Medical Products to Combat the COVID-19 Crisis: Products Liability Issues



Written By: Partner Susan Burnett, Partner Patrick Cleary and Associate Daniel Rock

In mere months, the spread of COVID-19 illness caused by the novel coronavirus (SARS-CoV-2) has caused a world crisis unparalleled in the last hundred years. The World Health Organization declared COVID-19 a global pandemic, emphasizing it is "not just a public health crisis[;] it is a crisis that will touch every sector." [1] In the United States, the crisis poses unique challenges and potential products liability issues for companies that make — or that will make for the first time — medical products needed to combat COVID-19, including testing for it, treating patients for it, and otherwise preventing its spread. In addition, many companies will also face the challenge of ensuring their products are properly approved or cleared for use by the FDA.

In this paper, we provide a basic overview of several federal statutes that provide, or may provide, defenses to products liability lawsuits involving medical products made, distributed, and used during a public health emergency. We focus primarily on the Public Readiness and Emergency Preparedness Act ("PREP Act"), originally enacted in 2005, which provides immunity for claims of loss arising from certain activities triggered by a special declaration of emergency issued by the Secretary of the Department of Health and Human Services (the "Secretary"). The Secretary issued such a declaration in connection with the COVID-19 pandemic on March 17,

[1] Available at https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

2020 (the "PREP Act Declaration"). We also briefly address the defense of implied conflict preemption in the context of the Public Health Service Act ("PHSA"), as amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 ("PAHPRA"), which permits the Federal Food and Drug Administration ("FDA") to issue Emergency Use Authorizations ("EUAs") in a declared public health emergency for previously unapproved medical products or unapproved uses of approved medical products in certain emergencies. Finally, we briefly discuss the unsettled state of the law on liability protection under the Defense Production Act of 1950 ("DPA"), a Cold War-era statute that authorizes the President to, among other things, "prioritize government contracts for goods and services over competing customers, and offer incentives within the domestic market to enhance the production and supply of critical materials and technologies" in national emergencies.[2]

This overview is only a starting point for understanding products liability issues that may arise in this still-evolving and unprecedented public health emergency. We encourage any company involved in the design, manufacture, testing, marketing, distribution, or use of medical

---

[2] *See* The Defense Production Act of 1950: History, Authorities, and Considerations for Congress (Congressional Research Service) (updated Mar. 2, 2020) at 1, available at: https://fas.org/sgp/crs/natsec/R43767.pdf.

Other statutes not specifically aimed at emergency situations may also offer provide a federal preemption defense to products liability lawsuits. One is the Medical Device Amendments of 1976, 21 U.S.C. § 360k ("MDA"), to the Federal Food, Drug, and Cosmetic Act ("FDCA" or "FD&C Act"), 21 U.S.C. § 301 *et seq.* (*See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323–25 (2008) (holding that the MDA expressly preempts claims with respect to medical devices subject to the Premarket Approval ("PMA") process but explaining that such preemption does not apply to medical devices cleared under the less rigorous 510(k) process). Another is the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 *et seq. See Bruesewitz v. Wyeth, Inc.*, 562 U.S. 223, 243 (2011) ("[W]e hold that the National Childhood Vaccine Injury Act pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects.").

products related to the COVID-19 crisis to consult its counsel regarding products liability litigation issues and risk mitigation strategies. [3]

I. THE PREP ACT

A. Immunity

The PREP Act authorizes the Secretary to issue a PREP Act Declaration providing immunity from liability, except for "willful misconduct," for certain tort claims. [4] In general, the immunity extends to "Covered Persons" with respect to all claims for loss relating to the administration or use of a "Covered Countermeasure" under the declaration. *See* 42 U.S.C. § 247d-6d(a)(1). Thus, the PREP Act's broad immunity protection is dependent on the terms and definitions of the specific declaration issued by the Secretary.

The HHS Secretary issued the required declaration with respect to the COVID-19 pandemic earlier this month. PREP Act Declaration, 85 F.R. 15198 (Mar. 17, 2020). [5] It extends statutory immunity for the following "Recommended Activities": the manufacture, testing, development, distribution, administration, and use of the "Covered Countermeasures," subject to the other conditions in the Declaration and PREP Act. 85 F.R. at 15201. Assuming that an entity is participating in one of those "Recommended Activities," the scope of liability immunity is tied to four basic categories: (1) whether the entity seeking immunity is a "Covered Person"; (2) whether the product is a "Covered Countermeasure" that meets the relevant regulatory

---

[3] This paper is for informational purposes only and does not provide legal advice or opinions with respect to any particular issue.

[4] *See generally* https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.

[5] Available at https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures).

requirements; (3) whether there are any limitations on the immunity provided by the PREP Act; and (4) whether there was willful misconduct.

1. Covered Persons

The Declaration provides that "Covered Persons" who may receive immunity include "manufacturers," "distributors," "program planners," "qualified persons," and their officials, agents, and employees, as those terms are defined in the PREP Act. 85 F.R. at 15201.

The definitions of those terms in the PREP Act are as follows:

- **"Manufacturer"** is defined as including "(A) a contractor or subcontractor of a manufacturer; (B) a supplier or licenser of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a Covered Countermeasure; and (C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer." § 247d-6d(i)(4).

- **"Distributor"** means "a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies." § 247d-6d(i)(3).

- **"Program planner"** means "a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration . . . ." § 247d-6d(i)(6).

- **"Qualified person"** means "(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) a person within a category of persons so identified in a declaration by the Secretary . . . ." § 247d-6d(i)(8).

In addition to these statutory categories, the PREP Act Declaration provides that the following are "Covered Persons":

- "Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction [6] . . . to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency"

- "Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act" (*i.e.*, the FD&C Act as amended by PAHPRA)

- "Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act."

85 F.R. at 15201-02.

2. Covered Countermeasures

"Covered Countermeasures" under the PREP Act Declaration include "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, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product." 85 F.R. at 15202.

Such a product, however, also must meet the statutory definition of "Covered Countermeasures" under the PREP Act, which also incorporates certain regulatory requirements. *Id*. The PREP Act specifies the following categories of "Covered Countermeasures":

- **"Qualified pandemic or epidemic product,"** which means a drug, biological product, or device that is, among other things, manufactured or used for the purpose of (1) diagnosis, treatment, cure, or mitigation of the pandemic; (2) diagnosis, treatment, cure, or mitigation of serious or life-threatening conditions caused by such a product; or (3) enhancing the use of such a product. § 247d-6d(i)(7)(A). However, any such product must be properly authorized, licensed, approved, or exempted from regulatory requirements. § 247d-6d(i)(1)(B).

- **"Security countermeasure,"** which means a drug, biological product, or device that the Secretary of Homeland Security determines to be (1) a necessary

[6] This term is discussed below and defined in the Declaration. It is essentially any local, state, tribal, or federal government entity with authority and responsibility to respond to incidents.

countermeasure to protect public health; and (2) a priority to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat (or to diagnose, prevent, or treat conditions potentially resulting from the administration of such necessary products). 42 U.S.C. § 247d-6b(c)(1)(B). Any such product must be properly authorized, licensed, approved, or exempted from regulatory requirements. *Id*.

- **"Drug"** (as defined in 21 U.S.C. 321(g)(1)); **"Biological product"** (as defined in 42 U.S.C. § 262(i)); or **"Device"** (as defined in 21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the FD&C Act. § 247d(i)(1)(C).

Note that the recently passed Families First Coronavirus Response Act, PL 116-127 (Mar. 18, 2020), and the Coronavirus Aid, Relief, and Economic Security Act, PL 116-136 (Mar. 27, 2020), added to and amended the statutory definition of "Covered Countermeasure" so that it now includes "personal respiratory protective device." 42 U.S.C. § 247d(i)(1)(D). The PREP Act Declaration, however, does not mention such devices. There is therefore some textual ambiguity as to whether the PREP Act immunity applies to the emergency production of respirators.[7] The conservative approach is to ensure that respiratory devices fit under another category of "Covered Countermeasures" such as a "device" or a "qualified pandemic product."

3. Limitations on Immunity

The Secretary has the authority to place limitations and conditions on the immunity afforded by the PREP Act. § 247d-6d(a)(3-5). He included some such limitations in the PREP Act Declaration. For example, the immunity provided by the PREP Act is limited to those activities related to (1) existing or future federal contracts, grants, transactions, or agreements; or (2) "Activities authorized in accordance with the public health and medical response of the Authority

[7] This category appears to apply to respirators, a type of personal protection equipment for healthcare workers, and not ventilators, which are used for patient care. FDA has issued guidance documents that indicate respirators and other similar personal protective equipment are encompassed by PREP Act immunity. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health

Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency." 85 F.R. at 15202.[8]

The first category is the cleanest way to ensure that the PREP Act immunity is not limited, as it appears to cover a wide variety of federal agreements. The second category is more ambiguous, but it appears to cover activities that are authorized by local, state, tribal, or federal entities that have the legal responsibility and authority to respond to COVID-19 incidents and who have issued a declaration indicating an immediate need for "Covered Countermeasures." *See id.* The spirit of this limitation is to require cooperation between "Covered Persons" seeking immunity under the PREP Act and the relevant government officials.

The PREP Act Declaration also states that the immunity applies regardless of where the "Covered Countermeasure" is used, regardless of who uses the "Covered Countermeasure," so long as the use occurs before either October 1, 2024, or the final day the PREP Act Declaration is in effect, whichever occurs first. 85 F.R. at 15202. There are an additional twelve months following the expiration of the effective time period during which the immunity will apply during the wind-down of the use of "Covered Countermeasures." *Id*.

4. Willful Misconduct

The only exception to the immunity afforded by the PREP Act, assuming the PREP Act applies to a given product, is the "exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person." 42 U.S.C. § 247d-6d(d)(1). While any exception to

[8] It is noteworthy that, apart from this statutory cause of action, those injured by "Covered Countermeasures" may seek compensation from the "Countermeasures Injury Compensation Program." The program was created and authorized by the PREP Act Declaration and 42 U.S.C. § 247d-6e in order "to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure." 85 F.R. at 15201.

statutory immunity for tort liability is a potential litigation-generator, Congress placed strict limits on the "willful misconduct" exception to PREP Act immunity. "Willful misconduct" under the statute means "an act or omission that is taken intentionally to achieve a wrongful purpose; knowingly without legal or factual justification; and in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." § 247d-6d(c)(1). The statute specifies that this definition "shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness." *Id*. Among other procedural safeguards, the statute requires a plaintiff invoking the willful misconduct exception to (1) plead with particularity each act or omission alleged to be willful misconduct facts supporting proximate cause and death or serious physical injury, (2) verify the complaint under oath, and (3) file a non-treating physician affidavit substantiating the claim as well as certified medical records document injury and causation. § 247d-6d(e)(3) & (4).

Limiting the exception still further, the PREP Act specifies that any act or omission by a manufacturer or distributor with respect to a "Covered Countermeasure" that is subject to regulation under Chapter 6A or the FD&C Act is not "willful misconduct" so long as (i) neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission; or (ii) such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy, as defined in the statute. § 247d-6d(c)(5).

The procedures for the filing, discovery, and trial of a willful misconduct suit are described in detail by the PREP Act. § 247d-6d(e). Notably, such a claim must be brought in the United States District Court for the District of Columbia. § 247d-6d(e)(1); *see also Kehler v. Hood*, No. 4:11CV1416 FRB, 2012 WL 1945952, at *3 (E.D. Mo. May 30, 2012) (dismissing claim for

willful misconduct under the PREP Act because claim had to be brought in the USDC for the District of Columbia).

B. Preemption

In addition to the immunity it offers, which applies to claims for loss, the PREP Act contains a section expressly preempting the establishment or enforcement of state laws and regulations with respect to a "Covered Countermeasure" that (1) is different from or in conflict with requirements under the PREP Act, and (2) relates to, *inter alia*, the development, manufacture, and distribution of a "Covered Countermeasure." § 247d-6d(b)(8). [9]

This section has been broadly interpreted to cover all state law tort claims. For example, in *Parker v. St. Lawrence Cty. Pub. Health Dep't*, 102 A.D.3d 140, 144, 954 N.Y.S.2d 259, 262 (2012), the HHS Secretary issued a declaration in response to an outbreak of the H1N1 influenza virus and recommended the application of antiviral vaccinations. One vaccine was administered to a child without first obtaining parental consent. The parent sued for negligence and battery. The defendant moved to dismiss based on the express preemption in the PREP Act. The court granted the motion and the appellate court affirmed, noting that "Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified person pursuant to a declaration by the Secretary . . . ." 102 A.D.3d at 144, 954 N.Y.S.2d at 262.

II. IMPLIED PREEMPTION OF CLAIMS ARISING FROM ACTIVITIES CONDUCTED PURSUANT TO AN EUA UNDER THE PHSA

The PREP Act Declaration specifically references Emergency Use Authorizations (EUAs) in defining "Covered Persons." 85 F.R. at 15201-02. So does the PREP Act itself, in requiring that "Covered Countermeasures" fall within certain defined categories, one of which is drugs,

[9] As discussed in subsection (II)(A), below, federal law supplants state law in the event of a direct conflict.

biological products, or medical devices subject to an EUA. *See id.*; 42 U.S.C. § 247d(i)(7)(C). To the extent a company obtains an EUA to produce or distribute a medical product qualifying as a "Covered Countermeasure" under the PREP Act Declaration (*i.e.*, "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, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product"), and complying with the other limitations in the PREP Act Declaration, then those activities would likely fall under the PREP Act's broad immunity provisions.

But even if a medical product governed by an EUA does not qualify as a "Covered Countermeasure," the doctrine of implied conflict preemption may offer protection from products liability claims. This doctrine is complex and a full discussion of it is beyond the scope of this paper. The following brief synopsis is designed to familiarize those outside the pharma and device industry with basic concepts.

A. The Role of the FDA and the Concept of Federal Preemption

First, some very basic background. The FDA is an agency within the Department of Health and Human Services that regulates drugs, medical devices, and biological products (*e.g.*, vaccines) through, respectively, the Center for Drug Evaluation & Research (CDER), the Center for Devices & Radiological Health (CDRH), and the Center for Biologics Evaluation & Research (CBER).[10] It conducts this regulatory function pursuant to federal statutes and through regulations it promulgates to implement those statutes. For purposes of federal preemption, the FDA's

[10] *See* https://www.fda.gov/about-fda/fda-organization-charts/fda-overview-organization-chart.

regulations in general have the force of federal law, as may certain other actions by the agency, such as rejecting a change to a drug's prescribing information proposed by the drug manufacturer.

The Supremacy Clause of the United States Constitution, U.S. Const. Art. IV, § 2, makes federal law "the supreme Law of the Land[.]" It follows that when federal law and state law directly conflict, the latter must yield to the former. Thus, even though there is no express statutory provision regarding preemption (like what was discussed above in the context of the PREP Act), any such federal law may have an implied preemptive effect. A state law requirement is preempted if it would be impossible for an actor to comply unilaterally with it without violating federal law, or when enforcement of the state law requirement would pose an obstacle to the purposes and objectives of Congress. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2012); *Wyeth v. Levine*, 555 U.S. 555, 568, 573–74 (2009).

Critically, state law in this context includes common law "enforced" through jury verdicts. To illustrate: Suppose that a state's common law would permit a jury to impose liability on a generic drug company on the ground that the drug's label inadequately warned about the adverse effect suffered by the plaintiff. Because federal law requires generic drug labels to match the brand drug's label, and the generic drug company would have violated federal law by changing the label without prior FDA authorization, the state law failure-to-warn claim is impliedly preempted by federal law. *Mensing*, 564 U.S. at 617.

Implied conflict preemption also can apply when federal law permits an actor to distribute a regulated product, but state law prohibits the distribution of that product. In the litigation context, this conflict could arise when, for example, the plaintiff argues that a drug is too dangerous to be sold; *i.e.*, that its risks outweigh its benefits for all classes of patients. In the context of generic prescription drugs, the Supreme Court rejected this "stop selling" theory of liability, finding it

impliedly preempted by federal law which permitted the sale of the drug. *Mut. Pharma. Co., Inc. v. Bartlett*, 570 U.S. 472, 488 (2013) ("Our preemption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability.").

B. Implied Conflict Preemption and EUAs

The PHSA,[11] as amended by PAHPRA,[12] authorizes the FDA, among other things, to issue EUAs[13] based on a determination by the HHS Secretary that there is a public health emergency or a significant potential for a public health emergency. 21 U.S.C. § 360bbb-3(b)(C). The Secretary issued this declaration, which is different from the PREP Act declaration, on January 31, 2020.[14] The EUA authority "allows the FDA to facilitate availability and unapproved uses of MCMs [medical countermeasures, including drugs, biological products, and devices] needed to prepare for and respond to CBRN [Chemical, biological, radiological and nuclear] emergencies." Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders (FDA Jan. 2017) ("EUA Guidance") at 4. A CBRN emergency is a public health, military, and domestic emergency that includes "emergency infectious disease threats." *Id.* at 1.

The FDA has been active in issuing guidance for medical devices to diagnose, protect against, and provide ventilation support for patients with COVID-19.[15] These guidance documents, while nonbinding recommendations, provide immediately effective recommendations

---

11 The Public Health Service Act.

12 The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013.

13 Emergency Use Authorizations.

14 *See* https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

15 https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders

for obtaining FDA EUAs. Before any client considers designing, manufacturing, or distributing previously unapproved medical products or unapproved uses of approved medical products for COVID-19 response, we recommend they read and follow the applicable guidance documents to ensure the fullest protection of the PREP Act liability immunity and, if applicable, maximize the chances that an implied preemption defense will succeed. For instance, clients who want to make ventilators (powered or mechanical) should review the Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.[16] This guidance document provides a process for contacting the FDA for EUA approval and provides guidance for existing manufacturers of medical devices and guidance for companies who have never manufactured medical devices but have strong manufacturing capabilities.[17]

Although the EUA Guidance is non-binding on the FDA and the public, and "does not establish any rights for any person," *id.*, the FDA expresses in it the agency's views on implied preemption when an EUA conflicts with state law requirements "governing the shipment, holding, dispensing, administration, or labeling of unapproved medical devices or approved medical devices for unapproved uses. *Id.* at 39. The FDA states that it believes "the terms and conditions of an EUA issued under section 564 [of PAHPRA] preempt state and local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of an emergency declared under

---

16 Available at: https://www.fda.gov/media/136318/download.

17 On March 31, 2020, FDA announced a Coronavirus Treatment Acceleration Program (CTAP), available at: https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap. This program is not a guidance and does not create EUAs but expresses the FDA's commitment to rapidly responding to written requests for novel pharmacological trials, approving protocols for proposed novel pharmaceutical treatments, and around-the-clock review of proposed single patient trials.

section 564." *Id.* at 40. These different or additional state and local requirements, the FDA finds, stand as an obstacle to the implementation of Congress' purposes and objectives. *Id.*

The FDA's position on implied conflict preemption in this context does not have the force of law, and the degree to which courts may defer to it is governed by complex and ambiguous legal precedents. Nonetheless, the FDA's position is helpful and bolsters a potential preemption defense should litigation arise from activities conducted pursuant to an EUA. Of course, to maximize the chances of success in making this argument, it is critically important that manufacturers follow, and document that they have followed, the precise terms and conditions of the EUA and any other relevant FDA standards and guidance.

III. THE DEFENSE PRODUCTION ACT

The Defense Production Act ("DPA") authorizes the President to force a company to accept, prioritize, and perform a contract that he deems is necessary for the national defense. 50 U.S.C. § 4511(a). President Trump recently used this power by instructing the HHS Secretary to require GM to accept, perform, and prioritize contracts or orders for the numbers of ventilators that the HHS Secretary determines to be appropriate.[18]

Compliance with an order under the DPA is enforced by the threat of a penalty against anyone who willfully disobeys any order or regulation issued pursuant to the DPA. 50 U.S.C. § 4513 (monetary fines or up to a year in prison).

The DPA also has a provision providing immunity from liability for any act or failure to act resulting directly or indirectly from compliance with a rule, regulation, or order issued pursuant

[18] *See* Memorandum on Order Under the Defense Production Act Regarding General Motors Company, available at https://www.whitehouse.gov/presidential-actions/memorandum-order-defense-production-act-regarding-general-motors-company/.

to the DPA. 50 U.S.C. § 4557. This immunity most clearly applies where, in order to comply with an order under the DPA, a company breaches a contract with a third party. *E. Air Lines, Inc. v. McDonnell Douglas Corp*., 532 F.2d 957, 994 (5th Cir. 1976). Some cases suggest, however, that this immunity does not apply to tort liability, or if it does, applies only to strict products liability, not other legal liability theories, such as negligence. *In re Agent Orange Prod. Liab. Litig.*, 597 F. Supp. 740, 843 (E.D.N.Y. 1984), *aff'd*, 818 F.2d 145 (2d Cir. 1987); *see also In re Aircraft Crash Litig. Frederick, Md.*, May 6, 1981, 752 F. Supp. 1326, 1330 (S.D. Ohio 1990), *aff'd*, 935 F.2d 269 (6th Cir. 1991).

Given this legal uncertainty, any company that becomes subject to a DPA Order over the course of the COVID-19 crisis should immediately consult with counsel to analyze the potential tort liability and implement risk mitigation strategies to the greatest extent possible.

* * *

In conclusion, we will continue to daily monitor the government response, and any legal and FDA regulatory implications as we continue to move through these unchartered waters. As warranted, we will provide informational updates to this paper and welcome any questions you may have.

Contributing authors to this article include Kim Schmid, Executive Managing Partner and Life Sciences Practice co-chair; Barry Koopmann, Managing Partner and Life Sciences Practice co-chair; Olga Tymouch, Associate; and Jon Smith, Associate.