

Third Amendment to PREP Act Declaration Expands Scope of COVID-19 Liability Immunity

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On August 24, 2020, the Secretary for the Department of Health and Human Services (HHS) issued a [Third Amendment](#) to the March 2020 Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for medical countermeasures against COVID-19. Citing to a recent CDC report identifying a decline in routine pediatric vaccine administration that might indicate an increased risk for outbreaks of vaccine-preventable diseases, and attributing that decline to changes in healthcare access, social distancing, or other COVID-19 mitigation strategies, the Third Amendment further expands the scope of “Covered Persons” and “Covered Countermeasures” under the PREP Act.

In the Third Amendment, the Secretary states that this decrease in childhood vaccination rates is a public health threat and a collateral harm caused by COVID-19. Noting that community pharmacists are well-positioned to expand access to childhood vaccinations and prevent outbreaks of vaccine-preventable diseases, the Secretary identifies as “Covered Persons” state-licensed pharmacists who order or administer (and licensed or state-board-registered pharmacy interns acting under their supervision who administer) vaccines to children ages three through 18 so long as the following requirements, among others, are met:

- The vaccine is FDA-authorized or FDA-approved;
- The vaccination is ordered and administered according to the Advisory Committee on Immunization Practices (ACIP) standard immunization schedule;
- The licensed pharmacist or intern has completed an accredited practice training program of at least 20 hours; and
- The licensed pharmacist or intern has a current certificate in basic cardiopulmonary resuscitation.

The Third Amendment notes that these and other enumerated requirements are consistent with those in many states that permit licensed pharmacists (or licensed or registered pharmacy interns acting under their supervision) to administer vaccines to children.

The Secretary also observed that both the PREP Act and the June 4, 2020 Second Amendment (previously discussed [here](#)) broadly define “Covered Countermeasures” to include qualified pandemic and epidemic products that “limit the harm such pandemic or epidemic might otherwise cause.” The Third Amendment thus clarifies that in light of the “troubling decrease in ACIP-recommended childhood vaccinations and the resulting increased risk of

associated diseases” due to COVID-19, such childhood vaccinations are “Covered Countermeasures” under the PREP Act and Second Amendment.

Similarly, the Third Amendment also expands the category of disease or threat for which the administration or use of the “Covered Countermeasures” is authorized (Section VIII) to include “other diseases, health conditions or threats that may have been caused by COVID-19, SARS-CoV-2, or a virus mutating therefrom, including the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases.”

Importantly, the Third Amendment does not affect the National Vaccine Injury Compensation program, including an injured party’s ability to obtain compensation under that program.

As discussed in our prior alerts (available [here](#) and [here](#)), the PREP Act Declaration provides broad immunity from liability to persons who qualify as “Covered Persons” engaging in certain authorized activities related to “Covered Countermeasures” in the fight against the pandemic. For COVID-19, the Declaration offers immunity under federal and state law against all claims of loss “caused by, arising out of, relating to, or resulting from” the “manufacture, testing, development, distribution, administration, and use” of “covered countermeasures.” “Covered Countermeasures” are defined in Section VI of the Declaration to include drugs, biological products, or devices used to treat, diagnose, prevent, or mitigate COVID-19. The immunity extends not only to COVID-19 drugs, but to other products and technologies intended to enhance the use or effect of a drug, biological product, or device, or to protect against adverse effects from those products. For a product to qualify as a covered countermeasure, it generally must be either approved, licensed, or authorized by the FDA; cleared for investigational or emergency use under an Investigational Drug Application or Investigational Device Exemption by the FDA; authorized for emergency use under an Emergency Use Authorization; or described in the Emergency Use Instructions issued by the CDC.

For any questions regarding the Third Amendment to the Declaration, please contact Sandra Edwards, Rand Brothers, or your Winston relationship attorney.

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