

Legal Liability and the Public Readiness and Emergency Preparedness Act

The **Public Readiness and Emergency Preparedness Act (PREP Act)** provides immunity for “covered persons” from liability against any claim of loss “caused by, arising out of, relating to, or resulting from” the distribution, administration, or use of COVID-19 vaccines approved by Federal Drug Administration (FDA) under an EUA or BLA. The only exception to immunity is for claims involving “willful misconduct” as defined in the PREP Act.

HHS most recently amended the PREP Act on December 3, 2020, to expand civil immunity under the PREP Act from tort claims related to the manufacture, distribution, administration, and nonadministration of COVID-19 countermeasures, which would include COVID-19 vaccines and specifically extended immunity to every person and entity in the public or private chain of distribution. It also expands immunity to certain licensed pharmacists who could administer COVID-19 vaccines if they have completed the immunization training required by their licensing state for pharmacists to order and administer vaccines.

The PREP also provides a “fund supplied by Congress, to compensate individuals who suffer an injury or death as a result of a COVID-19 vaccine approved under an EUA or a full FDA approval.” The fund operates as a remedy of last resort and would be offset by any health insurance or workers’ compensation payments received by the employee.

PREP Act immunity “without geographic limitation” begins February 4, 2020, and ends as late as October 1, 2025.

Covered Person is defined to include: the United States and manufacturers, distributors, program planners, qualified persons and their officials, agents and employees

- “Manufacturers” includes a manufacturer’s contractors, subcontractors, affiliates, parents, subsidiaries, successors, assigns and suppliers or licensors of certain things and services used in the development or manufacturing of a covered countermeasure
- “Distributors” are those parties engaged in the distribution of drugs, biologics, or devices, including manufacturers, repackers, carriers, own-label and private-label distributors, jobbers, brokers, warehouses, independent wholesale drug traders, and retail pharmacies
- “Program Planner” is: person[s] who supervised or administered a program with respect to the administration, dispensing, distribution, provision or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with [the Secretary’s declaration].
- “Qualified Person” is: 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; or a person within a category of persons so identified in a declaration by the Secretary.”
- “[a]ny person authorized ... to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures” in “accordance with the public health and medical emergency response”[11] of a local, state, or federal agency with “legal responsibility and authority for responding to an incident.”

NOTE: Act also addresses the training required to administer the vaccine.

Detailed information related to legal immunity can be found [here](#) and [here](#). If you are concerned about potential liability, we recommend speaking with your attorney directly.