

April 28, 2020

## COVID-19: HHS Clarifies Scope of PREP Act COVID-19 Declaration in Advisory Opinion

On April 14, 2020, the Department of Health and Human Services (HHS) General Counsel issued an Advisory Opinion clarifying the scope of liability immunity granted by its Public Readiness and Emergency Preparedness Act (PREP Act) COVID-19 Declaration published on March 17, 2020. The omnibus Opinion, which is neither binding law nor a final agency action or order, addresses the influx of questions following the release of its Declaration. Specifically, it expands on four aspects of the COVID-19 Declaration: (1) Covered Countermeasures, (2) Covered Persons, (3) liability immunity under the “Reasonable Belief” standard, and (4) liability limitations.

***This is an update to our Client Alert on “Liability, Immunity, and Your Business: Answers to the Top 10 Questions About the PREP Act COVID-19 Declaration.” For the complete explanation of the COVID-19 Declaration, click here.***

### **1. Which COVID-19 products qualify as “Covered Countermeasures?”**

According to the Opinion, the following products qualify for the COVID-19 Declaration’s definition of “Covered Countermeasures.” (See our Client Alert for the full definition.)

- “Any drug, device, or biological product that is approved, cleared, or licensed by the FDA and is used to diagnose, mitigate, prevent, treat, cure, or limit the harm of COVID-19”;<sup>[i]</sup>
- Respirators that are approved by the National Institute for Occupational Safety and Health (NIOSH) and subject to an Emergency Use Authorization (EUA); and

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- “Any drug, device, or biological product authorized for emergency use with respect to COVID-19 under an EUA, described in Emergency Use Instructions (EUI) issued by the CDC, or being researched under certain investigational provisions (i.e., IND, IDE) to treat COVID-19.”[iii]

Since the “number of products used for COVID-19 that are approved, licensed, or cleared are too numerous to list,” the Opinion also provides a link to an FDA list of products covered by EUAs.[iii]

## **2. Which persons/entities qualify as “Covered Persons?”**

The Opinion addresses confusion about the COVID-19 Declaration’s definition of “qualified persons,” one of the four categories of “Covered Persons.” (See our Client Alert for descriptions of each category.)

According to the COVID-19 Declaration, a “qualified person” may be “[a]ny person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction...to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency.”[iv] The Opinion clarifies the role of an “Authority Having Jurisdiction,” which the COVID-19 Declaration defines as “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.”[v] The Opinion explains:

[A]n Authority Having Jurisdiction has broad powers to extend PREP Act immunity to additional individuals as part of a public health and medical emergency response... authorizing ‘any person’ to ‘prescribe, administer, deliver, distribute or dispense the Covered Countermeasures’...As the lead federal public-health agency that has legal responsibility and authority for responding to the COVID-19 emergency, HHS is an Authority Having Jurisdiction, but it is not the only Authority Having Jurisdiction to respond to the COVID-19 emergency.[vi]

## **3. When may the “Reasonable Belief” standard grant liability immunity either to Covered Persons using non-covered countermeasures or to non-covered persons acting under the belief that they are Covered Persons?**

Perhaps the most crucial aspect of the Opinion is its broad liability standard for determining the satisfaction of certain PREP Act requirements (its “reasonably-could-have-believed” standard)[vii]. A Covered Person using what they reasonably could have believed was a Covered Countermeasure may qualify for liability immunity. Similarly, liability immunity may extend to a non-covered person that takes certain actions because they reasonably could have believed that they were a Covered Person.

Regarding Covered Persons using non-covered products, the Opinion states, “Given the broad scope of PREP Act immunity, Congress did not intend to impose a strict liability standard...Instead, we believe that a person or entity that otherwise meets the requirements for PREP Act immunity will not lose that immunity—even if the product is not a covered countermeasure—if that person or entity reasonably could have believed that the product was a covered countermeasure.”[viii] Thus, the use of a product that does not technically meet the requirements of a Covered Countermeasure may still receive PREP Act immunity under the “Reasonable Belief” standard.

As for non-covered persons acting under the reasonable belief of PREP Act coverage, the Opinion posits that “an entity or person that otherwise meets the requirements for PREP Act immunity will not lose that

immunity—even if the entity or person is not a covered person—if that entity or person reasonably could have believed, under the current, emergent circumstances, that the person was a covered person.”[ix]

#### **4. What are the limitations on liability immunity under the COVID-19 Declaration?**

Despite the Opinion’s broad interpretation of the PREP Act liability immunity standard, it pointedly notes the following “caveats about PREP Act immunity.”[x]

- “PREP Act immunity is not absolute.”[xi] It extends neither to federal government enforcement actions (civil, criminal, or administrative) nor to “claims under federal law for equitable relief,” and it is limited “to claims for personal injury or damage to property.”[xii]
- “[T]he PREP Act replaces certain damages claims that would normally be brought in court with a no-fault compensation system.”[xiii]
- Finally, “PREP Act immunity must be read in light of the PREP Act’s broad, express-preemption provision.”[xiv]

The Opinion also seeks to clarify the COVID-19 Declaration’s liability limitations. As we explained in our Client Alert, the COVID-19 Declaration extends immunity only to Covered Persons engaging in Recommended Activities that have been authorized either by the federal government (in connection with present or future federal agreements, e.g. federal contracts, cooperative agreements, grants, interagency agreements, memoranda of understanding, or other transactions) or by the Authority Having Jurisdiction after a declaration of emergency.

That said, the Opinion ostensibly broadens the scope of immunity, advising that “any arrangement with the federal government, or...any activity that is part of an authorized emergency response at the federal, regional, state, or local level” may receive PREP Act immunity if authorized “through, among other things, guidance, requests for assistance, agreements, or other arrangements.”[xv] Furthermore, it states that PREP Act immunity may apply “regardless of whether state or local authorities have declared states of emergencies.”[xvi] This interpretation of the language of the COVID-19 Declaration may suggest that “express authorization from an Authority Having Jurisdiction may not be required to comply with the Act, particularly if the ‘covered person’ ‘reasonably believed’ its conduct/product constituted a ‘covered countermeasure.’”[xvii]

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

#### **Footer Details**

[i] “Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act,” <https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-april-14-2020.pdf>, 3.

[ii] Ibid.

[iii] Ibid, 4.

[iv] “Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19,” 85 FR 15198, <https://www.federalregister.gov/d/2020-05484>,

[v] Ibid.

[vi] Advisory Opinion, 6.

[vii] Ibid, 4.

[viii] Ibid, 4.

[ix] Ibid, 7.

[x] Ibid, 2.

[xi] Ibid.

[xii] Ibid.

[xiii] Ibid.

[xiv] Ibid.

[xv] Ibid.

[xvi] Ibid.

[xvii] Erik K. Swanholt and Alyssa L. Titcher, “How the Health and Human Services Advisory Opinion Impacts Liability Immunity for Covered Persons and Coronavirus Countermeasures under the PREP Act,” *The National Law Review*, April 17, 2020, <https://www.natlawreview.com/article/how-health-and-human-services-advisory-opinion-impacts-liability-immunity-covered>.

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