Federal Government Provides Liability Immunity to Manufacturers and Distributors in Fight Against COVID-19: What Companies Need to Know

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Over the past several weeks, the Firm has received a number inquiries from clients (on both coasts) who are interested in manufacturing or selling test kits, respirators, masks, and other PPE in response to the COVID-19 pandemic, with respect to potential liability risks associated with such activities.

On March 10, 2020, pursuant to authority granted in the Public Readiness and Emergency Preparedness Act (the PREP Act) and the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), the U.S. Department of Health and Human Services (HHS) published a "Notice of Declaration" titled "Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19" (the "Declaration"). The Declaration encourages companies to leverage and use their resources to assist in efforts to diagnose, mitigate, prevent, treat, or cure COVID-19, or to limit the harm that the pandemic would otherwise cause.

In exchange for those efforts, defined as "Medical Countermeasures ("MCMs")," the Declaration provides broad liability immunity to product manufacturers, distributors and others against claims arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of MCMs designed to combat COVID-19. While the scope of the Declaration's immunity provisions is intentionally broad, there are a number of provisions governing its application to particular activities, as well as some definitional ambiguities in the Declaration, that companies need to assess prior to manufacturing or selling MCMs. For example, liability immunity is afforded only to activities related to present or future federal agreements, or "[a]ctivities 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." While it is unlikely that HHS intended this language to significantly limit the broad immunity provided by the Declaration, it is written as a

The following chart summarizes the key provisions of the Declaration. Before manufacturing or distributing MCMs companies are advised to seek guidance from counsel as to application of the Declaration to the planned MCM activities. Companies should also confer with their insurance professionals with respect to liability insurance coverage for any residual liability exposures associated with the planned activities.

Sources of Law:	Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (HHS March 17, 2020). The Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. 247d-6d; 42 U.S.C. 247d-6e. The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), 127 Stat. 161.
Covered Persons:	The Declaration covers manufacturers and distributors, as defined below: 1. **Manufacturer**—a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer. 2. **Distributor**—distributor means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to: manufacturers; re-packers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.
Covered Countermeasures:	The Declaration covers 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-

	• or a product or technology intended to enhance the use or effect of such a drug, biological product, or device. or 2. **Security Countermeasure**—a drug or device . . . or a biological product . . . that (i)(a) The Secretary determines to be a priority to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat . . ., or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined . . . to be a necessary countermeasure to protect public health.
Distribution:	Liability immunity is afforded to Covered Persons for the Recommended Activities that are related to: • Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or • Activities authorized in accordance with the public health and medical response of the relevant governmental authority to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency.
Liability Immunity:	Subject to other provisions of the PREP Act, a covered person shall be immune 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.”
Other Limitations:	• Countermeasures must be approved or cleared under the Federal Food, Drug, and Cosmetic Act; licensed under the Public Health Service Act; or authorized for emergency use under Sections 564, 564A, or 564B of the FD&C Act. • Liability immunity does not apply to injury caused by willful misconduct.

Geographic Area:	No geographic limitation. **Note**: Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in any designated geographic area.
Effective Time Period:	From February 4, 2020 through October 1, 2024
Additional Time Period of Coverage:	An additional 12 months of liability protection has been afforded to allow for the manufacturer to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

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