Business & Practice

INSIGHT: Liability Risks for Companies Pivoting to Covid-19 Supplies

By Gail Zirkelbach, Mana Elihu Lombardo, and Gabrielle Trujillo

June 17, 2020, 4:01 AM

The rapid transformation by manufacturers to switch gears and design and produce equipment related to the Covid-19 pandemic raises potential liability issues. Crowell & Moring attorneys explore the legal risks associated with these rapid developments and provide tips to mitigate them.

In the wake of the Covid-19 pandemic, companies are stepping up—and in some cases, out of their wheelhouse—to respond to reported shortages of medical supplies like ventilators and personal protective equipment (PPE).

We've seen face shields being 3D-printed for health-care professionals, car manufacturers pivoting to manufacture ventilators, and doctors in Italy using 3D-printers to modify scuba masks to produce ventilators.

These fast-paced efforts to alleviate the crisis are laudable, but the quick adaptation to the design and/or manufacture of equipment outside of traditional operations raises potential legal risks.

Consumer Protection Concerns and the PREP Act

Consumer protection laws and regulations could expose manufacturers to considerable liability. The Public Readiness and Emergency Preparedness Act (PREP Act), however, provides limited product liability protection for manufacturers and distributors of covered countermeasures facing claims of negligence, product liability, wrongful death, or related state claims.

Contractors can obtain PREP Act immunity for products manufactured in response to Covid-19 that are:

1. either FDA-approved or subject to an FDA Emergency Use Authorization (EUA);
2. purchased by a local, state, or federal entity or pursuant to government authorization; and
3. distributed for use in response to the pandemic.

Under the PREP Act, manufacturers and distributors, "covered persons," receive immunity from liability from the use of their "covered countermeasures" identified in a declaration from the secretary of the Department of Health & Human Services (HHS).

The HHS secretary's March 17 declaration, as amended on April 10, provides immunity for FDA approved or authorized drugs, biological products, or devices (including respiratory devices) developed, manufactured, tested, distributed, used, and administered in response to the pandemic. Liability immunity extends through Oct. 1, 2024, with a 12-month grace period.

A company desiring PREP Act immunity must ensure its products are covered countermeasures and that their use is in connection with a federal agreement, such as a contract or cooperative agreement, or in accordance with local, state, or federal declarations of emergency.

PREP Act immunity does not extend to acts of "willful misconduct" or to products supplied after the coverage period. Appropriate warnings on products and date and lot code traceability can mitigate risks from use outside of the coverage period.

Selling Newly Manufactured PPE to the Government

Compliance Risks and Safeguarding Measures Unique to Government Contractors

Government contracts include different requirements from commercial contracts and may contain non-negotiable terms. Of note, the federal government always has the right to terminate a contract for convenience, unilaterally ending the contract at any time, for any reason. Although the contractor will recover its costs, it generally cannot dispute the decision or recover anticipated profits.

A contractor should seek to protect itself from events it cannot control that impact its ability to satisfy its contractual obligations. Federal government contractors should attempt to include the Federal Acquisition Regulation (FAR) commercial items clause that contains protections, including an excusable delay clause shielding contractors from liability for nonperformance caused by epidemics or quarantines and language safeguarding contractors if the government terminates for convenience. These provisions also provide some protection from certain supply chain disruptions.

Federal government contracts may also contain domestic source restrictions such as the Buy American Act (BAA), requiring generally that articles, materials, or supplies be produced, or manufactured in the U.S.

Similarly, the Trade Agreements Act (TAA) requires products be manufactured or "substantially transformed" in the U.S. or a "designated country." Contractors are sometimes asked to certify they meet these requirements.

Contractors should not inadvertently convey intellectual property rights to the government. Although many FAR clauses protect background inventions created separately from the contract and owned or licensed by the contractor, the FAR generally does not protect subject inventions developed or reduced to practice during contract performance.

Thus, contractors should identify their background IP and attempt to negotiate limitations on government rights to subject inventions.

DPAS Ratings

The Defense Priorities and Allocation System (DPAS) was established to ensure the timely availability of resources for national defense and emergency preparedness and protect contractors' supply chains. The DPAS authorizes agencies to place "rated orders" to support approved programs. With a narrow exception, U.S. companies are required to accept rated orders for items they normally supply.

While a company must reject rated orders that the company cannot deliver, it must inform the government of its earliest delivery date and offer to accept the order for that date. Companies must also prioritize rated orders and reschedule unrated orders if they conflict. Contractors must comply with rated orders to avoid criminal penalties for willful noncompliance with the DPAS.

False Claims Act Liability

Pivoting manufacturers should be aware of potential liability under the False Claims Act (FCA) based on claims by the government and whistleblowers against entities who knowingly submit false claims/statements to the government for payment. Government contractors often submit certifications regarding their organization and the products being supplied. Any "knowing" misrepresentation in a certification constitutes a false statement.

Also, under an implied certification theory, any "knowing" failure to meet statutory, regulatory or contractual requirements material to payment could constitute a false claim.

Moreover, "knowledge" only requires acts in "deliberate ignorance" or "reckless disregard" of the truth or falsity of the information, and does not require any specific intent to defraud. FCA liability includes treble damages, and large statutory penalties. Thus, manufacturers must carefully avoid potentially false claims or statements.

This column does not necessarily reflect the opinion of The Bureau of National Affairs, Inc. or its owners.

Author Information

Gail Zirkelbach is a Government Contracts and Investigations partner in the Los Angeles office of Crowell & Moring. In addition to conducting internal investigations, she counsels aerospace and technology contractors on all aspects of government contracts and compliance at the federal, state and local levels.

Mana Elihu Lombardo is a partner in Crowell & Moring's Government Contracts Group in Los Angeles. She concentrates her practice on government contracts litigation, investigations, and counseling and co-leads the firm's False Claims Act working group.

Gabrielle Trujillo is an associate in Crowell & Moring's Los Angeles office and is a member of the firm's Government Contracts and White Collar and Regulatory Enforcement groups.