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HHS Declares Liability Immunity for Certain COVID-19 “Countermeasures”; Response Act Expands Protections for Mask Makers

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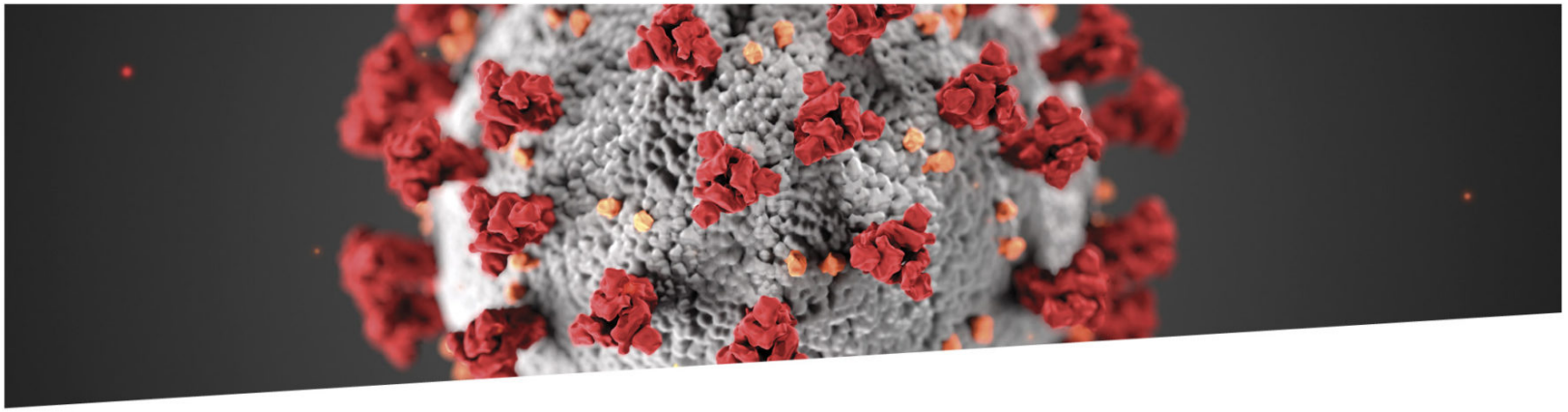

HHS DECLARES LIABILITY IMMUNITY FOR CERTAIN COVID-19 “COUNTERMEASURES”; RESPONSE ACT EXPANDS PROTECTIONS FOR MASK MAKERS

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March 19, 2020

Earlier this week, we **discussed (https://www.butlersnow.com/2020/03/covid-19-and-product-liability-current-trends-and-future-implications/)** current trends and future implications of COVID-19 on businesses operating in the products arena, noting the most direct impact so far on the pharmaceutical and medical device spaces. Recognizing the potential liabilities this products sector could face in the future, on March 17, 2020 the Secretary of Health and Human Services (“Secretary”) issued a “PREP Act Declaration” proclaiming legal immunity for manufacturers and suppliers of certain products used to combat COVID-19. The following day, Congress passed, and **the President signed, the Families First Coronavirus Response Act (https://www.butlersnow.com/2020/03/president-signs-families-first-coronavirus-response-act/)**, H.R. 6201, which expands protections for makers of masks not previously covered under the PREP Act. Businesses in these spaces should be aware of these developments.

WHAT IS THE PREP ACT?

The Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. § 247d-6d, is the federal authority that allows the Secretary to issue declarations immunizing certain individuals and entities from liabilities arising from the administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or likely future, public health emergency.[1] It was enacted on December 30, 2005 and is an amendment to the Public Health Service Act.

WHAT IS THE COVID-19 DECLARATION?

The Secretary's March 17, 2020 Declaration ("COVID-19 Declaration") provides certain individuals and entities ("Covered Persons") with immunity from suit and liability under Federal and State law against "all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure" by way of a Recommended Activity, except for willful misconduct.

Many of these terms have specific meanings under several federal acts and regulations. The discussion below addresses these terms and may aid businesses in assessing whether the Declaration applies to them.

WHAT ARE THE RECOMMENDED ACTIVITIES COVERED BY THE COVID-19 DECLARATION?

The PREP Act allows the Secretary to declare that certain undertakings will enjoy immunity when Covered Persons engage in them with respect to Covered Countermeasures. Under the COVID-19 Declaration, the Secretary has declared "the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures" are Recommended Activities.[2]

WHAT IS A COVERED COUNTERMEASURE?

The COVID-19 Declaration defines covered countermeasures as 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, or any device used in the administration of any such product, and all components and constituent materials of any such product."[3] Coverage, however, is limited to three categories of countermeasures: (1) "qualified pandemic or epidemic products," (2) "security countermeasures," or (3) drugs, biological products, or devices authorized for investigational or emergency use."[4] Each category is defined in other federal acts.[5]

WHO IS A COVERED PERSON?

"Manufacturers," "distributors," "program planners," "qualified persons," and their officials, agents, and employees are immune from liability under the COVID-19 Declaration.[6] These terms are defined in the PREP Act (42 U.S.C. § 247d-6d(i)) and are broad in their reach. For example, "distributor" covers persons and entities "engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; 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." And "manufacturer" includes contractors, subcontractors, parents, subsidiaries, affiliates, successors, and assigns of a manufacturer, as well as suppliers or licensers of products, intellectual property, services, research tools, or components used to design, develop, test, investigate, or manufacturer Covered Countermeasures.

The Secretary has also extended coverage to persons authorized "to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers" under delineated circumstances, and those "authorized to perform an activity under an Emergency Use Authorization" under the Federal Food, Drug, and Cosmetic Act.[7]

WHAT IMMUNITY IS AFFORDED UNDER THE COVID-19 DECLARATION?

The Secretary has declared that the liability immunity set forth under the PREP Act "and conditions stated in this Declaration" are in effect for the Recommended Activities, i.e. "the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures."[8] Under the PREP Act, the scope of immunity extends to "any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure," and protects Covered Persons "from suit and liability under Federal and State law."[9] Willful conduct is the sole exception to immunity.[10]

Losses covered by the Declaration include death, personal injury (physical, mental, or emotional), fear of personal injury, property damage, and "business interruption loss."[11] Significantly, coverage "applies without regard to the date of the occurrence, presentation, or discovery of the loss."[12]

The PREP Act sets forth certain conditions better defining what constitutes a causal relationship for purposes of coverage as well as exceptions to those conditions.[13] Moreover, it includes a rebuttable presumption that immunity will apply to Covered Persons engaged in Recommended Activities pertaining to Covered Countermeasures: "[T]here shall be a rebuttable presumption that any administration or use, during the effective period of the emergency declaration … of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued."[14] In other words, a claimant will have to come forward with evidence sufficient to overcome the presumption that an individual or entity is not entitled to the immunity afforded by the COVID-19 Declaration in order to move forward with suit.

As a final note on this section, the PREP Act generally covers the distribution of Covered Countermeasures "by donation, commercial sale, or any other means of distribution"; however, the Act allows the Secretary to limit immunity "only to a particular means of distribution."[15] The Secretary has done that here. The COVID-19 Declaration limits immunity for distribution pursuant to: "(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, 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."[16] Distribution entities should closely consider these provisions in assessing whether the COVID-19 Declaration provides them with immunity.

WHAT IS WILLFUL MISCONDUCT?

The COVID-19 Declaration does not afford immunity to Covered Persons engaged in willful misconduct. The PREP Act defines willful misconduct as "an act or omission that is taken (i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) 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."[17] A plaintiff bears the burden of proving willful misconduct by clear and convincing evidence.[18]

WHAT IS THE EFFECTIVE TIME PERIOD FOR IMMUNITY UNDER THE COVID-19 DECLARATION?

Currently, Covered Persons are afforded immunity through October 1, 2024.[19] This time period may be extended for certain distributors based on government contracts and other agreements identified in the COVID-19 Declaration.[20] Further, manufacturers have until October 1, 2025 to arrange for the disposal of their Covered Countermeasures, as well as other Covered Persons who may need to take action to limit the administration or use of Covered Countermeasures once the pandemic is over.[21] These time periods—and any other provisions in the COVID-19 Declaration—are subject to change, as the Declaration may be amended "as warranted."[22]

HOW HAS CONGRESS EXPANDED PROTECTIONS FOR MAKERS OF FACE MASKS?

On March 18, 2020, the President signed into law, effective no later than 15 days after enactment, the Families First Coronavirus Response Act ("Response Act"), **H.R. 6201 (https://www.congress.gov/bill/116th-congress/house-bill/6201/text)**. Among other things, it amends the Prep Act's definition of Covered Countermeasures to include "personal respiratory protective device[s]" that are (1) "approved by the National Institute for Occupational Safety and Health" ("NIOSH"); (2) "subject to the emergency use authorization issued by the Secretary on March 2, 2020, or subsequent emergency use authorizations"; and, (3) "used during the period beginning on January 27, 2020, and ending on October 1, 2024, in response to the public health emergency declared on January 31, 2020, pursuant to section 319 as a result of confirmed cases of 2019 Novel Coronavirus[.]" *See* Sec. 6005, "Treatment of personal respiratory protective devices as covered countermeasures." While face masks approved by the FDA were already covered under the PREP Act, masks approved only by NIOSH, which are more numerous, were not. The statutory amendment effectively extends PREP Act liability immunity to the NIOSH-approved masks.

WHAT ARE THE SIGNIFICANT TAKE-AWAYS FROM THE COVID-19 DECLARATION AND RESPONSE ACT AMENDMENT?

Overall, the COVID-19 Declaration and Response Act amendment should provide covered businesses with some reassurance as they continue the fight against COVID-19. As one article said, "[t]he clear import of the declaration is to clear the way for science-based organizations and public health professionals to take control of the situation immunized from legal second-guessing."[23] However, notwithstanding the broad range of persons and activities covered by the Declaration, there are strict requirements as to what constitutes a covered product or device. Further, those businesses in distribution should closely consider the regulations identifying which distribution methods will receive immunity protection, as the COVID-19 Declaration expressly limits covered distribution methods.

Ultimately, pharmaceutical and medical supply and device companies should continue using reasonable care and best practices in the design, manufacture, distribution, and sale of their products, notwithstanding the potential availability of immunity under the COVID-19 Declaration.

[1] 42 U.S.C. § 247d-6d(b); U.S. Department of Health & Human Services, Public Health Emergency: Public Readiness and Emergency Preparedness Act, *available at* https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx (last accessed Mar. 18, 2020).

[2] 85 Fed. Reg. 15198-01 § III.

[3] 85 Fed. Reg. 15198-01 § VI.

[4] *Id.*

[5] For the definition of "qualified pandemic or epidemic product," *see* 42 U.S.C. § 247d-6d(i)(7); for "security countermeasure," *see* 42 U.S.C. § 247d-6d(c)(1)(B); and for regulations pertaining to authorization for medical products for use in emergencies, *see* 21 U.S.C. § 360bbb-3.

[6] 85 Fed. Reg. 15198-01 § V.

[7] *Id.*

[8] 85 Fed. Reg. 15198-01 § IV.

[9] 42 U.S.C. § 247d-6d(a)(1), (2)(B).

[10] 42 U.S.C. § 247d-6d(d)(1).

[11] 42 U.S.C. § 247d-6d(a)(2)(A).

[12] *Id.*

[13] 42 U.S.C. § 247d-6d(a)(3)-(5).

[14] 42 U.S.C. § 247d-6d(a)(6)

[15] 42 U.S.C. § 247d-6d(a)(5), (b)(2)(E).

[16] The COVID-19 Declaration provides definitions for "Authority Having Jurisdiction" and "Declaration of Emergency" as used in the Declaration. *See* 85 Fed. Red. 15198-01 § VII.

[17] 42 U.S.C. § 247d-6d(c)(1)(A).

[18] 42 U.S.C. § 247d-6d(c)(3).

[19] 85 Fed. Red. 15198-01 § XII.

[20] *Id.*

[21] 85 Fed. Reg. 15198-01 § XIII.

[22] 85 Fed. Reg. 15198-01 § XV.

[23] Beck, James M., Drug & Device Law: We Finally Have Something To Say About COVID-10 (Mar. 18, 2020), *available at* https://www.druganddevicelawblog.com/2020/03/we-finally-have-something-to-say-about-covid-19.html (last accessed Mar. 18, 2020).

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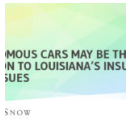

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