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HHS Issues Advisory Opinion Encouraging a Broad Reading of its PREP Act Declaration

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On April 14, 2020, the Department of Health and Human Services (HHS) General Counsel issued an advisory opinion ("the Opinion") on the March 10, 2020 Public Readiness and Emergency Preparedness Act ("PREP Act") Declaration ("the Declaration") related to COVID-19, in response to numerous requests for guidance from manufacturers, distributors, and health care providers. Although the Opinion is not binding law and does not answer every question about the Declaration, it does provide insight into the intended scope of the Declaration.

By way of background, the PREP Act[1] confers a significant benefit to manufacturers, distributors, and providers of certain products by providing an affirmative defense to product liability lawsuits with respect to use of those products to respond to a declared emergency. The PREP Act provides immunity "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 use by an individual of a covered countermeasure if a Declaration has been issued with respect to such countermeasure."[2] There are three key elements necessary to obtain PREP Act immunity, all of which are addressed in the Opinion and are discussed below:

"Reasonable Belief" Standard

Importantly, the Opinion provides further confirmation on the intended breadth of the PREP Act's immunity protections by adding critical language suggesting a "reasonable belief" standard for determining whether PREP Act requirements have been satisfied. Specifically, the Opinion states that "Given the broad scope of PREP Act immunity, Congress did not intend to impose a strict-liability standard on covered persons for determining whether a product is a covered countermeasure. Instead, we believe that a person or entity that otherwise meets the requirements for PREP Act immunity will not lose that immunity—even if the product is not a covered countermeasure—if that person or entity reasonably could have believed that the product was a covered countermeasure." Opinion at 4-5. The Opinion goes on to explain that the same "reasonable belief" standard applies to the "covered persons" requirement under the PREP Act. Opinion at 7.

[1] Codified at 42 USC § 247d-6d.

[2] 42 USC § 247d-6d(a)(1).

Covered Person

The Declaration limits PREP Act immunity to covered persons, which comprises manufacturers, distributors, program planners, and "qualified persons" who prescribe, administer, or dispense a covered countermeasure. The Declaration defines "qualified persons" as "a licensed health professional or other individual authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the Covered Countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's Declaration." Declaration at Section V.

The Opinion clarifies two points with respect to "covered person". First, it explains that a state, Federal, or local agency has the authority to designate additional qualified persons that would be eligible for PREP Act immunity. As discussed above, the Opinion also provides that an entity need not actually be a covered person to receive PREP Act immunity "if that entity or person reasonably could have believed, under the current, emergent circumstances, that the person was a covered person." Opinion at 7 citing 42 USC 247d-6d(a)(4)(B).

Covered Countermeasure

The Declaration defines "covered countermeasure", in relevant part, as "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." Moreover, to be a covered countermeasure, the product must be a qualified pandemic or epidemic product or a drug, biological product, or device authorized for investigational or emergency use, as those terms are defined in the PREP Act, the Food Drug & Cosmetic (FD&C) Act, and the Public Health Service Act.

In turn, a "qualified pandemic or epidemic product" is defined in the Declaration as "a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that is (i) manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device."

The Opinion provides a more in-depth discussion about covered countermeasures under the Declaration, including links to the long list of Emergency Use Authorizations that FDA has issued in response to COVID-19 regarding therapeutics and medical devices. The Opinion also highlights the fact that the Coronavirus Aid, Relief, and Economic Security (CARES) Act expanded the definition of covered countermeasure to include certain respirators that may not meet the definition of medical device under the FD&C Act. As with covered person, the Opinion explains that PREP Act immunity could extend to a product that does not meet the technical definition of covered countermeasure, "if [a covered] person or entity reasonably could have believed that the product was a covered countermeasure." Opinion at 4 citing 42 USC 247d-6d(a)(4)(B).

Limitation on Distribution

The Declaration provides that PREP Act immunity is afforded to Covered Persons only for Recommended Activities related to:

a. Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or

b. Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency.

This section of the Declaration has proven to be the most difficult to parse, and the Opinion provides helpful explanation. HHS explains that paragraph (a) of the Limitation on Distribution is satisfied by "any arrangement with the federal government" and that paragraph (b) can be read more simply to mean "any activity that is part of an authorized emergency response at the federal, regional, state, or local level." Although the "Authority Having Jurisdiction" requirement is not perfectly clear, the Opinion states that a covered person undertakes "activities in accordance with the public health and medical response" of an Authority Having Jurisdiction if such activities are authorized through, "among other things, guidance, requests for assistance, agreements, or other arrangements." Opinion at 2. Consistent with our prior analysis of HHS's April 8 Guidance for Licensed Pharmacists, COVID-19 Test, and Immunity Under the PREP Act, the Authority Having Jurisdiction can be either a state, local, or even Federal agency. The Opinion then explains that HHS itself constitutes an Authority Having Jurisdiction under the PREP Act, though it notes "it is not the only Authority Having Jurisdiction to respond to the COVID-19 emergency." Opinion at 6. Finally, the Opinion provides that the HHS Secretary's Public Health Emergency Declaration dated January 31, 2020 fulfills the emergency declaration requirement at the end of paragraph (b), without the need for a state or local government declaration, although all 50 states have now issued such declarations.

Willful Misconduct and Serious Physical Injury or Death

The Opinion reiterated that PREP Act immunity is broad, but it does not cover claims involving willful misconduct causing death or serious physical injury (Willful Misconduct Exception). And the PREP Act sets a high bar for demonstrating willful misconduct: a plaintiff must show clear and convincing evidence that the conduct must be (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." HHS also noted two key instances where the Willful Misconduct Exception does not apply. First, where program planners[3] or qualified persons "acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure" as long as certain notice requirements are met. Second, if the misconduct involves an FD&C Act or Public Health Service regulated activity, the action will not constitute "willful misconduct" if neither HHS or DOJ has initiated an enforcement action[4] or an enforcement action has been resolved without a covered remedy.[5]

[3] Defined as a "State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program." 42 U.S.C. § 247d-6d(i)(6).

[4] Defined as a criminal prosecution, an action seeking an injunction, a seizure action, a civil monetary proceeding based on willful misconduct, a mandatory recall of a product because voluntary recall was refused, a proceeding to compel repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i), 360j(g)], a debarment proceeding, an investigator disqualification proceeding where an investigator is an employee or agent of the manufacturer, a revocation, based on willful misconduct, of an authorization under section 564 of such Act [21 U.S.C. 360bbb–3], or a suspension or withdrawal, based on willful misconduct, of a biologics approval or clearance or of a licensure.

[5] A criminal conviction, an injunction, or a condemnation, a civil monetary payment, a product recall, a repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i), 360j(g)], a debarment, an investigator disqualification, a revocation of an authorization under section 564 of such Act [21 U.S.C. 360bbb–3], or a suspension or withdrawal of a biologics approval or clearance under chapter 5 [1] of such Act or of a licensure; and that results from a final determination by a court or from a final agency action.

Where companies, states, municipalities, and individuals meet the elements of PREP Act immunity, the immunity protection is broad, and the willful misconduct exception sets a high hurdle for plaintiffs to overcome. Injured parties, however, are not without any recourse. The Secretary noted that parties with claims of serious physician injury or death may apply for benefits to the Health Resources and Services Administration's Countermeasures Injury Compensation Program (CICP). HHS noted that CICP should be the "payer of last resort." Under the Declaration, 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." The CICP was established by Congress in 2010, and it is administered by the Health Resources and Services Administration. More information on the CICP can be found at https://www.hrsa.gov/cicp/.

If you have any questions about how the PREP Act may apply to a product that your company is selling or donating to assist in the response to COVID-19, please do not hesitate to contact our team.

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