Corporate Governance

INSIGHT: Litigation Risks Related to the Defense Production Act

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A direction from the government to manufacture or distribute a product will not necessarily shield a company from lawsuits. Crowell & Moring attorneys examine the Defense Production Act and say it's imperative that manufacturers pivoting to produce FDA-regulated products manage liability now and think strategically about future litigation defenses.

To help hospitals and other health care providers address shortages of critical medical products, the Food and Drug Administration has issued a dizzying array of emergency use authorizations and relaxed its enforcement policies. Shortages are likely to continue for some time, however, and we anticipate pressure will build to expand use of the Defense Production Act of 1950.

The DPA grants the president an assortment of broad authorities, including authority to direct manufacturers (and others) to give preferential treatment to government contracts "necessary or appropriate to promote the national defense" or to pivot to producing FDA-regulated products.

Notably, with only limited exceptions, compliance is not optional. The DPA and its implementing regulations and orders carry criminal penalties for noncompliance, as well as the possibility of injunctive relief.

Manufacturers must therefore prepare for litigation risks that flow from DPA orders. There are several questions to consider:

Does the DPA Provide Immunity for Damages From Performance of a DPA Order?

Yes, however the extent of immunity under the DPA remains uncertain. Under the DPA, no person can be "held liable for damages or penalties for any act or failure to act resulting directly or indirectly from compliance with [the law], or an official action, notwithstanding that such provision or action shall subsequently be declared invalid by judicial or other competent authority."

This provision affords the contractor protection from claims by customers whose orders have been set aside to prioritize the government's orders. If, for some reason, the government contractor settles these claims, there is no automatic right to indemnification against the federal government.

But what about tort liability? This is particularly significant given the inherent litigation risk associated with medical devices intended to treat vulnerable populations during the Covid-19 crisis.

Manufacturers may argue that DPA immunity should extend to tort claims because their hands are tied once a DPA order is made, but this theory has not been tested. Tort protections from the DPA itself are thus, at best, uncertain and likely limited.

May Companies Seek Tort Immunity Under the Government Contractor Defense?

Possibly. This defense shields contractors from tort liability for products manufactured for the government in accordance with a government specification.

As explained by the U.S. Supreme Court in *Boyle v. United Technologies Corp*., immunity extends to state law design defect claims where:
1. The government "approved reasonably precise specifications";
2. The equipment was manufactured in accordance with those specifications; and
3. The contractor warned the government about dangers in the equipment known to the contractor but unknown to the government.

The first prong of the analysis is critical as companies work closely with the government to produce medical equipment and supplies for the first time. As the Fourth Circuit noted, a "mere rubber stamp or acceptance of the contractor's design" by the government is insufficient to establish the first element of the *Boyle* defense. Instead, the federal government must direct the contractor to follow detailed specifications and/or collaborate with the contractor during the entire design process.

To the extent the design features are left to the discretion of the contractor and the government only approves the final product, the government contract defense does not attach.

For those that are "drafted" into the production of new items, careful planning can enhance the possibility that the immunity may be available. The FDA has announced its willingness to assist companies, advising that it "welcomes the opportunity to work with [new ventilator] manufacturers … [and] intends to work collaboratively" with them.

This collaboration may shield a company from tort immunity down the road but it must be well documented. Thus, if called upon by the government to manufacture supplies under the DPA, businesses should build a record to demonstrate the level of government involvement in designing or overseeing the development of the product.

What Contractual Provisions Should Companies Seek?

While the Anti-Deficiency Act generally prohibits the government from indemnifying contractors, contractors receiving DPA orders in this environment may:

- **Avail themselves of the immunity from suit available in the Public Readiness and Emergency Preparedness Act (PREP Act).** The PREP Act provides liability immunity to companies involved in the development, manufacture, testing, distribution, administration, and use of medical countermeasures to Covid-19. Companies should ensure the products they are providing are covered by the PREP Act and the product liability immunity provided therein.
- **Request P.L. 85-804 indemnification from the federal government.** P.L. 85-804 permits the government to contractually indemnify prime and subcontractors against claims from third persons for death, personal injury, and property loss or damage, as well as loss or damage to the contractor's or government's property (excluding lost profits), to the extent such claims, losses, and damages relate to risks defined in the contract as "unusually hazardous or nuclear" and are not compensated by insurance.
- **Request commercial indemnification from higher-tier contractors.** Contractors may seek limitations of liability to reduce government claims against the contractor. Subcontractors obligated to prioritize DPA orders over other orders may ask the prime contractor to provide standard commercial indemnifications. However, these terms likely will not provide third-party liability protections.

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