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Liability, Immunity, and Your Business: Answers to the Top 10 Questions About the PREP Act COVID-19 Declaration

On March 17, 2020, the Secretary of Health and Human Services (HHS) published the Public Readiness and Emergency Preparedness Act (PREP Act) COVID-19 Declaration granting liability immunity to certain individuals and entities involved in the production, supply, or use of products to combat COVID-19. Which entities does the COVID-19 Declaration cover, and what are its specific implications? The summary below answers your top 10 questions about the recent PREP Act Declaration.

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1. **What is the PREP Act?**

The PREP Act authorizes the Secretary of HHS to issue declarations granting certain entities and individuals immunity from liabilities related to the administration or use of medical countermeasures against "diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency," except for claims involving willful misconduct.[1] Enacted on December 30, 2005 to incentivize the production of critical resources during crises, the PREP Act is an amendment to the Public Health Service Act.

2. **What does the COVID-19 Declaration do?**

Published on March 17, 2020 and applying retroactively to February 4, 2020, the "Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19" provides "Covered Persons" with liability immunity from "any claim of loss caused by, arising out of, relating to, or resulting from" their engagement in "Recommended Activities," i.e. the "manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures)" against COVID-19.[2]

3. **Who are "Covered Persons?"**

The COVID-19 Declaration extends liability immunity to the United States; "manufacturers," "distributors," and "program planners" of Covered Countermeasures; "qualified persons" who have manufactured, distributed, administered, prescribed, or used Covered Countermeasures; and the officials, agents, and employees of each of these categories. The PREP Act's broad definitions of these terms, as detailed in the COVID-19 Declaration, are below.[3]

The "manufacturer" category includes contractors; subcontractors; the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer; and suppliers and licensers of products, intellectual property, services, research tools, or components used in the design, development, clinical testing, investigation, or manufacturing of Covered Countermeasures.

The "distributor" category includes entities involved in the distribution of drugs, biologics, or devices, including 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.

The "program planners" category includes state or local governments (including Indian tribes), employees of state or local governments, and individuals or entities supervising or administering programs involved in the administration, dispensing, distribution, provision, or use of Covered Countermeasures. Under this definition, a private sector employer or community group carrying out the aforementioned activities could be considered a "program planner."

Finally, the "qualified persons" category includes licensed health professionals or other individuals authorized to prescribe, administer, or dispense Covered Countermeasures either (1) under the laws of the states in which they carry out said activities, (2) following the Declaration of an emergency, or (3) under an Emergency Use Authorization in accordance with Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

4. **What are the Covered "Recommended Activities?"**

The COVID-19 Declaration grants liability immunity to Covered Persons who have engaged in the "manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures."[4]

5. **What are the "Covered Countermeasures?"**

According to the COVID-19 Declaration, Covered Countermeasures must fit into at least one of three broad categories, as defined in the PREP Act, the FD&C Act, and the Public Health Service Act: (1) "qualified pandemic or epidemic products," (2) "security countermeasures," or (3) "drugs, biological products, or devices authorized for investigational or emergency use."[5] The Declaration extends immunity to any antiviral, drug, biologic, diagnostic, device, or vaccine "used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom," in addition to any device used to administer such a product and all of its components and constituent materials.[6]

It is important to note that the COVID-19 Declaration does not mention the off-label use of antivirals, drugs, biologics, diagnostics, devices, or vaccines in its list of Covered Countermeasures. As such, "[c]ompanies with previously approved or cleared products that could be repurposed to diagnose or treat COVID-19 should exercise caution in responding to requests for information on such uses."[7] Before repurposing existing devices, diagnostics, or therapies to respond to COVID-19, they should "evaluate all applicable requirements, including quality process requirements, validation requirements and labeling obligations and must carefully scrutinize all available data (both internal and public data), before making any changes to existing devices or making representations to the public or customers that are inconsistent with approved labeling."[8]

FDA recently issued a guidance for industry and FDA staff regarding a temporary flexible policy towards the modification of preexisting ventilators, anesthesia gas machines, other respiratory devices, and their accessories for COVID-19 patients. The guidance states: "FDA does not intend to object to limited modifications to the indications, claims, functionality, or to the hardware, software, or materials of FDA-cleared devices used to support patients with respiratory failure or respiratory insufficiency, without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.815, for the duration of the declared public health emergency."[9] The guidance also describes FDA's intent to expedite its Emergency Use Authorization (EUA) process to "interact…with manufacturers of ventilatory support devices that are not currently legally marketed in the U.S. as well as manufacturers who have not previously been engaged in medical device manufacturing with capabilities to increase supply of these devices."[10]

6. **What is the Covered Time Period?**

Currently, Covered Persons have liability immunity for the ***distribution*** of Covered Countermeasures through October 1, 2024, with potential time extensions for certain distributors with government contracts or other agreements identified in the COVID-19 Declaration. Liability immunity for the ***administration and use*** of Covered Countermeasures lasts through October 1, 2024 or the final day that the emergency Declaration is in effect, whichever happens first.

After the Declaration's expiration, Covered Persons have an additional 12 months of liability protection to dispose of Covered Countermeasures, return the Covered Countermeasures to their manufacturer(s), and "take such other actions as are appropriate to limit the administration or use of the Covered

Countermeasures."[11] As a proactive response to this policy, manufacturers and suppliers may consider "[u]niquely identifying each item now by date code, to ensure they can be identified for retrieval later…[to] help mitigate any residual risk."[12] Furthermore, "[e]ntities that are supplying a component should be sure to alert customers of the need for traceability."[13]

7. **What is the Scope of the Liability Immunity?**

Under the PREP Act, the COVID-19 Declaration offers Covered Persons immunity protection against "any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure," as long as (1) the Covered Person administered or used the countermeasure during the effective period of the Declaration, and (2) the Covered Person administered or used the countermeasure against COVID-19.[14] If the Covered Person in question is a ***"program planner"*** or ***"qualified person,"*** they also must have administered or used the countermeasure (3) in a population specified in the Declaration and (4) in a geographic area specified by the Declaration or with a connection to such geographic area. Finally, in the case of ***governmental program planners***, the COVID-19 Declaration only extends liability immunity if the governmental program planner has obtained the Covered Countermeasures "through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles."[15]

The PREP Act's definition of "loss" includes the loss of property; damage to property; business interruption loss; "physical, mental, or emotional injury, illness, disability, or condition"; "fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring"; and death.[16]

As for the geographical scope of the COVID-19 Declaration, ***manufacturers*** and ***distributors*** receive liability immunity for engaging in Recommended Activities "without geographic limitation."[17] Meanwhile, ***program planners*** and ***qualified persons*** receive liability immunity for engaging in Recommended Activities "in any designated geographic area, or [when] the program planner or qualified person reasonably could have believed the recipient was in that geographic area."[18]

8. **What are the Limitations on the Liability Immunity?**

First, the PREP Act and COVID-19 Declaration do not extend immunity to acts of "willful misconduct." Thus, a claimant may pursue a claim against a Covered Person for death or serious injury related to a Covered Countermeasure if he or she can establish through "clear and convincing evidence" that the Covered Person conducted an act or omission (1) "intentionally to achieve a wrongful purpose," (2) "knowingly without legal or factual justification," and (3) "in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit."[19] Given this high burden of proof, "[a]ny claimant seeking to bring a suit for alleged willful misconduct faces additional hurdles, including stricter pleading standards, verification of allegations in the complaint, a pre-filing expert affidavit supporting causation, strict limitations on discovery and limits on damages."[20]

Second, the COVID-19 Declaration only extends immunity to Covered Persons engaging in Recommended Activities that have been authorized by a governmental entity. At the ***federal*** level, a Covered Person must conduct Recommended Activities in connection with present or future federal agreements, e.g. federal contracts, cooperative agreements, grants, interagency agreements, memoranda of understanding, or other transactions. At the ***state and local*** levels, a Covered Person

must conduct Recommended 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" after a declaration of emergency by any authorized local, regional, state, or federal official to "indicate an immediate need to administer and use the Covered Countermeasures."[21] The COVID-19 Declaration defines the "Authority Having Jurisdiction" as "the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical…or functional…range or sphere of authority," e.g. a public health department, mayor, governor, or other state official.[22]

9. **Does the COVID-19 Declaration Offer Injury Compensation for Plaintiffs?**

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP), which provides benefits to (1) certain individuals or their estates who sustain "a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures" and (2) "certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures."[23] These individuals must establish a "causal connection between the countermeasure and the serious physical injury" through "compelling, reliable, valid, medical and scientific evidence."[24]

10. **How can Businesses Repurposing Products as COVID-19 Countermeasures Protect Themselves against Product Liability?**

Businesses that plan to modify existing FDA-approved products to supply needed COVID-19 countermeasures should exercise caution and be aware of potential product liability claims, including claims of defective product design, defective product manufacture, improper or incomplete product labeling, and inaccurate advertising or marketing, as well as claims specific to different states' laws.[25] COVID-19 class action lawsuits have already begun to enter the court system, such as a putative class action complaint filed against Vi-Jon, Inc., the makers of alcohol-based hand sanitizer Germ-X, for Vi-Jon's "false and misleading promotion of its products' purported medicinal and virus preventive benefits."[26] *David, et al. v. Vi-Jon, Inc. d/b/d Germ-X*, Case No. 3:20-cv-00424-CAB-AGS (S.D. Cal.).

To best insulate themselves against product liability suits, businesses should ascertain that their products are designed for their purported purpose; that their labels sufficiently inform consumers about proper product use and limitations; that their marketing accurately describes their products; and that their products conform to the laws of the states in which they are marketed and/or sold.[27]

This article was co-authored by Magdalene M. Beck, Intern at Michael Best.

Footer Details

[1] https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

[2] https://www.federalregister.gov/d/2020-05484

[3] Ibid.

[4] Ibid.

[5] Ibid.

[6] Ibid.

[7] https://www.law360.com/productliability/articles/1259196?utm_source=shared-articles&utm_medium=email&utm_campaign=shared-articles

[8] https://www.jdsupra.com/legalnews/tort-immunity-under-prep-act-and-covid-71394/

[9] https://www.fda.gov/media/136318/download Page 7

[10] https://www.fda.gov/media/136318/download Page 12

[11] https://www.federalregister.gov/d/2020-05484

[12] https://www.law360.com/productliability/articles/1259196?utm_source=shared-articles&utm_medium=email&utm_campaign=shared-articles

[13] Ibid.

[14]https://www.hrsa.gov/sites/default/files/gethealthcare/conditions/countermeasurescomp/covered_countermeasures_and_prep_act.pdf

[15] https://www.federalregister.gov/d/2020-05484

[16]https://www.hrsa.gov/sites/default/files/gethealthcare/conditions/countermeasurescomp/covered_countermeasures_and_prep_act.pdf

[17] https://www.federalregister.gov/d/2020-05484

[18] Ibid.

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[21] https://www.federalregister.gov/d/2020-05484

[22] Ibid.

[23] Ibid.

[24] Ibid.

[25] https://www.jdsupra.com/legalnews/minimizing-products-liability-when-86524/?origin=CEG&utm_source=CEG&utm_medium=email&utm_campaign=CustomEmailDigest&utm_term=jds-article&utm_content=article-link

[26] David, et al. v. Vi-Jon, Inc. d/b/d Germ-X, Case No. 3:20-cv-00424-CAB-AGS (S.D. Cal.), p. 2

[27] https://www.jdsupra.com/legalnews/minimizing-products-liability-when-86524/?origin=CEG&utm_source=CEG&utm_medium=email&utm_campaign=CustomEmailDigest&utm_term=jds-article&utm_content=article-link

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