

ALERTS

Retooling Your Business for COVID-19: Product Liability Immunity & Insurance for Manufacturing Pandemic Products

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One thing, among many, that enduring the COVID-19 crisis is reminding us of is that the resilience of the human spirit is remarkable. Amidst calls for more personal protective equipment for the dedicated healthcare workers on the front lines and more ventilators for vulnerable patients fighting for their lives, company after company (and individuals) have responded by retooling their operations to manufacture the items needed to support the herculean effort to treat those infected and to stay ahead of and flatten the curve of this pandemic. The U.S. Food and Drug Administration recently issued guidance described as a “boost” that will help address manufacturing limitations and supply shortages by allowing medical device makers to make changes to products more easily and other types of manufacturers “such as auto makers [to] more easily repurpose production lines to help increase supply.” While generosity and a sense of unity may be motivation to join the ranks of businesses supporting the effort, many still wonder, and rightfully so, whether they will open themselves up to liability by producing these products. There are lines of inquiry businesses should explore with their counsel to determine both their potential exposure to liability for products they manufacture and their potential coverage for liability arising out of any viable claim made against them.

Immunity from Product Liability

Under the Public Health Service Act, 42 U.S. Code § 247d-6d (PHSA), *Targeted liability protections for pandemic and epidemic products and security countermeasures*, a manufacturer will have immunity from federal and state lawsuits and liability for producing a product, as long as the product falls within the statutory definition of “covered countermeasure” and the product is the subject of a declaration by the Secretary of Health and Human Services (HHS Secretary) pursuant to the Public Readiness and Emergency Preparedness Act (PREP Act) that (1) recommends the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures and (2) invokes the liability immunity provisions with respect to the recommended activities. The immunity provided is broad and would apply to a range of product liability claims:

The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

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The only exception to the immunity provided under the statute is in the event of willful misconduct that leads to death or serious physical injury, in which case a federal suit may be brought in the U.S. District Court for the District of Columbia.

In response to COVID-19, the HHS Secretary issued a PREP Act declaration that was published in the Federal Register on March 17, 2020 and is effective as of February 4, 2020. On March 18, 2020, the Families First Coronavirus Response Act, H.R. 6201, Pub. L. No. 116-127 (Family First Act), was signed into law. Section 6005 of the Families First Act amended the PHS Act to extend immunity from liability for certain approved respiratory protective devices that are subject to emergency use authorizations during the COVID-19 outbreak. These respiratory protective devices were added to the definition of covered countermeasure and the immunity extends to those devices used from January 27, 2020 to October 1, 2024.

Product Liability Insurance Coverage

In the usual course of business, a company will hold a comprehensive general liability policy (or CGL policy) that will cover, to some extent, claims of personal injury and property damage arising out of its products or completed work. This coverage is known as products-completed operations coverage. In addition to a general liability policy, companies that manufacture and sell products also should consider adding specific coverage for product liability claims. Product liability claims can include design defects, manufacturing defects, warning or use defects, and strict liability. The extent to which claims will be covered will depend upon the specific language of a CGL or product liability policy, including any applicable exclusions.

Companies should discuss with counsel whether the immunity provided under the PHS Act applies to the new products they are considering manufacturing, and whether any applicable insurance policy will provide coverage if they face a product liability lawsuit. The review of a company's insurance policies should include an analysis of whether the change in the product they will produce will have an impact on available coverage, *e.g.*, whether the new product is subject to an exclusion or the policy is restricted to certain products.