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COVID-19 Vaccines Unlikely To Create Litigation Opportunities

By **Eric Kraus and Jennifer Shah** (December 7, 2020, 6:19 PM EST)

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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.

Background

Manufacturers of these vaccines, as well as those who may be charged with distributing and administering them, are well-protected under federal law. The protections do not flow from the National Vaccine Injury Compensation Program, which protects manufacturers of routine vaccines (e.g., childhood vaccines and vaccines for seasonal flu) from liability, but by virtue of the Public Readiness and Emergency Preparedness Act.[1]

Since December 2005, the PREP Act has provided protections for "pandemic and epidemic products and security countermeasures."[2] Countermeasures include a drug, biologic product or device, as those terms are defined in the Federal Food, Drug and Cosmetic Act, which has been authorized for emergency use in accordance with Section 564 of the FDCA.

Section 564 of the FDCA[3] contemplates certain circumstances in which the U.S. Food and Drug Administration commissioner may allow an unapproved drug, biologic or medical device to be used in an emergency to diagnose, treat or prevent serious injury where alternative therapies may not be available.

Such emergency use authorizations have been issued for a variety of products being used to treat COVID-19 infections, such as remdesivir[4] and convalescent plasma,[5] and will also likely be used by manufacturers of COVID-19 vaccines to make them available to the public as quickly as possible.

The provisions of the PREP Act are invoked when the U.S. secretary of Health and Human Services "makes a determination 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."[6]

The PREP Act provisions were extended to cover COVID-19 vaccines by virtue of an official declaration issued by HHS Secretary Alex Azar on March 10,[7] which cited a number of findings, including "that the

spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease, COVID-19, constitutes a public health emergency for purposes of this Declaration under the PREP Act."[8]

In addition to vaccines, covered countermeasures contemplated by the secretary's declaration include products that may be "used to treat, diagnose, cure, prevent or mitigate COVID-19 or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product."

Thus, products such as personal protective equipment, drugs used to treat COVID-19 infections or diagnostics may also be considered covered countermeasures.[9]

Immunity Provisions of the PREP Act

The provisions of the PREP Act make clear that:

> 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 if a declaration under subsection (b) has been issued with respect to such countermeasure.[10]

In order to take advantage of this grant of immunity, the person or entity seeking immunity must be a covered person under the PREP Act. Included in the definition of a "covered person" is any person or entity that is:

> (i.) A manufacturer of such countermeasure;
>
> (ii.) A distributor of such countermeasure;
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> (iii.) A program planner of such countermeasure;
>
> (iv.) A qualified person who prescribed, administered, or dispensed such countermeasure; or
>
> (v.) An official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).[11]

Each of these terms are defined broadly to cover virtually any person or entity in the supply chain (such as air carriers who will need to transport vaccines in ultra-cold containers)[12] or anyone administering the vaccine to patients (including a "licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed.").[13]

Amendments, Advisory Opinions and Guidance

Several amendments to the HHS secretary's declaration have further illuminated the scope of immunity. For example, on April 15, the secretary issued an amendment specifically to include respiratory protective devices as a covered countermeasure.[14]

On June 8, he issued another amendment, this time to include even more broadly "qualified products that limit the harm COVID-19 might otherwise cause."[15] On Aug. 24, the secretary issued an

amendment that clarified the circumstances under which pharmacists in various jurisdictions may enjoy immunity under the PREP Act.[16]

Most recently, on Dec. 4, the secretary issued a rather sweeping amendment that provided the clearest statement to date that virtually all persons and entities, in the public and private sectors, involved in the provision of countermeasures to the public are entitled to immunity.

For example, the December amendment now specifically makes clear that those who use "telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are permitted to practice" are now covered.[17]

It also expands the definition of a covered person by adding "a third method of distribution … that would provide liability protections for, among other things, additional private-distribution channels."[18] Perhaps most broadly, in justifying these and other protections extended in related statements from the secretary and HHS, this amendment makes explicit that:

> There are 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. The world is facing an unprecedented pandemic. To effectively respond, there must be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world.[19]

In addition, the HHS Office of the General Counsel has issued several advisory opinions concerning the scope of the PREP Act immunity for COVID-19-related countermeasures. Although these advisory opinions do not carry the force of law, they are persuasive authority.[20]

Notably, HHS holds the opinion that PREP Act immunity extends even to persons and countermeasures that are not covered if there could have been a reasonable belief that the person or countermeasure was covered, and all other conditions for PREP Act immunity are satisfied.[21] Thus, HHS espouses a fairly broad view of the scope of immunity.

HHS has also issued several guidance documents to clarify who may be considered a covered person pursuant to the PREP Act and the associated COVID-19 declaration. These guidances have attempted to clarify and illuminate protections provided to pharmacists,[22] as well as to nursing home facilities and other congregate facilities and staff.[23]

Preemption

The language of the PREP Act makes clear that Congress intended to expressly preempt state law during the period in which the HHS secretary has determined a potential public health emergency.

> During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—
>
> (A) is different from, or is in conflict with, any requirement applicable under this section; and
>
> (B) relates to the design, development, clinical testing or investigation, formulation, manufacture,

distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this Act, or under the Federal Food, Drug, and Cosmetic Act.[24]

Exemptions to Immunity

The PREP Act does provide certain exemptions to this immunity blanket. In broad terms, immunity is not available in the face of willful misconduct. "Willful misconduct" is defined in the PREP Act as "an act or omission that is taken (i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit."[25]

This definition, and other limitations under the secretary's declaration, do not grant much wiggle room to those who wish to pursue liability claims outside of the compensation provisions of the PREP Act, but surely, some may try.

Even if an exemption to immunity might be warranted, the path forward for a potential claimant is not easy. The PREP Act presents a number of hurdles that a claimant must clear before a more traditional tort claim might be allowed to proceed:

- The burden of proving a willful misconduct is on the plaintiff and must be pled with particularity.[26] This is the standard for pleading fraud claims in federal court, a more onerous pleading requirement than usually the case in garden-variety personal injury claims.

- The statute makes clear the legislative intent to limit circumstances in which willful misconduct will allow a claimant to circumvent the protections of the PREP Act: A rule of construction states that willful misconduct should be construed "as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness."[27]

- Cases may only be brought in the D.C. federal court and will initially be heard by a three-judge panel.[28]

- Discovery has certain limits not generally part of the Federal Rules of Civil Procedure. For example, discovery cannot take place until a sued covered person has had the opportunity to file a motion to dismiss; moreover, interlocutory appeals, normally not favored in the federal courts, are permitted if a motion to dismiss is denied.[29]

- A person seeking to sue for personal injury or wrongful death must first seek compensation under the Countermeasures Injury Compensation Program, which is discussed more fully below. If an individual accepts CICP compensation, that person will be precluded from pursuing any further claim in federal court.[30]

- Regulatory compliance is a complete defense to allegations of willful misconduct.[31]

Obviously, claimants are encouraged by the process established by the PREP Act to pursue their claims outside of the usual personal injury/tort system.

Compensation Provisions

If PREP Act immunity applies, then the remedy available to a claimant seeking damages for a loss that is causally related to the use of a covered countermeasure is to seek compensation as provided in the CICP. Such claimants will be left without a common law remedy.

The CICP was established "to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures."[32]

Importantly, compensation under the CICP is narrower than the immunity granted under the PREP Act. The PREP Act provides immunity for all claims of loss. CICP compensation, however, is available only for death or serious physical injury, defined as one warranting hospitalization or causing substantially limited function or disability.[33]

The CICP contains clear causation criteria that must be met for those seeking compensation under this program: "The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation."[34]

Arguably, this is no different than standards that apply in traditional state tort cases, but it is articulated more clearly than is seen in some cases.

Congress appropriates funding of the CICP through Section 319F-4(a) of the PREP Act. While billions of dollars have been appropriated by Congress to combat COVID-19 that can support the fund for the CICP, it is not expected that much will be needed.

According to a recent publication of the Health Resources and Services Administration, since October 2009, the CICP has received 494 claim filings from individuals who alleged they were injured by covered countermeasures and requested compensation. Of the 494 filings, 450 were ineligible for compensation and five cases are in the medical review process.

The CICP has compensated 29 claims totaling more than $6 million since the program began in 2010. The CICP determined 39 claims were eligible for compensation; however, 10 claims did not receive compensation because they did not have any compensable expenses or losses.[35]

Conclusions

The federal government has provided significant liability protections to almost any person or entity involved in providing vaccines or other COVID-19-related products to the public. While the nuances and interplay among various statutes, amendments, advisory opinions and guidance require careful attention, the overall goal of all of these is to immunize the actors in the efforts to stem the tide of this scourge.

From the manufacturer of the vaccine and its distributor to the pharmacist dispensing the vaccine and the health care professional administering it, all are covered by the liability-restricting provisions of the PREP Act and related laws and declarations intended to expedite medical countermeasures to help the country overcome the current health care burden and economic crisis engendered by the virus.

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[1] 42 U.S.C. 247d-6d.

[2] Id.

[3] 21 U.S.C. 360bbb-4.

[4] Remdesivir EUA Letter of Authorization, reissued October 22, 2020, https://www.fda.gov/media/137564/download (last visited Dec. 4, 2020).

[5] COVID-19 Convalescent Plasma EUA Decision Memo (https://www.fda.gov/media/141480/download (last visited Dec. 4, 2020).

[6] 42 U.S.C. 247d-6d (b)(1).

[7] 85 Fed. Reg. 15198 (Mar. 17, 2020).

[8] Id.

[9] 85 Fed. Reg. 15202 (Mar. 17, 2020).

[10] 42 U.S.C. 247d-6d (a)(1).

[11] 42 U.S.C. 247d-6d(i)(2)(B).

[12] 42 U.S.C. 247d-6d(i)(3).

[13] 42 U.S.C. 247d-6d(i)(8)(A).

[14] 85 Fed. Reg. 21013 (Apr. 15, 2020).

[15] 85 Fed. Reg. 35101 (June 8, 2020).

[16] 85 Fed. Reg. 52138 (Aug. 24, 2020).

[17] Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19 and Republication of the Declaration, https://www.phe.gov/Preparedness/legal/prepact/Pages/4-PREP-Act.aspx (last viewed Dec. 4, 2020). ("Notice: This HHS-approved document has been submitted to the Office of the Federal Register (OFR) for publication and has not yet been placed on public display or published in the Federal Register... The document published in the Federal Register is the official HHS-approved document.").

[18] Id.

[19] Id.

[20] Perhaps in an effort to make the advisory opinions a bit less "advisory," the December 4, 2020 Amendment specifically states that the "the Declaration must be construed in accordance with the Department of Health and Human Services(HHS) Office of the General Counsel (OGC) Advisory Opinions on the Public Readiness and Emergency Preparedness Act and the Declaration (Advisory Opinions). The Declaration incorporates the Advisory Opinions for that purpose. Id.

[21] Advisory Opinion On the Public Readiness and Emergency Preparedness Act and the March 10, 2010 Declaration Under the Act, April 17, 2020, as modified on May 19, 2020, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf (last visited Dec. 3, 2020). This advisory opinion contains a list of covered countermeasures for which EUAs have been granted. Id. at 1, Appxs. A, B.

[22] Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act (April 8, 2020), https://www.phe.gov/Preparedness/legal/prepact/Documents/pharmacist-guidance-COVID19-PREP-Act.pdf (last visited Dec. 3, 2020); and Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act (September 30, 2020) https://www.phe.gov/Preparedness/legal/prepact/Documents/pharmacist-guidance-COVID19-vaccines-immunity.pdf (last visited Dec. 3, 2020).

[23] Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities (August 31, 2020), https://www.phe.gov/Preparedness/legal/prepact/Documents/screening-guidance-prep-act-coverage.pdf (last visited Dec. 3, 2020).

[24] 42 U.S.C. 247d-6d(b)(8).

[25] 42 U.S.C. 247d-6d (c)(1)(A).

[26] 42 U.S.C. 247d-6d(c)(3) and 42 U.S.C. 247d-6d(e)(3).

[27] 42 U.S.C. 247d-6d(c)(1)(B).

[28] 42 U.S.C. 247d-6d(e)(1) and 42 U.S.C. 247d-6d(e)(5).

[29] 42 U.S.C. 247d-6d(e)(6)(A)(i-iii).

[30] PREP Act Q&As, https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx (last visited Dec. 3, 2020).

[31] 42 U.S.C. 247d-6d(c)(4) and (5).

[32] HRSA Countermeasures Injury Compensation Program (CICP), https://hrsa.gov/cicp/ (last visited Dec. 3, 2020).

[33] See Advisory Opinion on the Public Readiness and Emergency Preparedness Act at 8.

[34] Notice of Declaration under the Public Readiness and Emergency Preparedness Act for medical countermeasures against COVID-19, https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID19.aspx (last visited Dec. 3, 2020).

[35] https://www.hrsa.gov/cicp/cicp-data, accessed on November 30, 2020, at 4:05 pm.