PREP Act Update: Liability Immunity for "Covered Countermeasures" During the COVID-19 Pandemic

By Gerald P. Schneeweis and Anthony B. Portuese


Public health emergencies like the current worldwide COVID-19 pandemic require assessment and balancing of risks in a short amount of time. As we've seen during this emergency, one of those risks is the potential unavailability of an adequate supply of safe and effective drugs and medical devices to allow healthcare providers to treat seriously ill patients. Another risk is that the infection rate will spin even further out of control before one or more vaccines can be properly researched, designed, tested, analyzed, approved, manufactured, distributed and made available to a large percentage of the world's population.

In recognition of the need to mitigate the effects of future pandemics, in December of 2005, Congress passed the "Public Readiness And Emergency Preparedness Act," 42 U.S.C. sections 247d-6d; 247d-6e (referred to herein as the "PREP Act" or "The Act").

The PREP Act incentivizes drug and device manufacturers to design, manufacture, test and supply (and healthcare providers to administer) critical medical products without the fear of incurring liability for actions that do not rise to the level of "willful misconduct." It is not automatically triggered by the declaration of a public health emergency; rather, it requires a formal, separate Declaration by the Secretary of the Department of Health and Human Services of enumerated "Covered Countermeasures" that would be subject to the Act's liability immunity.

Before the current public health emergency caused by the spread of COVID-19, there had been nine such "Covered Countermeasures" Declarations under the Act.

March 10, 2020 Declaration Regarding the SARS-2-CoV-2 Virus and COVID-19 Pandemic

On March 10, 2020, following his earlier declaration of a national public health emergency posed by COVID-19, an acute respiratory disease caused by the SARS-CoV-2 betacoronavirus, or a virus mutating therefrom, Alex Azar, the Secretary of the Department of Health and Human Services, issued a PREP Act Declaration. It has an effective date of February 4, 2020, and a general expiration date of October 1, 2024. Secretary Azar's Declaration listed various medical products and activities as "Covered Countermeasures" that would qualify for the liability immunity when used against COVID-19 during this time frame including future vaccines, and existing drugs and devices that receive an Emergency Use Authorization from FDA. (85 Fed. Reg. 15,198,15,202 (March 17, 2020). The Declaration has been amended to list additional countermeasures, including those qualifying for a new FDA Emergency Use Authorization.

On April 14, 2020, HHS' Office of General Counsel issued an Advisory Opinion to provide further guidance about the "scope of the PREP Act immunity during the COVID-19 pandemic." Among other things, the Advisory Opinion emphasizes the broad nature of the immunity and reflects the view that a "good faith," but mistaken, belief that a product is a "Covered Countermeasure" should render the immunity applicable.

Features of the PREP Act Liability Immunity

The scope of the immunity conferred for "covered countermeasures" is quite broad:

> (a) Liability protections
>
> (1) In general
>
> Subject to the other provisions of this section, 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) of this section has been issued with respect to such countermeasure.
>
> (2) Scope of claims for loss
>
> (A) Loss
>
> For purposes of this section, the term "loss" means any type of loss, including—
>
> (i) death;
>
> (ii) physical, mental, or emotional injury, illness, disability, or condition;
>
> (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and
>
> (iv) loss of or damage to property, including business interruption loss.
>
> Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

PREP Act, 42 U.S.C, 247d-6d (a)(1)(2).

A "Covered Countermeasure" must be a "qualified pandemic or epidemic product," or a "security countermeasure"; or a drug, biological product or device authorized for emergency use in accordance with Sections 564, 564A, or 564B of the FDCA, including products that have received Emergency Use Authorization (EUA) from FDA, which is issued where a drug or device has not yet been approved for specific use and FDA determines that there is no current FDA-approved or cleared product available. Section 247d-6d(i)(1)(A).

Once the formal Declaration by the HHS Secretary is issued, the PREP Act confers immunity to any "covered person" against:

> *… claims for loss sounding in tort or contract, as well as claims for loss relating to compliance with local, state, or federal laws, regulations, or other legal requirements*. Immunity applies when a covered person engages in activities related to an agreement or arrangement with the federal government, or when a covered person acts according to an Authority Having Jurisdiction to respond to a declared emergency.

These acts include any arrangement with the federal government, or any activity that is part of an authorized emergency response at the federal, regional, state, or local level. April 14, 2020 HHS Advisory Opinion, p. 2 (emphasis added).

This is a strong, if not "absolute," immunity and reflects the public policy behind it: to ensure the availability of resources to combat a national public health emergency.

The Secretary's Declaration is not subject to review by any court. The Act contains an express federal preemption provision. It immunizes against any claims for personal injury brought under either U.S. federal or state law as a result of a "covered countermeasure." It provides a sole

exception for "willful misconduct," which must be established under a "clear and convincing" evidentiary standard, and cannot be based on a manufacturer's acts to comply with an FDA or other governmental directive or guidance. While a claim can be brought to allege "willful misconduct," it can only be brought in the U.S. District Court for the District of Columbia, before a 3-judge panel, and a claimant needs to first exhaust the administrative claim remedy under the "Countermeasure Injury Compensation Act."

As to vaccines, The Act supplants the otherwise applicable "National Vaccine Injury Compensation Act" which provides for a different administrative compensation system in the Federal Court of Claims for injuries or death caused by enumerated vaccines administered during "normal" circumstances.

One who complies with all other requirements of the PREP Act and the conditions of the Secretary's Declaration will not lose PREP Act immunity—even if the medical product at issue is not in fact a covered countermeasure—if that entity or individual "reasonably could have believed" that the product was a "covered countermeasure." (HHS General Counsel's Advisory Opinion, p. 2)

And as the HHS Advisory Opinion points out, not all operations are immunized just because the entity manufactures or distributes a product that has been declared a covered countermeasure.

> [A] liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use.
>
> In each case, whether immunity is applicable will depend on the particular facts and circumstances.

April 14, 2020 HHS Office of General Counsel Advisory Opinion.

The only statutory exception to this immunity is for actions or failures to act that constitute "willful misconduct," defined as:

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 likely that the harm will outweigh the benefit.

PREP Act, section 247d-6d (c)(1)(A).

Under the Act, "willful misconduct" cannot generally constitute an act by a covered entity to comply with an FDA regulation, unless a government enforcement action has been instituted. (42 U.S.C. 247d-6d(c)(4)).

As a corollary to the temporary liability immunity granted to "covered countermeasures," there is a "no-fault" system—the "Countermeasures Injury Compensation Program" (CICP), which is administered by an agency within the HHS. It is designed to compensate those who sustain "serious injury" (an injury that would usually require hospitalization, even if the patient was not actually hospitalized). It provides enumerated 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, and benefits to certain survivors of individuals who die as a direct result of the administration or use of a Covered Countermeasure. 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. *See* Final Rule, published at 42 CFR Part 110 (October 7, 2011).

Limited Judicial Interpretation of the PREP Act

While consumer groups protested its enactment, the PREP Act appears to have generated virtually no case law in connection with other post-2005 pandemics. *Kehler v. Hood*, a decision from the United States District Court for the Eastern District of Missouri, did address some jurisdictional issues under the PREP Act. No. 4:11-CV-1416, 2012 WL 1945952 (E.D. Mo. May 30, 2012).

In June 2009, the HHS Secretary identified the H1N1 influenza virus as a public health emergency and designated the H1N1 vaccine a covered countermeasure under the PREP Act. The *Kehler* plaintiff received an H1N1 vaccine from his doctor in January of 2010 and later developed a severe case of transverse myelitis. He sued the doctor and her medical group in state court, alleging that before receiving the vaccine, he did not give informed consent, and that his physician was negligent in failing to consult with a specialist prior to administering the vaccine. Plaintiff did not sue the vaccine manufacturer, Novartis, but it was impleaded into the state court case by the medical provider defendants as a third-party defendant. It then removed the case to federal court on the basis of "federal officer" jurisdiction pursuant to 42 U.S.C. section 1442(a)(1).

The parties did not dispute that third-party defendant Novartis was protected by the PREP Act immunity and did not allege that Novartis had engaged in willful misconduct so

as to bring its claim within the statute's only recognized exception to the immunity. The district court found that since the PREP Act applied, as to Novartis, exclusive jurisdiction over the doctor's third-party complaint was in the District of Columbia, and thus granted Novartis' motion to dismiss it on the basis of lack of subject matter jurisdiction. The doctor and medical group (non-diverse, "local" defendants) argued that the PREP Act applied to them as well, and that the court should thus retain federal question jurisdiction as to the clams asserted in the Plaintiff's complaint. The court declined and issued an order of remand, noting that the complaint itself alleged medical negligence before the vaccine was administered. *Id.* at *4. The court reasoned that "the assertion of a federal defense, including the defense that claims are preempted by federal law, does not give rise to federal question jurisdiction." *Id.* at *3.

Parker v. St. Lawrence County Public Health Department, 102 A.D. 3d 140, 954 N.Y.S. 259 (2012) upheld PREP Act protections for a county that conducted a school-based vaccination clinic in response to the H1N1 outbreak. During the clinic, a nurse employed by St. Lawrence County inadvertently vaccinated a kindergartener in the absence of parental informed consent. The child's mother filed suit, arguing that the county had committed negligence and battery. The county moved to dismiss the complaint on the basis that the claim was preempted under the PREP Act. The lower court denied the defendant's motion to dismiss, asserting that the PREP Act was not intended by Congress to protect against claims arising from failure to obtain informed consent. The county appealed and both the United States and State of New York submitted amicus briefs supporting the county.

The appellate court dismissed the plaintiff's claims, finding that the federal PREP Act preempted the claims under state law and that the breadth of liability immunity provided under the PREP Act precluded the plaintiff's claims of negligence and battery. The court noted the alternative remedy provided by the countermeasure injury compensation program and the possibility of a federal cause of action for willful misconduct claims. *Id.* at 142–143.

Questions will no doubt arise regarding the existence and extent of PREP Act immunity as well as its intersection with other laws and regulations.

What Next?

The landscape of the current public health emergency seems to change constantly, and there has already been litigation commenced outside of the PREP Act "covered countermeasures" context alleging that businesses negligently failed to protect an individual from the risk of contracting COVID-19 disease. It is the authors' view that if there are widespread serious adverse effects from the administration of eventual COVID-19 vaccines, Plaintiffs' counsel may try to test the boundaries of the immunity in court. If that occurs, the authors believe that some questions may need to be answered:

- What types of facts underlying actions by manufacturers during the immunity period would be considered "willful misconduct" as defined under the PREP Act, so that the immunity would not apply?
- Would some courts refuse to apply express federal preemptive effect to such a claim?
- Will Plaintiffs' counsel attempt to state a separate claim for violation of an individual's civil rights as a result of a covered countermeasure?
- In instances in which a defendant mistakenly believes that a product is a covered countermeasure, is there any basis on which to allow a jury to decide whether a "reasonable person could have believed" it to be covered?
- Would a state court lawsuit that names a "local" defendant-manufacturer be removable to federal court under federal question or federal officer subject matter jurisdiction?
- Will PREP Act immunity completely bar lawsuits in another country–under its laws–for injuries allegedly caused by a vaccine manufactured by a U.S. company?

If and when issues about the application of the PREP Act immunity are framed, the authors believe that most courts will resolve them by applying the underlying purpose of the immunity—to provide incentives to those who can act to mitigate and potentially end a public health crisis.

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