Liability Immunity under the PREP Act for Medical Device Manufacturers for Qualified Medical Countermeasures against COVID-19

Amundsen Davis Health Care Alert
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Among the most pressing challenges for the Federal and state governments as they respond to the ongoing and unprecedented COVID-19 pandemic is the well-publicized shortage of medical equipment and supplies required by front-line medical providers who are treating patients with COVID-19. In light of the ongoing public health crisis, at the request of (or, in some cases, compulsion by) government entities, some private companies have begun manufacturing medical devices and other products, including ventilators for COVID-19 patients and personal protective equipment for medical providers treating those patients. Businesses undertaking efforts to assist in medical device and equipment manufacturing should be aware that they may be protected from liability under the Public Readiness and Emergency Preparedness ("PREP") Act. This article will address the scope of liability immunity for device manufacturers under the PREP Act Declaration relating to the COVID-19 pandemic.

The PREP Act

The PREP Act, enacted in 2005 and codified at 42 USC §247d-6d, 247d-6e, authorizes the Secretary of the Department of Health and Human Services ("Secretary"), after determining that a public health emergency exists, to issue a Declaration providing liability immunity to certain individuals and entities ("covered persons") against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures ("covered countermeasures"), except for claims involving willful misconduct.

The PREP Act is designed to incentivize the expeditious production of vital medical equipment and other products during a public health crisis. In general, the liability immunity that it provides applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of medical countermeasures described in a specific Declaration.

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Edna McLain
Partner

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PREP Act Declaration for Medical Countermeasures Against COVID-19

On March 17, 2020, Secretary Alex Azar, pursuant to his authority under the PREP Act, issued a **Declaration for Medical Countermeasures against COVID-19** ("Declaration"). The Declaration is retroactively effective as of February 4, 2020 and will remain in effect until October 1, 2024.

(Note: The Declaration and its specific application to medical providers is discussed in more detail in a previous Amundsen Davis health care alert, entitled **Liability Immunity for Health Care Workers during the COVID-19 Crisis**.)

In the Declaration, the Secretary determined that COVID-19 constitutes a health emergency and, through his authority under the PREP Act, provided liability immunity to all manufacturers, distributors, and other qualified persons engaged in the manufacture, testing, development, distribution, administration, and use of any covered countermeasures. (*See* Declaration, §§ I, III, IV and V.)

Covered Persons

Covered persons under the Declaration include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, as well as the United States. (*See* Declaration, § V.) Importantly for businesses seeking to produce medical devices to assist with the COVID-19 response, the PREP Act defines "manufacturers" to include, among others, suppliers or licensers of any product, intellectual property, service, research tool, or component used in the design, development, clinical testing, investigation or manufacturing of a covered countermeasure. (*See* 42 USC § 247d-6d(i)(4)).

Covered Countermeasures

Pursuant to the Declaration, covered countermeasures are "any antiviral, any other drug, any biologic, **any diagnostic, any other device**, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2. . .**or any device used in the administration of any such product, and all components and constituent materials of any such product**." (Declaration, § VI.) Additionally, covered countermeasures must fall into one of three statutory categories: (1) "qualified pandemic or epidemic products;" (2) "security countermeasures;" or (3) drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act. (*See* Declaration, § VI.) A qualified pandemic or epidemic product is one manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic. (*See* 42 U.S.C. 247d-6d(i)(1)(7)(A)(i-iii).)

Generally speaking, the statutorily defined categories of countermeasures listed above are those that are approved by FDA; authorized for investigational use by FDA, authorized under an emergency use authorization ("EUA") by FDA; or

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otherwise permitted to be held or used for emergency use in accordance with Federal law. 42 U.S.C. 247d-6d(i)(1)(7). In the setting of a public health crisis, the FDA may provide an EUA for a product that is not approved, licensed or cleared. As of April 8, 2020, the FDA has issued **EUAs related to COVID-19** for personal protective equipment and ventilators, among other products.

Taken together, the PREP Act, Declaration, and FDA guidance provide that ventilators and personal protective equipment are covered countermeasures for which immunity liability likely attaches (assuming that the manufacturer is a covered person).

What is Liability Immunity?

Under the PREP Act, covered persons are immune from "any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure." 42 U.S.C. 247d-6d(a)(2)(B). Immunity extends, but is not limited to, claims for death; physical, mental, or emotional injury, illness, disability, or condition or fear of any such injury, illness, disability, or condition; any need for medical monitoring; or property damage or loss, including business interruption loss. 42 U.S.C. 247d-6d(a)(2)(A). There is a rebuttable presumption that the immunity applies to covered entities for covered countermeasures. 42 U.S.C. 247d-6d(a)(6). Practically speaking, if immunity attaches, courts must dismiss claims brought against any entity or individual covered by the PREP Act, including claims for any loss described above that is related to any stage of design, development, testing, manufacture, or distribution of a countermeasure recommended in a Declaration.

Exceptions to Immunity

While immunity under the PREP Act is broad, it is not unlimited. There is a statutory exception for claims involving 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." 42 U.S.C. § 247d-6d(c)(1)(A).

Additionally, the Declaration applies only to activities involving covered countermeasures that are related to "(a) Present or future federal contracts, cooperative agreements, grants, other transactions…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." (Declaration, § VII.) A declaration of emergency is a declaration by a government official of an emergency specific to events to indicate the immediate need to administer and use the covered countermeasures. (*See* Declaration, § VII.) While this provision appears to function as another limitation on the scope of immunity, given the myriad federal

and state declarations of emergency in light of COVID-19 and the very public calls from state and local governments for assistance with medical device production from private industry, companies manufacturing products specifically in response to the COVID-19 pandemic likely would fall within these enumerated categories to which the Declaration applies.

Similar Legal Authority in Illinois

Section 21 of the Illinois Emergency Management Agency Act ("IEMA Act") protects from civil liability claims involving death, personal injury, and property damage against any private individuals and organizations working under a contract with, and at the direction of, the state and any private individuals and organizations rendering "assistance or advice" at the state's request during a disaster. (*See* 20 ILCS 3305/21(b-c)). As with the PREP Act, willful misconduct is not shielded under the IEMA Act. Notably, on April 1, 2020, Illinois Governor J.B. Pritzker issued **Executive Order No. 19, 2020**, which granted **explicit immunity to health care facilities, health care professionals, and health care volunteers providing services in response to the COVID-19 outbreak**. In doing so, he invoked Section 21 of the IEMA Act, among other statutory authority. (*See* Amundsen Davis's prior **alert on liability immunity for health care workers** for more detail.) The executive order does not apply to other private actors, such as device manufacturers, responding to the pandemic. Because there is no reported case law interpreting the IEMA Act's liability immunity provisions, the extent of its immunity for other actions undertaken in response to a public health emergency is unclear. However, given that the entities shielded from liability under the IEMA Act explicitly must either be working under a contract with the state or rendering "assistance or advice" specifically at the state's request, these protections appear to be more limited in scope than the broad immunity afforded under the PREP Act.

Practical Application – Who is Protected from Liability?

Various companies have pledged to manufacture medical devices and equipment to assist with the care and treatment of COVID-19 patients. To name just a few, Apple has sourced over 20 million masks through its supply chain; Tesla has begun efforts to produce a prototype ventilator; and Ford and General Electric have partnered to produce ventilators. Based on the foregoing discussion of the scope of the PREP Act and Declaration, these companies likely are afforded liability immunity, as they are producing covered countermeasures in response to a declaration of emergency.

Further, it is important to note that, while these companies are voluntarily undertaking the manufacturing of certain medical devices, several companies have been compelled to manufacture specific products. For example, President Trump, using his authority under the Defense Production Act (50 U.S.C. § 4501 *et seq.)*, has ordered General Motors and 3M to produce ventilators and face masks, respectively. In contrast to the PREP Act, the Defense Production Act does not

provide for broad immunity from tort claims. In fact, the courts have not resolved the issue of whether the Defense Production Act immunizes contractors from tort liability or merely from breach of contract claims. There is a lack of authority on the interplay between the Defense Production Act and the PREP Act, but it appears that the Defense Production Act (and its attendant lack of immunity) would apply to contracts entered into between the Federal government and the companies it compelled to manufacture products.

Finally, as it concerns hospitals and other medical facilities, based on its language including among covered countermeasures products that are "modified" to treat a pandemic, the PREP Act appears to grant liability immunity to health care entities modifying their current equipment for use in treating COVID-19 patients.

Recommendations

Broadly speaking, the Declaration applies to companies producing medical equipment and other countermeasures to support states or the Federal government in combatting COVID-19, and it provides broad protections from tort liability for the manufacturing of those covered countermeasures. However, given the qualifying criteria for both covered persons and covered countermeasures, private businesses should carefully review the language of the Declaration and the PREP Act to determine whether their planned activities fall within the ambit of the statute. Businesses located in Illinois should also consider whether the IEMA Act protects their planned activities in response to the pandemic. **Whether immunity attaches will depend on the particular facts and circumstances** of each case.

Additionally, it is unclear based on existing guidance whether or not the PREP Act provides immunity for covered countermeasures undertaken prior to the effective date of the Declaration, i.e. February 4, 2020. However, as the scope of the pandemic was largely unforeseen at that time, it is unlikely that companies not already doing so had reason to manufacture ventilators, personal protective equipment, or other covered countermeasures for purposes of the COVID-19 response before that date. Whether countermeasures undertaken prior to February 4, 2020 are protected from liability should also be evaluated on a case-by-case basis.