KILPATRICK TOWNSEND

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Legal Immunity: A Reward for Innovators Combatting COVID-19

by Gunjan R. Talati , Jason M. Wenker , Matthew Chung

Please note: The below information may require updating, including additional clarification, as the COVID-19 pandemic continues to develop. Please monitor our main COVID-19 Task Force page and/or your email for updates.

In light of the public health emergency, the Secretary of Health and Human Services has issued a Notice of Declaration providing immunity from legal liability for activities relating to combatting the new coronavirus.[1] Under the Declaration as authorized by the Public Readiness and Emergency Preparedness (PREP) Act, certain individuals and entities will be immune from liability under federal and state law with respect to all claims for loss relating to the manufacture, testing, development, distribution, administration, or use of medical countermeasures against the coronavirus disease (COVID-19).[2]

The liability immunity granted by the Declaration is intended to incentivize companies to quickly develop and test new products while protecting them from threats of future liability that may arise from such early actions.

To qualify for legal immunity under the PREP Act, an entity must satisfy the following requirements:

1. The entity must be a Covered Person under the PREP Act;
2. Activities performed by the entity must fit within the definition of Recommended Activities;
3. The devices manufactured and distributed by the entity must be Covered Countermeasures; and
4. The activities performed by the entity are authorized in accordance with any limitation of distribution set forth in the Declaration.

A Covered Person under the Declaration includes manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States. The Declaration further defines "qualified persons" to include, among others, any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction.[3] Recommended Activities under the PREP Act are defined as the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures.[4]

To be considered as a Covered Countermeasure under the Declaration, a product should be an antiviral, drug,

biologic, diagnostic, device, or vaccine that is: (i) used to treat, diagnose, cure, prevent, or mitigate COVID-19 or the transmission of the new coronavirus; and (ii) authorized for use by the Food and Drug Administration (FDA) or otherwise permitted for emergency use in accordance with Federal law.[5] [6]

For product authorizations, the Declaration specifically requires the product to be approved or cleared under the FD&C Act, licensed under the Public Health Service (PHS) Act, or authorized for emergency use under Sections 564, 564A, or 564B of the Food, Drug, and Cosmetic (FD&C) Act.[7] For example, an FDA authorization may include an Emergency Use Authorization (EUA) under Section 564 of the FD&C Act, in which the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by COVID-19 threat agents when there are no adequate, approved, and available alternatives.[8]

In the past, several N-95 respirators did not qualify as Covered Countermeasures under the Declaration, because they are not FDA-approved but instead regulated by the National Institute for Occupational Safety and Health.[9] N-95 respirator masks are personal protective equipment used to protect against airborne particles and liquid contamination. The Coronavirus Aid, Relief, and Economic Security (CARES) Act has modified the PREP Act such that N-95 respirators are afforded with legal immunity if approved by the National Institute for Occupational Safety and Health (NIOSH).[10]

With respect to any limitation of distribution, the Declaration states that liability immunity is afforded to Covered Persons for Recommended Activities related to (a) present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or 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.[11] According to the Declaration, the Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, state, or federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority.[12]

Finally, the immunity does not extend to claims involving willful misconduct.[13]

The Declaration is retroactively effective as of February 4, 2020 and expires on October 1, 2024.[14] Manufacturers are protected from legal liability for an additional 12 months from the above expiration date.[15]

Footnotes

[1] Summary, Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures

[2] *Id.* at Supplementary Information

[3] *Id.* at Section V.

[4] *Id.* at Section III.

[5] *Id.* at Section VI.

[6] https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx

[7] Section VI, https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID19.aspx

[8] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

[9] N95 Respirators in Industrial and Health Care Settings, https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks

[10] Section 4113, CARES Act; and Section VI, Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, https://www.federalregister.gov/documents/2020/04/15/2020-08040/amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical

[11] Section VII, Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19

[12] See *Id.*

[13] Section XI, https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID19.aspx

[14] *Id.* at Section XII.

[15] *Id.* at Section XIII.