

Insights

U.S. LIABILITY CONSIDERATIONS FOR PRODUCT MANUFACTURERS SHIFTING PRODUCTION TO NEW PRODUCTS TO ASSIST IN PANDEMIC RESPONSE

Apr 22, 2020

An issue of concern for some manufacturers during the COVID-19 outbreak is the issue of potential liability in a product liability lawsuit if they switch their manufacturing process to produce items they don't normally produce to help combat the pandemic. This includes the production of masks, ventilators and other medical equipment. Additionally, concerns over compliance arise in cases where manufacturers receive pressure from outside sources to speed up production.

Liability protections currently exist through the PREP Act, which extends immunity to manufacturers and distributors of products considered "covered countermeasures" to COVID-19. 42 U.S.C.A. § 247d-6d; See [Immunity from Liability under the U.S. PREP Act for Medical Countermeasures during the SARS-CoV-2/COVID-19 Pandemic](#). There is also evidence from prior health emergencies that the government will provide manufacturers with liability protection if they decide to produce items for the pandemic. For example, the Project BioShield Act of 2004 provided that during a declared emergency, the HHS Secretary has the authority to authorize the emergency use of a product that has not yet been approved for distribution. *Id.*; Project BioShield Act of 2004, PL 108–276, July 21, 2004, 118 Stat 835. Then, during the anthrax health scare, a 2005 provision to the Act allowed the FDA to issue an Emergency Use Authorization for use of the anthrax vaccine. *Id.* During this time, the FDA waived current manufacturing practice requirements regarding design, manufacture, packaging, labeling, and storage for the distribution of the vaccine. John D. Blum & Jordan Paradise, *Public Health Preparedness & Response: An Exercise in Administrative Law*, 20 DePaul J. Health Care L. 1, 20 (2018).

A main policy objective of federal, tribal, state, and local governments has been to provide stronger liability protections to incentivize the private sector to respond to an emergency. James G. Hodge, Jr., JD, LLM et. al., *From (a)nthrax to (z)ika: Key Lessons in Public Health Legal Preparedness*, 15 Ind. Health L. Rev. 23, 38 (2018). Therefore, it is possible that additional liability protections will be implemented to encourage manufacturers to participate in emergency efforts. We have seen this play out in the present situation, where the FDA has continued to expand its Coronavirus-related Emergency Use Authorizations to cover additional products to respond to the COVID-19 pandemic,

many of which may qualify for immunity under the PREP Act. See [FDA's Coronavirus Emergency Use Authorizations for Medical Devices](#).

Manufacturers may also qualify for increased liability protection through individual state laws. Currently, there are state statutes that provide liability protection to parties acting pursuant to government or legal authority. For example, in Delaware, a corporation that provides assistance at the request of the state or a local government during a public health emergency is eligible for immunity. Del. Code Ann. tit. 20, § 3144. In New Jersey, civil immunity is granted to private entities that perform a contract with a public entity, or provide a public entity with assistance during a public health emergency. N.J. Stat. Ann. § 26:13-19. As with the PREP Act and other statutes providing immunity for emergency countermeasures, this immunity does not extend to injuries caused by an act that is outside the scope of authority granted by this statute, or for conduct that constitute crimes, fraud, actual malice, gross negligence, or willful misconduct. *Id.*

Several other states have statutes that provide some level of immunity for persons and private entities acting in response to public health emergencies. See, e.g., California Emergency Services Act (Cal. Gov't Code § 8657.5); North Carolina Emergency Management Act (N.C. Gen. Stat. Ann. § 166A-19.60); the Louisiana Homeland Security and Emergency Assistance and Disaster Act (La. Stat. Ann. § 29:735.3.1); Mississippi's Emergency Management Law (Miss. Code. Ann. § 33-15-21); Virginia's Emergency Services and Disaster Law (Va. Code Ann. § 44-146.23); and Connecticut's Civil Preparedness and Emergency Services (Conn. Gen. Stat. Ann. § 28-13).

Furthermore, to the extent companies are manufacturing products at the direction of the government, companies may be able to assert the "government contract defense" to receive liability protection in the event of a product liability claim. The defense provides companies that contract with a public body for the performance of public work protection from liability for damages resulting incidentally or necessarily from performance of the contract. Commander Charles W. Tucker, *The Government Contract Defense in Products Liability Cases*, 34 Naval L. Rev. 157 (1985). The justification of the government contract defense rests on public policy grounds and is a complete bar to claims based on strict liability, breach of warranty, and negligence. The Government Contactor Defense, C607 ALI-ABA 1321 , 1329.

Moreover, companies should check state and local laws to determine whether the government contract defense applies to specific claims. Although the Supreme Court applied the government contract defense to design defect claims, jurisdictions have differing opinions regarding whether to apply the defense to failure to warn and manufacturing defect claims. *In re "Agent Orange" Prod. Liab. Litig.*, 304 F. Supp. 2d 404, 437 (E.D.N.Y. 2004), *aff'd sub nom. In re Agent Orange Prod. Liab. Litig.*, 517 F.3d 76 (2d Cir. 2008).

As governments and manufacturers work to quickly respond to the ongoing public health crisis posed by COVID-19, the legal landscape regarding liability protections for these activities is evolving

rapidly. Before switching manufacturing processes to respond to COVID-19, manufacturers should consult with an attorney and examine all applicable protections under State and Federal law.

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