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CRISIS PRACTICE

Coronavirus

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HHS Advisory Opinion Buttresses Broad Immunity Under PREP Act For COVID-19 Countermeasures But Important Considerations For Manufacturers Remain

The U.S. government has taken several steps in recent weeks to encourage companies to respond rapidly to the COVID-19 pandemic and resulting medical-supply shortage. As discussed here, to assuage concerns about potential tort liability, the Secretary of Health and Human Services ("HHS") published a Declaration under the Public Readiness and Emergency Preparedness ("PREP") Act immunizing entities from liability related to the manufacture, testing, development, distribution, and use of certain drugs, biologics and devices used to diagnose or treat COVID-19.

In response to requests for advisory opinions on whether certain products qualify for PREP Act immunity, on April 14, 2020, the General Counsel for HHS issued an Advisory Opinion concerning the scope of PREP Act immunity during the COVID-19 pandemic. Although not a binding document, the Advisory Opinion reinforces that immunity under the PREP Act for COVID-19 countermeasures is intended to be broad.

The U.S. Food and Drug Administration ("FDA") has also issued a number of guidances in recent weeks exercising its discretion to suspend certain enforcement actions with respect to a number of product categories, including ventilators and other respiratory devices, face masks and respirators, and oxygen and nitrogen containers, among others. These guidances reflect FDA's intention not to object to the sale of or limited modifications to certain FDA-regulated devices during the emergency without the sponsor first obtaining approval, clearance, or an Emergency Use Authorization. FDA has also suspended other regulatory requirements impacting these devices.

The actions of both HHS and FDA reflect a desire to immunize broadly pharmaceutical and medical device manufacturers from potential liability

stemming from urgent efforts to meet healthcare demands for life-saving products intended to mitigate COVID-19's adverse impacts. Read collectively, however, there remain potential avenues by which pharmaceutical and medical device manufacturers could still be exposed to product liability risk. It is important to understand the full landscape, including the interplay between the FDA guidances suspending enforcement activity for various categories of medical devices and the PREP Act providing immunity for when manufacturing various products to combat COVID-19. King & Spalding's experienced crisis management, FDA Regulatory, and product liability attorneys can work with companies developing COVID-19 related countermeasures to identify these issues and help implement plans to reduce potential future product liability and regulatory risk.

PREP Act Immunity For Off-Label Uses

Pursuant to recent guidances describing FDA's current enforcement policies, manufacturers of certain specified product categories can immediately begin making certain limited modifications and selling products that might otherwise be considered adulterated or misbranded in that they do not comport with existing FDA approvals, clearances, or Emergency Use Authorizations. But while such activities will be free from FDA enforcement scrutiny for now (provided that they meet certain requirements specified in FDA's guidances), they may not be covered by the PREP Act's grant of immunity.

There has been limited case law interpreting the scope of the PREP Act, and no cases address specifically what qualifies as a "qualified countermeasure" under the PREP Act generally or HHS's COVID-19 Declaration specifically. HHS's COVID-19 Declaration, however, does not expressly include as covered countermeasures unapproved products or uses of products in manners not indicated by the terms of an FDA approval or clearance. To the contrary, HHS's Advisory Opinion reinforces that to be a "Qualified Pandemic or Epidemic Product" under the PREP Act the product must be approved or cleared by FDA, subject of a research exemption, covered by an Emergency Use Authorization ("EUA"), or described in a Centers for Disease Control and Prevention Emergency Use Instruction. Therefore, an "off-label" use might not qualify for immunity under the PREP Act absent an express exemption, such as an EUA.

Manufacturers should be cognizant of this and continue to be guided by their internal policies on off-label communications in speaking with customers and healthcare providers about a product's potential modification or off-label use to treat the symptoms of COVID-19 absent an express exemption by FDA. Also, when making modifications to a product or its indicated uses or claimed functionality, manufacturers should do so in close coordination with FDA, including evaluating whether an EUA is appropriate under the circumstances to minimize future product liability risk. FDA has already granted dozens of EUAs across various product types and made clear that it is available to work with manufacturers to rapidly authorize other COVID-19 countermeasures for emergency use.

Manufacturers Must Continue To Use All Due Care In Making COVID-19 Countermeasures And Comply With All Applicable Regulatory Requirements.

HHS's Advisory Opinion makes clear that the PREP Act's grant of immunity for COVID-19 countermeasures is broad.[1] The Opinion stakes out a broad interpretation of PREP Act immunity by:

1) extending PREP Act immunity to entities and products that do not qualify as covered entities or countermeasures under the terms of the Declaration if a person could "reasonably believe" they qualified;

2) explaining the Declaration's limitations on methods of distribution are satisfied when a covered person engages in activities related to "any arrangement" with the federal government or part of an authorized emergency response at

the federal, state or local level, including activities consistent with "guidance[s], requests for assistance, agreements, or other arrangements;" and

3) explaining that the PREP Act immunity must "be read in light of the PREP Act's broad, express-preemption provision," suggesting that immunity should be interpreted by courts to apply broadly consistent with the express preemption provision.

However, even if a prescription drug or medical device meets the requirements of HHS's COVID-19 PREP Act Declaration, the Act does not immunize manufacturers from "willful misconduct" that results in death or serious injury.[2] Decisions manufacturers are making now on suppliers, materials, labeling, and testing should be expected to be scrutinized after the pandemic dissipates in the event patients pursue personal-injury claims. Manufacturers should therefore be careful to document the precautions they have taken in designing, labeling and manufacturing COVID-19 countermeasures, something HHS's Advisory Opinion also expressly recommends.

The PREP Act also does not suspend requirements under the Food, Drug and Cosmetic Act or FDA regulations. Manufacturers thus need to be aware of any applicable regulatory requirements, including those in FDA's recent guidances, and closely follow these requirements absent express exemption or waiver from FDA. For purposes of reducing potential product liability exposure, it is particularly important that manufacturers closely follow applicable requirements on labeling, FDA's quality systems regulations and Current Good Manufacturing Practices, and post-marketing surveillance requirements. A failure to meet these various requirements creates product-liability risk even if the product otherwise satisfies the requirements for PREP Act immunity.

For Products That Do Not Qualify For PREP Act Immunity, Compliance With FDA's Guidances Suspending Some Enforcement Actions Alone May Not Preempt State Tort Claims.

FDA guidance documents setting forth FDA's current enforcement policies for certain categories of medical devices contain specific requirements with which manufacturers must comply to avoid being subject to an enforcement action for marketing misbranded or adulterated devices. These include detailed requirements for labeling, design validation, and post-market surveillance. Compliance with these requirements alone, however, is not likely to preempt state-law tort claims for personal injuries arising from the use of such devices for products that do not otherwise qualify for PREP Act immunity.

Courts have traditionally concluded that compliance with non-binding FDA guidance documents alone does not give rise to federal preemption. While there are situations where guidance documents have imposed device-specific requirements that courts have found to be preemptive, it is not clear that FDA's COVID-19 related guidances do so. While FDA's recent guidances do impose general requirements, they leave much of the detail on how to comply with those requirements to the manufacturer's discretion. Moreover, the guidances state that they "do[] not establish any rights for any person and [are] not binding on FDA or the public," language courts often rely on in finding that FDA guidance documents do not have preemptive effect.

While it is uncertain how individual courts will view the impact of these FDA documents on the viability of state-law tort claims in the context of the COVID-19 crisis, and recognizing that preemption is necessarily a fact-dependent inquiry, manufacturers of devices subject to these guidances should be cautious in evaluating whether compliance with the guidances' requirements is likely to preempt state-law product-liability claims.

Manufacturers Should Implement Measures To Track And Recover Products Following Conclusion Of The Current Pandemic.

FDA guidances suspending certain enforcement actions do not address manufacturers' obligations to recover products following the conclusion of the COVID-19 pandemic. Medical devices that have not received FDA

premarket clearance that remain on the market following the conclusion of the COVID-19 emergency and concomitant expiration of the PREP Act Declaration on October 1, 2024 pose liability risks to manufacturers. Accordingly, manufacturers making COVID-19 products not cleared or approved to be on the market notwithstanding the current pandemic should be implementing measures that satisfy FDA's tracking requirements and ensure that devices are returned or otherwise disposed of following the conclusion of the current health crisis. HHS's COVID-19 Declaration provides manufacturers an additional 12-months of immunity following expiration of the Declaration to dispose of these products.

It is possible that FDA provides a window after the emergency ends for companies to clear or approve products that were created or modified during the emergency. It is also possible that FDA employs different enforcement approaches for products that remain on the market after the emergency and for products with varying risk profiles. For example, in some Emergency Use Authorizations FDA has issued during the COVID-19 emergency, the Agency has explicitly required that manufacturers and distributors track the distribution of their products closely (i.e. ventilators and facemasks), but FDA has been silent on the issue for other products (i.e. imported, non-NIOSH-approved respirators). This may suggest that FDA is less concerned with non-compliant products that will be quickly used up during the pandemic and no longer have a large presence in the market following the pandemic, such as disposable personal protective equipment (PPE).

[1] Indeed, the Advisory Opinion uses the words "broad" or "broadly" 6 times. (*See, e.g.*, p. 4 ("Given the broad scope of PREP Act immunity…"); p. 7 ("Under the PREP Act, immunity is broad.").

[2] As explained in a prior Alert, "willful misconduct" claims are subject to a number of stringent requirements and limitations on venue, pleadings, damages, and discovery.