KING & SPALDING

CRISIS PRACTICE

Coronavirus

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Tort Immunity under PREP Act and COVID-19 Response Declaration

Pursuant to the Public Readiness and Emergency Preparedness Act ("PREP Act"), on March 17, 2020, the Secretary of Health and Human Services ("HHS") published the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. The COVID-19 Declaration immunizes broadly certain entities from "suit and liability under federal and state law with respect to all claims of loss" related to the manufacture, testing, development, distribution, administration and use of certain countermeasures to COVID-19.

WHO IS COVERED?

The COVID-19 Declaration covers entities that manufacture, distribute, administer, prescribe and use covered countermeasures, as well as their officials, agents and employees, among others. These terms, which are defined in the PREP Act, are broad in their reach.

WHAT COUNTERMEASURES ARE COVERED?

The COVID-19 Declaration applies to the manufacture, testing, development, distribution (with certain limitations), administration and use of a drug, biologic, diagnostic, device or vaccine used to treat, diagnose, cure, prevent or mitigate COVID-19 that also falls within one of three statutorily defined categories of countermeasures: (1) "qualified pandemic or epidemic products;" (2) "security countermeasures;" and (3) products authorized for emergency use. A "qualified pandemic or epidemic product" is defined as a drug, device or biologic (1) produced or used to diagnose, mitigate, or treat a pandemic or epidemic or to limit the harm of a pandemic or epidemic; (2) produced or used to diagnose, mitigate or treat a serious or life-threatening condition caused by a product in category (1); or (3) intended to enhance the use or effect of a product in categories (1) or (2). Additionally, these products must be approved or cleared by FDA, the object of an investigational exemption under sections 505(i) or 520(g)

of the Food, Drug and Cosmetic Act ("FDCA") or authorized for emergency use pursuant to an Emergency Use Authorization under sections 564, 564A, or 564B of the FDCA.

WHAT IS THE SCOPE OF THE IMMUNITY?

Under the PREP Act and COVID-19 Declaration, qualified entities 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." The immunity provides protection from both serious personal injury and death (including physical, mental and emotional loss), fear of future personal injury and property damage (including "business interruption loss."). There is a rebuttable presumption that the immunity applies to covered entities for covered countermeasures.

WHAT TIME PERIOD IS COVERED UNDER THE COVID-19 DECLARATION?

The period of immunity is in effect through October 1, 2024 and can be extended for certain means of distribution of covered countermeasures. The Declaration also gives covered entities 12 months following expiration of the Declaration to dispose of any covered countermeasures and to take appropriate steps to limit further administration or use of covered countermeasures.

WHAT ARE THE LIMITS OF IMMUNITY UNDER THE PREP ACT AND THE COVID-19 DECLARATION?

"Willful misconduct" is not immune from liability under the PREP Act and COVID-19 Declaration. Therefore, even if a product manufactured by a covered entity qualifies as a covered countermeasure, a claimant may still pursue a claim for death or serious injury against the entity if he/she can establish by "clear and convincing evidence" that the manufacturer engaged in misconduct exceeding mere negligence or recklessness. Under the PREP Act, "willful misconduct" is "an act or omission that is taken intentionally to achieve a wrongful purpose; knowingly without legal or factual justification; and in disregard of a known or obvious risk that is so great as to make it highly probably that the harm will outweigh the benefit." Conduct is not "willful misconduct" as a matter of law where neither HHS nor the Attorney General have initiated an enforcement action regarding the alleged misconduct or an enforcement action is terminated, and in some situations, where the conduct is done pursuant to the direction of or under the guidance of HHS. Any claimant seeking to bring a suit for alleged willful misconduct faces additional hurdles, including stricter pleading standards, verification of allegations in the complaint, a pre-filing expert affidavit supporting causation, strict limitations on discovery and limits on damages.

Companies should also be cognizant that the COVID-19 Declaration does not expressly include as a covered countermeasure use of a drug, biologic or device in a manner not expressly indicated by the terms of its approval (i.e., off-label use). Companies with previously approved or cleared products that could be repurposed to diagnose or treat COVID-19 should exercise caution in responding to requests for information on such uses and should continue to be guided by their internal policies and procedures on off-label promotion absent contrary instruction or authorization from FDA.

Despite this broad grant of immunity, manufacturers should continue to use all due care in designing and manufacturing all products. This is particularly true with respect to manufacturers seeking to repurpose existing devices, diagnostics, therapies or manufacturing processes aimed at responding to COVID-19. Before repurposing existing devices and manufacturing facilities, companies must evaluate all applicable requirements, including quality process requirements, validation requirements and labeling obligations and must carefully scrutinize all available data (both internal and public data), before making any changes to existing devices or making representations to the public or customers that are inconsistent with approved labeling. FDA has issued recent guidance indicating its openness to suspending enforcement actions against companies repurposing certain devices and to expedite Emergency Use Authorizations. To preserve the immunity conferred under the COVID-19 Declaration and to avoid

potential regulatory violations, companies should make any proposed modification to existing devices or manufacturing facilities in consultation with regulatory authorities, including considering whether obtaining an Emergency Use Authorization is appropriate. King & Spalding's experienced FDA regulatory, crisis management and litigation attorneys stand ready to assist companies as the legal and business challenges related to COVID-19 continue to evolve.

For the latest guidance and information on responding to these novel challenges, please visit King & Spalding's Coronavirus Task Force webpage.