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Maintaining Product Liability Immunity During The Pandemic

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Lawsuits have been filed in various industries related to COVID-19, and advertisements seeking plaintiffs are now appearing online. As many companies are racing to fill voids in the marketplace regarding COVID-19 prevention and treatment, they are understandably also concerned about potential liabilities.

To address those very real concerns, the U.S. Department of Health and Human Services published an administrative declaration under the Public Readiness and Emergency Preparedness, or PREP, Act on March 17 that provides broad-based legal immunity for manufacturers, suppliers and administrators of certain products and technologies used to combat COVID-19.[1]

Despite the broad protections extended by the declaration, it does not provide immunity from liability for death or serious physical injury caused by willful misconduct. So who is entitled to protection under the declaration, and what steps should companies take now to ensure they do not waive immunity?

What the COVID-19 Declaration Covers

The PREP Act, codified at Title 42 U.S. Code Section 247d-6d, has existed since 2005, and authorizes the secretary of the HHS to issue a declaration to provide liability immunity in the event of a public health emergency. The PREP Act extends protection to covered entities and individuals against claims under federal and state law relating to the manufacture, distribution, administration or use of medical countermeasures.

For COVID-19, the declaration under the PREP Act provides immunity against all claims of loss "caused by, arising out of, relating to, or resulting from" the "manufacture, testing, development, distribution, administration, and use" of "covered countermeasures." Covered countermeasures include drugs, biological products or devices used to diagnose, mitigate, prevent, treat or cure COVID-19, or limit the harm COVID-19 might cause.

Respiratory protective devices approved by the National Institute for Occupational Safety and Health are included within the definition of a covered countermeasure as codified in Section 3103 of the Coronavirus Aid, Relief, and

Economic Security Act. The immunity extends to COVID-19 drugs, and to other products and technologies intended to enhance the use or effect of a drug, device or biological product, or protect against adverse effects from those products.

For a product to qualify as a covered countermeasure, it generally must be approved, licensed or authorized by the U.S. Food and Drug Administration. A covered countermeasure can also, however, be a product cleared for investigational use (under an investigational drug application or an investigational device exemption) by the FDA, or otherwise authorized for investigational or emergency use by an appropriate authority as set forth in the PREP Act.

Covered losses include death; physical, mental or emotional injury, illness, disability or condition; fear of physical, mental or emotional injury, illness, disability or condition (including the need for medical monitoring); and loss of or damage to property, including business interruption loss.

Under the declaration, manufacturers, distributors, program planners (or those involved in planning, administering or supervising programs for the distribution of a countermeasure) and other qualified persons (including those who prescribe, administer or dispense countermeasures such as health care and other providers) are covered. Additionally, certain countermeasures are immune from suit and liability under federal and state law, when the claim relates to or results from the use or administration of these defined and approved countermeasures.

On April 14, the general counsel for the HHS issued an advisory opinion offering guidance to address questions about the scope of PREP Act immunity during the COVID-19 pandemic. While the opinion is not a final agency action or a final order, nor is it binding on HHS or federal courts, it does shed further light on the scope of, and limits to, the extent to which immunity may apply.

If a company complies with all of the requirements of the PREP Act and the declaration, immunity covers tort and contract claims, and claims relating to compliance with local,[2] state and federal laws and regulations. It further clarifies that immunity applies when a covered person engages in activities related to an agreement with the federal government, or when acting according to authorities having jurisdiction to respond to a declared immunity.

Those are interpreted broadly to include any arrangement — not just a contract — with the federal government, or any activity that is part of an authorized emergency response at the federal, regional, state or local level. Immunity granted under the PREP Act declaration applies whether or not state or local authorities have declared a state of emergency.

While the PREP Act declaration does provide liability immunity, entities are not immune from enforcement actions by the FDA or other federal agencies.[3] The advisory opinion likewise confirms that the declaration does not provide immunity against federal enforcement actions brought by the federal government, whether civil, criminal or administrative.

The advisory opinion further states that immunity does not extend to liability for claims under federal law for equitable relief, and (exempting preemption) is limited to claims for personal injury or damage to property. And the opinion notes that immunity under the PREP Act must be read in light of the PREP Act's broad, express-preemption provision.[4]

The PREP Act authorizes the Countermeasures Injury Compensation Program to compensate eligible individuals who suffer a serious physical injury or death as a direct result of the administration or use of a covered countermeasure. If funds are appropriated by Congress into this account, compensation may be available to eligible requesters.

Steps Companies Can Take to Avoid Engaging in Willful Misconduct and Waiving Immunity

While under the PREP Act, immunity is broad, it does not does not exist for death or serious physical injury caused by willful misconduct. A serious physical injury is defined as one that is life-threatening, results in or requires

medical or surgical intervention to preclude permanent impairment of a body function, or causes permanent damage to a body structure.[5]

Willful misconduct is defined as an act or failure to act that is taken (1) intentionally to achieve a wrongful purpose, (2) knowingly without legal or factual justification, and (3) 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.[6] It is "a standard of liability that is more stringent than a standard of negligence in any form or recklessness."[7]

Lawsuits alleging an exception to immunity for covered persons can be brought only before a three-judge court in the U.S. District Court for the District of Columbia.[8] A plaintiff will need to establish by clear and convincing evidence that the willful misconduct proximately caused death or serious injury.[9]

Companies currently covered under the declaration should take definitive steps to ensure they do not engage in willful misconduct and waive liability immunity. Indeed, the advisory opinion stresses that the HHS encourages all covered persons using a covered countermeasure to "take reasonable precautions" to ensure safe use of products and make information available to end users to "provide greater transparency" whenever possible.

While the list below is not exhaustive, it sets forth certain steps manufacturers, distributors and others can implement now to avoid liability later.

Maintain quality assurance safeguards to ensure that clinical data is accurately reported.

While the COVID-19 pandemic has resulted in a race to market potential prophylactics or treatments, companies should ensure any clinical trials for COVID-19 countermeasures are conducted and reported in accordance with good industry practices.

Even in normal circumstances, fraud in clinical research can be a widespread problem. In a 2005 study, 17% of surveyed authors of clinical drug trials reported that they personally knew of intentionally fabricated or falsified research findings.[10]

Depending on intent, clinical data falsification, and other types of research misconduct, such as selective reporting of results, failure to follow protocols and improper use of statistical methods, can be potentially be considered willful misconduct, as shown in analogous situations. For example, in 2019, Duke University entered into a $112.5 million settlement for knowingly submitting falsified research data to obtain millions in grants from the National Institutes of Health.[11] Case law is similarly replete with instances of courts finding allegations of intentional manipulation or misrepresentations of clinical trial findings to be sufficiently pled to support claims based in fraud.[12]

With COVID-19, individuals and organizations may face pressure to generate positive clinical research results. However, to avoid falling under the willful misconduct exception and potentially waiving tort immunity for COVID-19 countermeasures, clinical trial sponsors should have rigorous quality assurance safeguards in place to ensure that fraud or falsified data is detected and clinical data is accurately reported. This can include oversight by trial committees, onsite monitoring and statistical monitoring to identify unusual patterns and data outliers.[13]

Confirm that product labels fully reflect known safety and efficacy data.

Companies should ensure any COVID-19 countermeasure conforms with relevant labeling regulations and requirements, such as those of the FDA, the Federal Trade Commission and the U.S. Consumer Product Safety Commission.[14] While each agency has its own procedural and substantive intricacies, each requires companies to produce product labels based on current safety and efficacy knowledge, and where appropriate, update product labels when new information becomes available.[15]

With the rush to develop and produce COVID-19 countermeasures, companies should make certain that any countermeasure label accurately reflects any known health risks, including for countermeasures approved for off-label use. Additionally, if any new safety information becomes available, manufacturers and developers should ensure that the countermeasure label reflects that new information.

While reasonably unforeseeable developments may arise with widespread use of a COVID-19 countermeasure — such as rare adverse events for a drug not seen in smaller clinical trials — prudent developers and manufacturers should inform the relevant agencies and update their countermeasure labels with any new information promptly. Failing to do so could constitute willful misconduct, and potentially waive liability protections afforded by the declaration under the PREP Act.

For example, courts and juries have regularly relied on failures to comply with agency labeling and reporting requirements to establish intent regarding claims for punitive damages.[16] As a result, robust regulatory processes should be in place to ensure that any COVID-19 countermeasure label reflects current safety knowledge, and that such labels are promptly updated with any new pertinent safety information that becomes available.

Ensure compliance with adverse event and safety reporting obligations.

Individuals and organizations should know that the declaration under the PREP Act does not override adverse event reporting requirements under the Food, Drug and Cosmetic Act, or FDCA, and related regulations.

Additionally, while in recent COVID-19 guidance the FDA has provided that companies dealing with high levels of pandemic-related employee absenteeism may delay submission of some adverse event reports up to six months after internal reporting processes have been restored to their prepandemic state, "reports related to medical products indicated for the treatment or prevention" of COVID-19 should be prioritized and submitted within standard timeframes where possible.[17]

The FDA has also clarified that this guidance does not apply to a company's adverse event reporting obligations to the FDCA for medical products authorized for emergency use or investigational drugs, biologics or devices, which are still governed by standard reporting obligations. Thus, best practices for covered COVID-19 medical countermeasures would be to report any observed adverse events to FDA promptly.

The CPSC has similarly stated that statutory reporting obligations under Section 15(b) of the Consumer Product Safety Act are still in effect during the current pandemic.[18]

Although inadvertent or otherwise excusable delay in submitting adverse event or safety reports for COVID-19 countermeasures would likely not constitute willful misconduct, an intentional decision to suspend or reduce reporting processes for COVID-19 countermeasures runs the risk of waiving product liability immunity. To the extent possible, any company seeking to preserve such immunity for covered COVID-19 countermeasures should ensure continued compliance with relevant adverse event or safety reporting obligations.

Refrain from off-label promotion and make certain that marketing materials are supported by sufficient data.

Companies should also make certain that any promotions for COVID-19 countermeasures are accurate, reflect the FDA-approved label and are supported with sufficient data. Already, the FDA and the FTC have issued warning letters to several companies for products that allegedly prevented, treated or cured COVID-19.[19] The FDA has also recently turned its attention to more than 70 COVID-19 serological test developers that have falsely asserted that such tests have been approved by the FDA.[20]

While these COVID-19 enforcement actions have largely focused on marketing claims related to unapproved products, developers and manufacturers for approved COVID-19 countermeasures should still ensure that any marketing or promotional claims are made in accordance with the approved label and available data. For example, in FDA off-label enforcement actions, felony charges for misbranding require proof of an "intent to defraud or mislead," while misdemeanor charges only require a showing of willfulness and not an intent to defraud or mislead.[21]

Thus, any off-label promotions for approved COVID-19 countermeasures may be deemed to constitute willful misconduct and waive product liability immunity. Companies should also refrain from any marketing claims, such as comparisons with alternative treatments or overstatements regarding effectiveness, that are not sufficiently supported by available scientific data. Doing so without clear supporting evidence similarly risks waiving COVID-19 product liability immunity by engaging in willful misconduct.

Conclusion

The declaration under the PREP Act affords broad product liability immunity under both federal and state law to those manufacturers and distributors of certain COVID-19 countermeasures, yet those same companies should be aware of the risk of waiving that immunity. Companies in the chain of manufacturing and distributing these critically necessary products can and should take affirmative steps now to ensure they do not inadvertently waive these protections.

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[1] The declaration is retroactively effective as of Feb. 4, and currently extends its protections through Oct. 1, 2024.

[2] PREP Act immunity does not expressly extend to local laws, but the PREP Act does expressly preempt any state and local law that is "different from, or is conflict with, any requirement applicable under" the PREP Act. 42 U.S.C. § 247d-6d(b)(8).

[3] 42 U.S.C. § 247d-6d(f).

[4] Under 42 U.S.C. § 247d-6d(b)(8)(A), (1) "no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that is different from, or is in conflict with, any requirement application under this section" and (2) relates to, among other things, use of administration of the covered countermeasure.

[5] 42 U.S.C. § 247d-6e Sec. 319F-3(i)(10).

[6] 42 U.S.C. § 247d-6e Sec. 319F-3(c)(1)(A).

[7] 42 U.S.C. § 247d-6e Sec. 319F-3(c)(1)(B).

[8] 42 U.S.C. § 247d-6d(e)(1), (5).

[9] 42 U.S.C. § 247d-6d(c)(3).

[10] Gardner W, Lidz CW, Hartwig KC. Authors' reports about research integrity problems in clinical trials. Contemp. Clin. Trials 2005; 26:244–251.

[11] https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related.

[12] See, e.g., Eidson v. Medtronic Inc. , 40 F. Supp. 3d 1202, 1235–36 (N.D. Cal. 2014) (finding fraud sufficiently pled where plaintiff alleged that defendant intentionally misstated or omitted data in scientific publications); Blackwood v. Atrium Med. Corp. , No. 16-CV-379-LM, 2019 WL 3779698, at *4 (D.N.H. Aug. 12, 2019) (finding plaintiff pled sufficient facts that "defendants manipulated clinical studies to make it appear as if their products were safe when they were not" to satisfy heightened Rule 9(b) allegations of fraud); Forsyth v. Eli Lilly & Co. , No. CIV. 95-00185 ACK, 1998 WL 35152135, at *8 (D. Haw. Jan. 5, 1998) (finding that plaintiff's evidence regarding allegations of intentional and improper reclassification of adverse events in clinical trial were sufficient to survive summary judgment on punitive damages claim).

[13] George S, Buyse M. Data fraud in clinical trials. Clin. Invest. (2005); 5(2):161–173.

[14] 21 C.F.R § 801.6 (FDA prohibiting misleading statements on medical device labels); 21 C.F.R. 201.6 (FDA prohibiting misleading statements on drug labels); 16 C.F.R. § 423 (FTC requiring specific instructions on clothing labels to avoid being a deceptive practice); 16 C.F.R. § 1500 (FTC requiring labeling for hazardous substances like cleaning products); 16 C.F.R. § 1107.30 (CPSC labeling requirements must be met for certain consumer products).

[15] Id.

[16] See, e.g., Bell v. Am. Int'l Indus. , 2018 WL 2745238, at *5 (M.D.N.C. June 7, 2018) (refusing to dismiss punitive damages on a failure to warn claim where the plaintiff's complaint alleged defendants were "forewarned by tests, standards, promulgations of rules and regulations, statutes, and ordnances").

[17] FDA Guidance for Industry: Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic (Mar. 2020), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic.

[18] CPSC Procedures Concerning COVID-19, available at https://www.cpsc.gov/Office-of-the-Secretary/Directives/CPSC-Procedures-Concerning-COVID-19.

[19] Coronavirus Update: FDA and FTC Warn Seven Companies Selling Fraudulent Products that Claim to Treat or Prevent COVID-19, available at https://www.fda.gov/news-events/press-announcements/coronavirus-update-fda-and-ftc-warn-seven-companies-selling-fraudulent-products-claim-treat-or (Mar. 9, 2020).

[20] FDA Warns Against False Advertising for COVID-19 Antibody Tests, available at https://news.bloomberglaw.com/pharma-and-life-sciences/fda-warns-against-false-advertising-for-covid-19-antibody-tests (Apr. 8, 2020).

[21] 21 U.S.C. § 333(a); United States v. Goldberg , 538 F.3d 280, 289 (3d Cir. 2008),as amended (Nov. 6, 2008).

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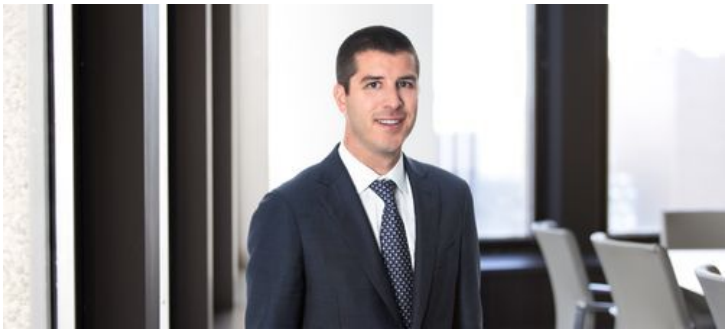

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