

TYPES NOT MAPPED YET May 08, 2020 | TTR not mapped yet | Carl J. Pesce, Booker T. Shaw

# From emergency medical products to chicken nuggets: What manufacturers and distributors need to know during COVID-19

As the country and the world continue to adjust to the ever-changing “new normal” of COVID-19, the need for essential products, ranging from emergency medical products to critical food supplies, is at an all-time high. Over the last two months, this country has watched the exceptional efforts of businesses in every industry come together to lend a helping hand to save lives. Pharmaceutical and biotech companies are innovating to develop vaccines and antiviral medicines to target this novel and potentially life-threatening virus. Automotive companies have switched gears to manufacture ventilators. Fashion designers have altered patterns to manufacture face masks. Meat processing plants have been full steam ahead to keep critical food supply chains operating for all Americans. And doctors, nurses, medical students nearing graduation, and even retired medical professionals have stepped up to the plate to work long hours to save those in dire need of help.

As this nation faces the uncertainty of what the next several months will look like, it is critical that manufacturers and distributors of essential products understand what their country may ask of them and whether their actions now will protect them from legal repercussions in the future. Below, we analyze the legal implications of the Defense Production Act of 1950 (the “DPA”), 50 U.S.C. § 4501 *et seq.*, and the United States Department of Health and Human Services’ Notice of Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (the “Declaration”), 85 Fed. Reg. 15198.

## Defense Production Act of 1950

Over the last few weeks, the DPA has received considerable media attention and even more speculation as to if and when President Trump will invoke it in response to the global pandemic. The DPA generally confers powerful, emergency authority to the President to enlist private businesses to aid in meeting demands of a national emergency.

### Broad grant of authority

Historically, the DPA was enacted to allow the President to mobilize the nation’s industrial base during wartime. 50 U.S.C. § 4502. Since the 1950s, the DPA has been expanded beyond war and military preparedness to a broader definition of national defense that now includes national emergencies and emergency preparedness activities. 50 U.S.C. § 4552. The DPA’s powerful grant of authority over the “national defense” encompasses the following:

- Programs for military and energy production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any directly related activity. 50 U.S.C. § 4552(14).
- Emergency preparedness activities and measures designed or undertaken to prepare for or minimize the effects of a hazard upon the civilian population, to deal with the immediate emergency conditions which would be created by the hazard. 42 U.S.C. § 5195(a)(3).
- Critical infrastructure, which includes any systems and assets, whether physical or cyber-based, so vital to the United States that the degradation or destruction of such systems and assets would have a debilitating impact on national security, including, but not limited to, national economic security and national public health or safety. 50 U.S.C. § 4552(2).

### Practical implications

With such an extensive definition of national defense and a broad grant of authority to promote it, the President has significant power and ample opportunities to require private companies to act during national emergencies. This practically means that the DPA allows the federal government, among other things, to:

- Require private companies to accept and prioritize certain contracts and the production of critical goods and services (50 U.S.C. § 4511);
- Allocate materials, services, and facilities in such manner, upon such conditions, and to such extent it deems necessary or appropriate (50 U.S.C. § 4511);
- Purchase materials or supplies it deems essential for the national defense (50 U.S.C. § 4533);
- Guarantee or extend loans to private companies to ensure that the supply of industrial resources, critical technology items, or materials essential to the national defense are available from reliable sources during a national emergency (50 U.S.C. § 4532);
- Suspend or prohibit a U.S. company's merger, acquisition, or takeover by a foreign entity transaction that threatens to impair national security (50 U.S.C. § 4565); and
- Consult with representatives of industry, business, financing, agriculture, labor, and other interests in order to provide for the making by such persons, with the approval of the President, of voluntary agreements and plans of action to help provide for the national defense and grant these representatives immunity from U.S. antitrust laws under certain circumstances (50 U.S.C. § 4558).

### Liability and immunity

Within narrowly defined parameters, the DPA affords immunity to private companies contracting with the federal government in the following ways:

- Defense in a breach of contract action against a dissatisfied contracting counterparty (50 U.S.C. § 4557; *E. Air Lines, Inc. v. McDonnell Douglas Corp.*, 532 F.2d 957 (5th Cir. 1976)); and
- Immunity from U.S. antitrust laws for developing and carrying out voluntary agreements and plans of action to help provide for the national defense (50 U.S.C. § 4558).

Overall, the expansiveness of the DPA allows the President to invoke it in radically different ways to promote the national defense. The course of the last few weeks serves as a perfect example. In late March, President Trump invoked the DPA to cope with unprecedented shortages of essential medical supplies. Just weeks later on April 28, President Trump invoked the DPA to keep meat processing plants open and declared that meat processing plants are a critical infrastructure to protect the nation from food shortages. The difference in these invocations exemplifies the vast breadth of authority conferred on the President. As the public health crisis continues, the extent to which President Trump intends to use the DPA remains uncertain.

### Notice of declaration for medical countermeasures against COVID-19

In late March, the United States Department of Health and Human Services ("HHS") published its Declaration, in which HHS conferred broad tort immunity under federal and state law for manufacturers and distributors engaging in "activities related to medical countermeasures against COVID-19." 85 Fed. Reg. 15198. This tort immunity was conferred pursuant to 42 U.S.C. § 247d-6d (the Public Readiness & Emergency Preparedness Act) and 21 U.S.C. §§ 564A-B (the Pandemic and All-Hazards Preparedness Reauthorization Act).

### Broad tort immunity

This Declaration provides manufacturers and distributors, as "Covered Persons," with much needed support to innovate, develop, and distribute COVID-19-fighting drugs, biological products, or medical devices without fear of legal repercussions in the future. Notably, this tort immunity is extensive and covers "any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures," as well as COVID-19-fighting drugs, "products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic." Only claims involving "willful misconduct" would be excepted from this tort immunity. Examples of precluded claims include "liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose." In contrast, "a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use."

### Covered countermeasures

For manufacturers and distributors to be covered by this tort immunity, their underlying conduct must be the manufacture or distribution of a "Covered Countermeasure," which includes "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19" and "any device used in the administration of any such product, and all components and constituent materials of any such product." To be a "Covered Countermeasure," the product must qualify as a "qualified pandemic or epidemic product," "security countermeasure," or "drug, biological product or device authorized for

emergency use.” Covered Countermeasures must also be FDA “approved or cleared,” “investigational” under the Federal Food, Drug, and Cosmetic Act, or otherwise “licensed” or “authorized for emergency use.”

A “qualified pandemic or epidemic product means a drug or device . . . or a biological product . . . that is

(i) manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause;

(ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; [or]

(iii) a product or technology intended to enhance the use or effect of such a drug, biological product, or device.”

A “security countermeasure is a drug or device . . . or a biological product . . . that (i)(a) [t]he Secretary determines to be a priority to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat . . . , or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined . . . to be a necessary countermeasure to protect public health.”

### Practical considerations

For manufacturers and distributors that are already producing and distributing emergency medical products, it may be worthwhile to have the product classified as a Covered Countermeasure and seek the related FDA approvals. For example, a company that is already producing the plastic tubing that connects a ventilator to a patient may want to consider moving forward with the technical FDA requirements that are included in the Declaration (i.e., the product must qualify as a Covered Countermeasure, as defined above, *and* must receive one of the aforementioned FDA authorizations). Notably, the underlying product must also be intended for a medical purpose and be used to fight COVID-19 in one of the ways outlined by the Declaration. By understanding the Declaration’s requirements to qualify for tort immunity related to COVID-19-fighting emergency medical products, manufacturers and distributors can weigh the benefits and drawbacks of moving forward to seek approvals for their products and ultimately determine if this course of action is a prudent business decision.

### Effective time period

Significantly, if manufacturers and distributors fall within the technical parameters for Covered Countermeasures, they have tort immunity retroactive to February 4, 2020 and can expect this liability immunity for different means of distribution to last until October 1, 2024, and even longer for Covered Countermeasures obtained for the Strategic National Stockpile.

### Conclusion

It has been said that COVID-19 has forever shaped the nation and the world at large, and in many ways that is likely true. While it remains to be seen how each essential industry will continue to evolve over the next several months, one thing is certain - this nation’s manufacturers and distributors will continue to provide essential products that the American people need to survive. Armed with knowledge of the DPA’s broad authorities during national emergencies and the Declaration’s broad tort immunity for COVID-19-fighting countermeasures, manufacturers and distributors of essential products can make informed decisions moving forward amid the ever-evolving crisis created by COVID-19.

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