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[Coronavirus Response](#)

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[Publications](#)

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Declaration Granting Immunity to Manufacturers and Distributors of COVID-19 Countermeasures Issued

On March 17, 2020, U.S. Secretary for Health and Human Services Alex Azar published a declaration in the Federal Register stating that “the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease COVID-19 constitutes a public health emergency.”

The [declaration](#), made pursuant to the Secretary’s authority under the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. 247d-6d, grants immunity from liability under federal and state law for any loss, including death, injury, emotional distress, or damage to property caused by, arising out of, relating to, or resulting from the administration or use of any antiviral, drug, biologic, diagnostic, device, or vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19 (the “Covered Countermeasures”).

This immunity covers all losses occurring through Oct. 1, 2024 and applies to all “covered persons” engaging in “recommended activities” with respect to the Covered Countermeasures. An additional 12 months of liability protection is also provided for manufacturers to arrange for disposition of Covered Countermeasures.

The scope of covered persons extends throughout the Covered Countermeasures supply chain and includes:

- Any manufacturer of a Covered Countermeasure;
- Any contractor or subcontractor of a manufacturer;
- Any supplier or licensor of any product, intellectual property, service, research tool, or component or other article used by a manufacturer;
- The parents, subsidiaries, affiliates, successors, and assigns of a manufacturer;
- Any person or entity engaged in the distribution of Covered Countermeasures, including but not limited to: repackers, common carriers, warehouseurs, and retail pharmacies;

- Licensed health professionals authorized to prescribe, administer, or dispense the Covered Countermeasures under state law;
- Any person authorized to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures pursuant to either an Emergency Use Authorization under the Food, Drug and Cosmetic Act or a declaration of emergency issued by a federal, state, or local agency that has authority for responding to an emergency health incident; and
- Any state or local government, including an Indian tribe, to the extent that they obtained the Covered Countermeasures through voluntary means (as opposed to seizing privately held stockpiles of Covered Countermeasures).

Any of the covered persons above are potentially shielded from liability or suit for loss arising from their having engaged in any of the “recommended activities” of manufacturing, testing, developing, distributing, administering, or using any Covered Countermeasure, **provided that** those activities related to either: **(a)** a federal agreement or **(b)** activities authorized by a declaration of emergency issued by a federal, state, or local agency that has authority for responding to an emergency health incident.

The PREP Act provides an exclusive federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct while the covered person was engaging in a recommended activity with respect to a Covered Countermeasure.

Importantly, with respect to a manufacturer or distributor, an act or omission can only constitute willful misconduct if the Secretary or the U.S. Attorney General initiates an enforcement action with respect to such act or omission. If the enforcement action is terminated or finally resolved without a “covered remedy” (as defined under the PREP Act) then the act or omission would cease to constitute willful misconduct.

The PREP Act provides that no court of the U.S., or of any state, has subject matter jurisdiction to review the Secretary’s declaration, and all conflicting state law is expressly preempted.

42 U.S.C.A. § 247d-6e established the Covered Countermeasure Process Fund (CICP) for purposes of providing timely, uniform, and adequate compensation to certain individuals or estates of individuals who suffer death or serious physical injury as the direct result of the administration or use of a Covered Countermeasure. Benefits can include payment or reimbursement for reasonable and necessary medical services, lost employment income, or death benefits.

42 C.F.R. § 110.20 establishes the processes for proving that an injury was sustained as the result of a Covered Countermeasure, including a system of “table injuries” that are presumed to be caused by a Covered Countermeasure, provided that the first sign or symptom of the injury occurs within the time period after administration or use of the covered countermeasures as listed in the table.

To provide guidance and support to clients as this global public-health crisis unfolds, Frost Brown Todd has created a [Coronavirus Response Team](#). Our attorneys are on hand to answer your questions and provide guidance on how to proactively prepare for and manage any coronavirus-related threats to your business operations and workforce.

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