize the urgent need for the federal judiciary to provide a consistent national interpretation of the PREP Act during a pandemic that has taken the lives of more than 500,000 citizens. But the Court must also respect the statutory scheme created by Congress and the plain meaning of the words selected by Congress to provide the immunity created in the PREP Act. Because Congress has not yet acted to align its intent with the United States’ interests expressed here, and for the foregoing reasons, the Court will . . . remand this matter.

Bolton, 2021 WL 1561306, at *9 (internal citation omitted). Congress has not acted yet to confirm whether the PREP Act completely preempts state law claims. However, PREP Act immunity defenses are not lost because defendants still may argue in state court that state law claims are barred under the PREP Act.²²

¹⁸ *Eaton*, 480 F. Supp. 3d at 1194.

¹⁹ *Advisory Opinion 21-01*, *supra* note 15, at 2.

²⁰ *Bolton v. Gallatin Ctr., LLC*, 2021 WL 1561306, at *7 (M.D. Tenn. Apr. 21, 2021) (citing cases).

²¹ *See, e.g., Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518 (D.N.J. 2020), *appeal filed sub nom. Kaegi v. Alliance HC Holdings* (3d Cir. Sept. 10,

2020); *Perez v. Southeast SNF LLC*, 2021 WL 1381232, at *2 (W.D. Tex. Apr. 12, 2021), *appeal filed subnom. Strait v. Southeast SNF* (5th Cir. May 14, 2021); *Smith v. Colonial Care Ctr.*, 2021 WL 1087284 (C.D. Cal. Mar. 19, 2021), *appeal filed*, (9th Cir. Apr. 19, 2021).

²² *Martin v. Serrando Post Acute LLC*, 2020 WL 5422949, at *2 (C.D. Cal. Sept. 10, 2020).

CICP v. VICP

The Vaccine Injury Compensation Program (“VICP”) is a pre COVID-19 “no-fault program” created to provide “an alternative legal avenue to ensure quick and fair compensation for vaccine injuries and to insulate manufacturers from liability to encourage manufacturers to pursue vaccine developments.”²³ Successful claims and *attorneys’ fees* are paid out of a VICP fund which to date exceeds \$4 billion.²⁴ For a new category of vaccines to be covered under the VICP, HHS requires three things to happen: “(1) Congress must enact an excise tax on the vaccine, (2) the [Centers for Disease Control and Prevention] must recommend it for routine administration to children or pregnant women, and (3) the Secretary must publish a notice in the Federal Register”²⁵ The VICP covers most vaccines administered in the United States but has not been extended to cover COVID-19 vaccines.²⁶ Rather, COVID-19 vaccines are covered countermeasures under the Countermeasure Injury Compensation Program (“CICP”).

Efforts to move COVID-19 vaccine-related injuries from the CICP to the VICP could prove to be a battleground moving forward. The process for obtaining compensation under the CICP is relatively unknown and has been referred to as a “black hole.” Compensation under the program is limited to cases involving death or serious injury, and does not include pain and suffering damages.²⁷ The protections and uncertainties have combined to make the CICP the “perfect target for anti-vaccinationists and others who believe that unsafe pandemic vaccines [are being] foisted upon a vulnerable public.”²⁸ Any efforts by claimants to shift from the CICP to VICP could impact manufacturers and distributors. If the VICP is extended to the COVID-19 vaccines and compensation is perceived as easier to obtain under the VICP (and lawyers are increasingly inclined to pursue claims (and fees) this way), plaintiffs may become less motivated to argue against PREP Act immunity and file suit in federal court and, instead, pursue a no-fault compensation program.

²³ Katherine Van Tassel, Carmel Shachar, and Sharona Hoffman, *Covid-19 Vaccine Injuries – Preventing Inequities in Compensation*, 34 NEW ENG. J. MED. 384 (Mar. 11, 2021).

²⁴ *Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP)*, HRSA (Apr. 2021), <https://www.hrsa.gov/cicp/cicp-vicp>.

²⁵ National Vaccine Injury Compensation Program: Recission of Revisions to the Vaccine Injury Table, 86 Fed. Reg. 21209 (Apr. 22, 2021).

²⁶ *Id.*

²⁷ Countermeasures Injury Compensation Program, HRSA (Dec. 2020), <https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicpfactsheet.pdf>

²⁸ Peter H. Meyers, *The Trump administration’s flawed decision on coronavirus vaccine injury compensation: recommendations for changes*, J. L. BIOSCIENCES 1 (2020) (citing Wendy E. Parmet, *Pandemics, Popularism and the Role of Law in the H1N1 Vaccine Campaign*, 4 ST. LOUIS U.J. HEALTH L. POL 113, 146 (2010)).

Conclusion

“[W]hether the PREP Act will inoculate as well as the vaccines” will play out within the court of public opinion, the Federal Courts of Appeal and the halls of Congress.²⁹ Just as no one predicted COVID-19, no one knows the extent to which the PREP Act’s protections will stand up to claims from creative plaintiffs’ counsel whose theories of liability inevitably will mutate and adapt much like the virus itself.

²⁹ Nathan Adams, *Do Virus Response Liability Protections Cover Vaccinations?*, LAW360 (Jan. 26, 2021), <https://www.law360.com/articles/1348629>.

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