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Insights

IMMUNITY FROM LIABILITY UNDER THE U.S. PREP ACT FOR MEDICAL COUNTERMEASURES DURING THE SARS-COV-2/COVID-19 PANDEMIC

May 22, 2020

Key Points

- **HHS Declaration Provides Immunity**: During a public health emergency, the Secretary of HHS can issue a Declaration providing broad tort immunity for "Covered Persons" engaging in "Recommended Activities" with "Covered Countermeasures."
- **Covered Persons**: The entities covered include, among others, manufacturers and distributors.
- **Recommended Activities**: The activities potentially subject to immunity include "the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures."
- **Covered Countermeasures**: This will include diagnostics, treatment, vaccines and other prevention modalities, masks and other medical equipment that are *FDA-approved or cleared, licensed under the PHS Act, or authorized for emergency use by the FDA*. Note that NIOSH-approved masks are now included.
- Limitations on Distribution: Under the Declaration's "Limitations on Distribution," these activities must be (1) pursuant to a federal contract or other federal agreement or (2) authorized by a "public agency or its delegate," including federal, state, and local governments, that have authority over the pandemic response.
- **Willful Misconduct**: This is not protected by the Act.
- **Compensation for Injured Parties**: Certain individuals that are seriously injured or die "as a direct result of the administration or use of a Covered Countermeasure" may be able to obtain benefits through the government's .
- **Timeline**: The immunity currently lasts from February 4th, 2020 until October 1st, 2024.

The PREP Act & HHS Declaration

Given the rapid spread of SARS-CoV-2, the novel coronavirus responsible for the coronavirus disease, COVID-19, a broad range of medical countermeasures will be needed to control the pandemic. The federal government has a number of tools it can deploy during a public health emergency, including providing immunity from suit under federal and state law for select drugs and devices. This is currently done through a Declaration by the Secretary of the Department of Health and Human Services (HHS) pursuant to the 2005 Public Readiness and Emergency Preparedness, or PREP, Act. 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e. A Declaration was published in the Federal Register at 85 Fed. Reg. 15198 on March 17th, 2020, but has been in effect retroactively since February 4th, 2020 and currently lasts until October 1st, 2024. The Declaration was amended on April 10, 2020, with an effective date of March 27, 2020, to address the addition of masks ("respiratory protective devices") that are approved by the National Institute for Occupational Safety and Health (NIOSH) following the passage of the Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security (CARES) Act. 85 Fed. Reg. 21012.

And on April 14th, 2020, the HHS Office of General Counsel (OGC) issued a nonbinding Advisory Opinion on the PREP Act and the accompanying Declaration. U.S. Dep't of Health & Hum. Serv., Advisory Opinion, (Apr. 14, 2020). The Congressional Research Service also released a helpful Legal Sidebar on the PREP Act on April 8, 2020.

As suggested by the statute, the goal of providing the immunity is to incentivize the development, manufacture, distribution, administration, and use of Covered Countermeasures. 42 U.S.C. § 247d-6d(b)(6).

The provisions of the PREP Act and the accompanying Declaration are complex and this Alert only provides a high-level overview, so entities should carefully evaluate to what extent certain activities and countermeasures are covered. This Alert serves as an update to our April 8, 2020 Alert.

The Scope of Immunity—Covered Persons, Recommended Activities, & Covered Countermeasures

It is important to understand that the Act and Declaration work together. For example, the Declaration can limit coverage or, in some situations, enlarge coverage. Thus, one must examine them together.

A. General Immunity

Under the Act and Declaration, Covered Persons engaging in Recommended Activities with Covered Countermeasures are "immune from suit and liability under federal and state law," when a plaintiff alleges he or she suffered a "loss," which was "caused by, [arose] out of, relat[ed] to or result[ed] from the administration or use" of Covered Countermeasures. 42 U.S.C. § 247d-6d(a)(1). Importantly, under the Limitations on Distribution section of the Declaration,

these activities must be pursuant to some kind of government agreement or authorization. 85 Fed. Reg. at 15202.

HHS has interpreted "federal and state law" to include tort and contract law, "as well as claims for loss relating to compliance with local, state, or federal laws, regulations, or other legal requirements." Advisory Opinion, at 2. The definition of loss under the Act is broad, encompassing both physical and emotional injuries. 42 U.S.C. § 247d-6d(a)(2)(A). While the law does provide immunity from suit, entities are not immune from injunctive relief or enforcement actions by the FDA or other federal agencies. *Id.* § 247d-6d(f). Willful misconduct, discussed further below, is also not immunized by the statute.

B. Covered Persons

A Covered Person includes manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States. Each of these is defined in detail in either the Act or the Declaration. *See* 85 Fed. Reg. at 15199.

- Manufacturers can include certain contractors, subcontractors, and suppliers of any product or component.
- Distributors can include particular repackers, common carriers, private-label distributors, warehouses, and retail pharmacies.
- Program planners may include persons who administer a program for dispensing two of the three countermeasures – a security countermeasure or a qualified pandemic or epidemic product. They are also defined as entities providing facilities to administer or use a covered countermeasure. The Advisory Opinion explains that, under the Declaration, program planners can include private sector employers. Advisory Opinion, at 6.
- Qualified persons generally include persons *authorized* by the government to prescribe, administer, deliver, or dispense a covered countermeasure. The Declaration expanded the definitions of "qualified persons" so that one could become authorized in various ways.
- The Declaration also provides a broad definition of "administration," which allows some persons not physically providing countermeasures to be covered. 85 Fed. Reg. at 15202.

Importantly, the immunity coverage is narrower for "program planners" and "qualified persons" than it is for manufacturers and distributors. The former two covered persons are only immune from suits brought by persons who are in certain populations and geographic regions who received the countermeasure from the program planner or qualified person. This limitation does not apply to manufacturers or distributors. 42 U.S.C. § 247d-6d(a)(3)-(4).

C. Recommended Activities and Covered Countermeasures

Recommended Activities, according to the Declaration, include "the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures." 85 Fed. Reg. at 15201.

The Declaration states that *eligible countermeasures* are "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, 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." 85 Fed. Reg. at 15202. As noted above, Congress recently broadened the scope of the immunity here to include masks that are approved by NIOSH.

However, not all of these eligible countermeasures are Covered Countermeasures under the Act and subject to immunity. To obtain immunity, a product also must meet the definition of a "qualified pandemic or epidemic product," a "security countermeasure," or a drug, biological product, or device authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service (PHS) Act. *Id*. Qualified pandemic or epidemic products and security countermeasures must also be approved or cleared by the FDA, licensed under the PHS Act, or authorized for emergency use by the FDA. *Id*. at 15199. In other words, the product must both: (1) be an eligible type of product; and (2) obtain the appropriate type of pre-approval from the government.

D. Limitations on Distribution

Under the Declaration, covered persons (other than governmental program planners) are limited to activities that are: (1) pursuant to a federal contract or other federal agreement or (2) authorized by an Authority Having Jurisdiction (i.e., a "public agency or its delegate"), including federal, state, and local governments that have authority over the pandemic response. 85 Fed. Reg. at 15202.

Guidance on the meaning and scope of this provision is scant. HHS has explained that they "interpret these two conditions broadly to include: (1) any arrangement with the federal government, or (2) any activity that is part of an authorized emergency response at the federal, regional, state, or local level." Advisory Opinion, at 2. Activities can be authorized by, for example, "guidance, requests for assistance, agreements, or other arrangements." *Id*. Under the Opinion, Authorities Having Jurisdiction include HHS as well as others. For many activities, like those related to the administration and use of Covered Countermeasures working under a government contract, the analysis may be fairly straightforward. But in many other contexts this requirement may need careful consideration.

E. Reasonable Belief Standard

Finally, the Advisory Opinion reasons that "Congress did not intend to impose a strict-liability standard on covered persons for determining whether a product is a covered countermeasure."

Id. at 4. In other words, so long as the other requirements of the Act are met, PREP Act immunity will not be lost if a drug or device turns out not to be a Covered Countermeasure or a person turns out not to be a Covered Person, so long as there was a reasonable belief that the product or person were covered by the Act. *Id*. at 2. This language is not stated in the statute and the Advisory Opinion does not have the force of law. Thus, one should be careful in relying too heavily on this opinion as plaintiffs will surely challenge its validity and deferential weight.

F. Case Law

Case law on the PREP Act is very limited. There are currently only three cases interpreting the statute, as well as some suggestive dicta from the Supreme Court.

Parker v. St. Lawrence County Pub. Health Dept., 102 A.D.3d 140 (N.Y. App. Div. 2012), the only case that provides any substantive analysis of the PREP Act, suggests that courts will interpret the PREP Act's immunity to shield a wide range of conduct. In that case, the appellate court upheld PREP Act protections for a county that conducted a school-based vaccination clinic in response to the H1N1 outbreak. *Id*. at 142. During the clinic, a nurse inadvertently vaccinated a child without parental informed consent. *Id*. at 141. The suit alleged that the county had committed negligence and battery due to the lack of consent. *Id*. at 141-42. The court reversed the lower court, holding that the PREP Act preempted the claims under state law and that the breadth of immunity provided under the PREP Act precluded the plaintiff's claims of negligence and battery related to lack of informed consent. *Id*. at 142. The plaintiff's argued that Congress could not have intended for the Act to cover nonconsensual vaccination. *Id*. at 144. But the court did not find this persuasive, reasoning that the preemption clause is broad and the immunity provision is "sweeping," so Congress must have "intended to preempt all state law tort claims arising from the administration of a covered countermeasure" consistent with the Act and Declaration. *Id*. at 143-44.

In *Kehler v. Hood*, No. 4:11CV1416 FRB, 2012 WL 1945952, at *2 (E.D. Mo. 2012), the Kehlers brought an action against Dr. Diane Hood and her employer, St. Luke's Hospital, for negligence because of a failure to obtain informed consent before administering a second dose of the H1N1 vaccine and subsequent loss of consortium due to injuries from the vaccine. The defendants then brought third-party products liability/failure to warn claims against the vaccine-maker, Novartis. *Id*. Novartis removed the case to federal court based on the Federal Officer Removal statute, 28 U.S.C. § 1442(a)(1), which is an exception to the well-pleaded complaint rule. *Id*. at *3. The parties conceded that Novartis was immune from suit here under the PREP Act, so the court dismissed the claims against Novartis for lack of subject matter jurisdiction. *Id*. The original state law claims brought by the Kehlers were then dismissed and remanded to state court under the well-pleaded complaint rule—there was no federal question presented in the complaint and the PREP Act was only raised as a defense. *Id*.

And in *Casabianca v Mount Sinai Medical Center,* No. 112790/10, 2014 WL 10413521, at *5 (N.Y. Sup. Ct. 2014), the court found that medical malpractice and wrongful death claims were *not* covered by PREP Act immunity when the Covered Countermeasure—again, the H1N1 vaccine—was not actually administered. Dr. Angelo Casabianca, the decedent, had gone to defendant Mount Sinai Medical Center for a procedure. *Id.* at *1. The plaintiffs alleged that the decedent contracted and died from the H1N1 virus during his weakened, postoperative state because he was not administered the vaccine. *Id.* Mount Sinai defended that the decedent was not eligible to receive the vaccine, which was in short supply. *Id.* But the court explained that in order for immunity to apply, the loss must relate to the *administration* or *use* of a Covered Countermeasure, and because the vaccine was not actually administered, the PREP Act does not apply. *Id.* at *4.

In addition to these cases, the Supreme Court has suggested in dicta that the PREP Act's immunity is, with certain limitations, categorical. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 253 (2011). The Court explained that the liability protection afforded under the PREP Act was an example of how Congress would word a statute (i.e., with words like "shall" and "all") to provide for a categorical preemption of design defect claims. *Id.* (stating that "when Congress intends to pre-empt design defect claims categorically, it does so using categorical (*e.g.,* 'all') and/or declarative language (*e.g.,* 'shall'), rather than a conditional term ('if').").

The FDA Wants to Work With You

The FDA posted a guidance on face masks encouraging "manufacturers who have not previously been engaged in medical device manufacturing" to contact the FDA and work collaboratively with them through their EUA process. Interested parties should email the FDA at CDRH-COVID19-SurgicalMasks@fda.hhs.gov and describe their proposal. The FDA also provides a Device Advice page for regulatory assistance regarding devices, including personal protective equipment like masks and respirators. For all of the most recent information from the FDA regarding COVID-19, see their COVID-19 Resources page.

Compensation for Injured Parties

Even though an injured party might not be able to file suit, they may be able to recover under the Countermeasures Injury Compensation Program (CICP). 42 U.S.C. § 247d-6e; 42 CFR pt. 110. According to the Declaration, individuals or their survivors/estate that are seriously injured or die "as a direct result of the administration or use of a Covered Countermeasure" may be able to obtain benefits from the program. According to a Fact Sheet on the program, "the CICP is the payer of last resort. This means that it only covers expenses or provides benefits that other third-party payers, such as health insurance, the Department of Veterans Affairs, or Workers' Compensation programs, don't have an obligation to pay."

The Declaration Does Not Cover Willful Misconduct

Finally, the law does NOT protect willful misconduct that proximately caused death or serious injury from liability. 42 U.S.C. § 247d-6d(c)-(d). This includes intentionally and knowingly engaging in wrongful conduct, but the statute clarifies that willful misconduct does not include negligent or even reckless conduct. *Id.* § 247d-6d(c)(1)(B). However, under certain circumstances defined by the Act, even willful misconduct may still be immune from suit. For example, manufacturers and distributors may still receive liability immunity for acts and omissions subject to regulation by the FDA or the Act if "neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission." *Id.* § 247d-6d(c)(5). Suits are brought under a federal cause of action for death or serious physical injury caused by willful misconduct, and courts are to use the substantive law of the state where the alleged conduct occurred. *Id.* § 247d-6d(d)(1) & (e).

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