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The PREP Act Provides Limited Liability Protection for Certain Coronavirus Countermeasures

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On March 17, 2020, Alex Azar, Secretary of the Department of Health and Human Services (HHS), issued a Declaration activating the Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. § 247d-6d. The Declaration extends immunity "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" administration or use of qualifying products used to combat or reduce the spread of COVID-19 (the "PREP Declaration").[1] Along with other recent FDA guidance relaxing regulatory oversight for certain COVID-19-fighting products, the PREP Declaration protects manufacturers, suppliers, distributors, and others helping to mitigate supply shortages during the current crisis. These protections are limited, however, and businesses should consider these limitations when evaluating whether the PREP Declaration protects their activities. The applicability of the PREP Declaration to activities involving products created for use by the general public to minimize the spread of coronavirus, such as face masks and hand sanitizer, creates particularly challenging questions.

Who is covered by the PREP Declaration?

The PREP Declaration, issued under the PREP Act, grants immunity to manufacturers, suppliers, and distributors of, and healthcare providers authorized to use, qualifying products that treat COVID-19 or help prevent the spread of coronavirus. The PREP Act defines "manufacturers" and "distributors" broadly to include suppliers and licensers, private label or own-label distributors, brokers, warehouses, wholesale drug traders, retail pharmacies, and carriers, among others.[2] The PREP Declaration also extends immunity to "qualified persons," such as licensed health care professionals or other individuals authorized to prescribe, administer, or dispense qualifying products.[3]

What activities and products come within PREP Act immunity?

The PREP Declaration makes immunity retroactive to February 4, 2020 and currently extends it to October 1, 2024.[4] The PREP Act only creates immunity for activities involving a limited universe of authorized products. Although the PREP Declaration extends immunity to activities directed to drugs, biologics, diagnostics, devices, and vaccines used to treat, diagnose, cure, prevent, or mitigate COVID-19, the product in question must meet two criteria in order for its manufacture, development, testing, distribution, use, or administration to be covered by the statutory immunity:

1) The product must be FDA approved, licensed for use under the Public Health Service Act, or cleared for use under a FDA emergency use authorization ("EUA");[5] and

2) The party seeking immunity must be manufacturing, testing, developing, distributing, administering, or using the product pursuant to a federal contract or a federal, state, local or tribal virus response.[6]

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These limitations require especially careful consideration by those involved in the production, distribution, or administration of protective products used by the general public, such as face masks and hand sanitizer. Examination of these two groups of products illustrates some of the issues to be considered.

Example 1: Face Masks for Use by the General Public. Some face masks, including hospital grade surgical masks and certain N95 respirators, were FDA-approved before the PREP Declaration was issued.[7] Other masks and respirators not intended for medical use, including respirators approved by the National Institute of Occupational Safety and Health (NIOSH) for use in manufacturing and similar workplaces, and certain imported respirators meeting NIOSH-like criteria in their home countries, were not previously FDA-approved.[8] In further response "to this evolving public health emergency and continued filtering facepiece respirator . . . shortages," FDA issued emergency use authorizations (EUA's) in March and April 2020 allowing the medical use of both NIOSH-approved respirators and respirators approved under certain foreign standards, [9] and HHS brought them within the PREP Act's definition of "Covered Countermeasures" by statute under the Families First Coronavirus Act.[10] On April 3, FDA issued an EUA allowing medical use of imported disposable masks made in China, provided that the masks are approved by a Chinese regulatory authority and meet FDA-approved testing standards.[11] In addition, FDA has authorized healthcare providers to reuse compatible, previously used N95 masks after decontaminating them pursuant to an approved system developed by the Battelle Memorial Institute.[12]

Activities directed to masks that are not approved by FDA or NIOSH (or otherwise authorized by FDA based on compliance with foreign agency standards), and that are not created pursuant to a federal contract or governmental response, such as fabric masks created for general use, are not likely to be afforded PREP Act immunity—potentially raising liability concerns for companies involved in the production, distribution, or administration of non-surgical cloth face masks, which the CDC has now recommended be worn by individuals when they go out in public.[13]

Another consideration that applies to face masks, in addition to whether the PREP Declaration provides immunity, is whether the manufacture and distribution of such masks could run afoul of FDA's regulatory scheme for such products, potentially triggering an enforcement action. On March 25, 2020, FDA issued guidance that it did not intend to initiate any enforcement action over non-surgical face masks that satisfy certain criteria, including that such masks: 1) have proper labeling that identifies the product as a face mask and includes a list of component materials, 2) have labeling that cautions against improper use, such as in surgical settings or other high-risk medical settings, or use in the presence of high heat or flammable gas; and 3) avoid labeling that misleadingly suggests that the mask will protect against viruses or allow for particulate filtration.[14] FDA's guidance also indicates that the agency will not enforce regulations governing surgical masks and face shields as long as they meet similar labeling and flammability criteria.[15] Therefore, even if the manufacture or distribution of a nonmedical mask is not covered by PREP Act immunity, it is unlikely to be the target of a FDA enforcement action.

Example 2: Hand Sanitizers. Another product widely used by the public to block the spread of coronavirus, and also facing a critical supply shortage, is alcohol-based hand sanitizer. As with other products used to fight COVID-19, any FDA-approved medical hand sanitizer or consumer hand sanitizer developed, supplied, or administered under a federal program or official virus response is likely to be covered by PREP Act immunity.

In contrast to respirators, however, FDA has not (as of this date) issued emergency use authorizations that would apply to hand sanitizers that were not previously FDA-approved.[16] While unapproved hand sanitizers may not be subject to immunity under the PREP Declaration, FDA has encouraged increased production of hand sanitizer by compounding pharmacies and manufacturers, and has indicated that it will not enforce regulations against those entities provided certain qualifying conditions are present. Specifically, the hand sanitizer must comprise only a list of approved ingredients, including

94% ethanol or isopropyl alcohol; be “de-natured” so that it is unsuitable for drinking; and be compounded according to a World Health Organization (WHO) formula.[17]

As these two examples illustrate, the availability of PREP Act protection for any manufacturer, supplier, distributor, or user of products designed to combat COVID-19 requires close analysis of the product; the relationship of the product and/or manufacturer to a federally contracted or governmental health program; and compliance with health and safety regulations that govern the product. Notably, even in certain instances where there is no PREP Act protection, FDA has nevertheless indicated that it will not institute enforcement actions.

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[1] 85 Fed. Reg. 15198 (March 17, 2020).

[2] 85 Fed. Reg. 15198 § V (“Covered Persons”); 42 U.S.C. §247d-6d(i)(2).

[3] 85 Fed. Reg. 15198 § V (“Covered Persons”); 42 U.S.C. §247d-6d(i)(8).

[4] 85 Fed. Reg. 15198 § XII (“Effective Time Period”).

[5] 85 Fed. Reg. 15198 § VI (“Covered Countermeasures”) (“To be a Covered Countermeasure, qualified pandemic or epidemic products or security countermeasures also must be approved or cleared under the FD&C Act; licensed under the PHS Act, or authorized for emergency use under Sections 564, 564A, or 564B of the FD&C Act.”).

[6] 85 Fed. Reg. 15198 § VII (“Limitations on Distribution”).

[7] *See* 21 U.S.C.A. § 321(h); U.S. Food & Drug Administration, *Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)* (April 2020), at 2-3.

[8] Letter from Denise M. Hinton, Chief Scientist, Food & Drug Administration, to Robert R. Redfield, MD, March 28, 2020 (“NIOSH EUA”); Letter from Denise M. Hinton to Stakeholders, March 28, 2020 (“non-NIOSH Imported Respirators EUA”).

[9] *Id*.

[10] *Id*.; *see* H.R. 6201 § 6005.

[11] Letter from Denise M. Hinton to Stakeholders, April 3, 2020 (“Chinese Masks EUA”).

[12] Letter from Denise M. Hinton to Jeff Rose, Battelle Memorial Institute, March 29, 2020 (“Battelle EUA”).

[13] *Recommendation Regarding the Use of Cloth Face Coverings, Especially in Areas of Significant Community-Based Transmission*, Centers for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover.html (last visited April 5, 2020).

[14] U.S. Food & Drug Administration, *Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)* (April 2020) at 4-5.

[15] *Id.* at 5-7.

[16] *See Antiseptic FDA Letters*, U.S. Food & Drug Administration, https://www.fda.gov/drugs/information-drug-class/antiseptic-fda-letters (last visited Apr. 3, 2020); *see also* 21 C.F.R. § 878.4040 (setting out approval criteria for topical hand

sanitizer products).

[17] U.S. Food & Drug Administration, *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19): Guidance for Industry* (updated March 27, 2020), at 3-5.

For additional questions about coronavirus-related product liability issues, please visit Gibson Dunn's Coronavirus Mass Tort Litigation resource page or contact the Gibson Dunn lawyer with whom you usually work, or the authors:

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