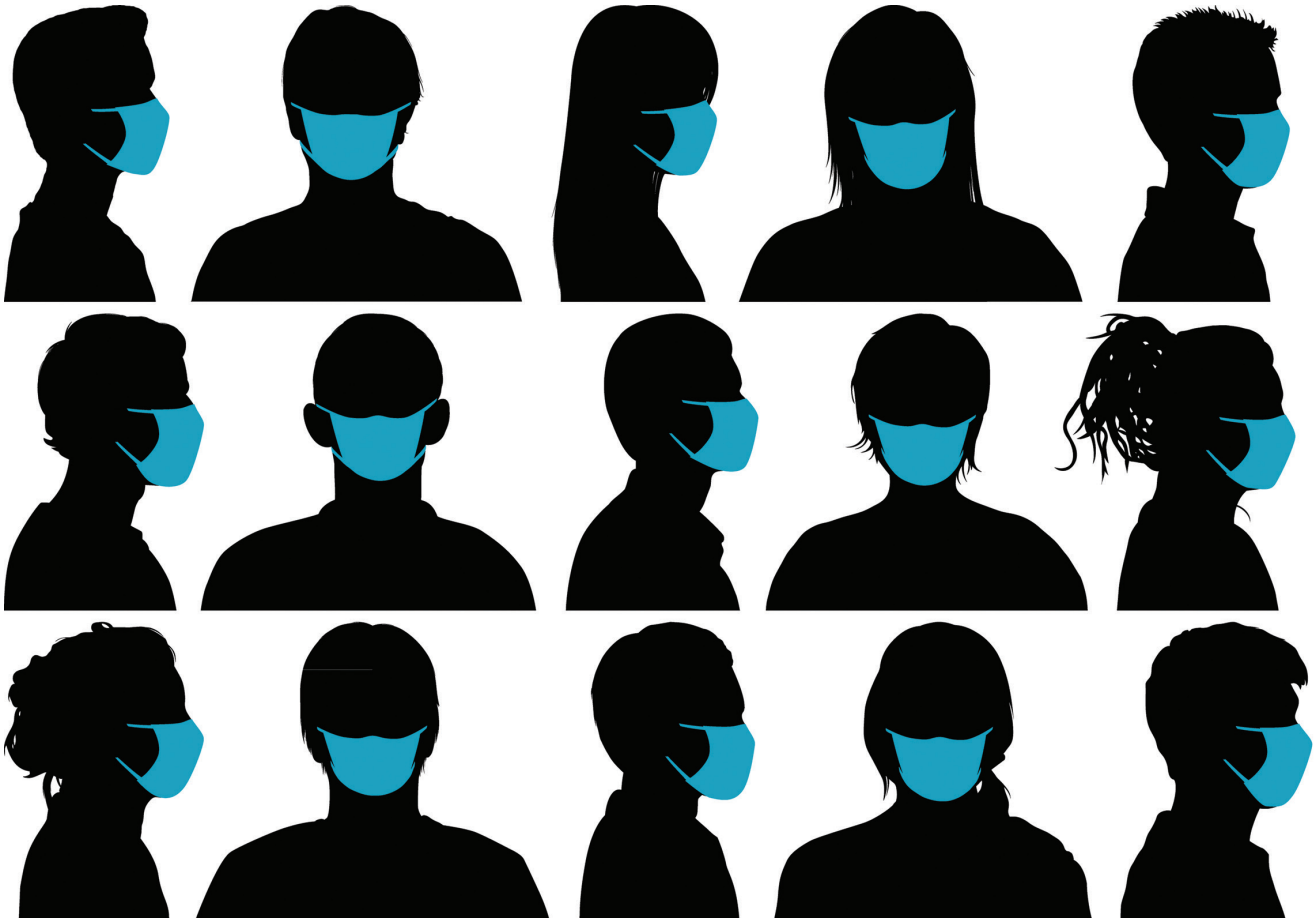
 By Susan Burnett, Patrick Cleary, and Daniel Rock

Potential Defenses to Product Liability Claims



Liability immunity emanating from different federal authorities may protect companies involved in designing, manufacturing, testing, marketing, distributing, or using medical products.

In mere months, the spread of COVID-19 caused by the novel coronavirus (SARS-CoV-2) has caused a world health crisis unparalleled in the last hundred years. In early March, the World Health Organization declared COVID-19 a global pandemic, emphasizing that it is "not just a public health crisis[;] it is a crisis that will touch

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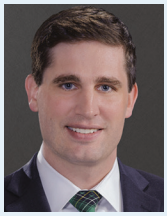

every sector." That prediction was accurate. Among the sectors affected in the United States is the court system, with an upward trend in lawsuits related to the novel coronavirus that is expected to continue.

The crisis poses unique challenges and potential product liability issues for companies that make—or that will make for the first time—medical products needed to combat COVID-19, including products for testing, treating patients, and otherwise preventing its spread. In addition, many companies will also face the challenge of ensuring that their products are properly approved or cleared for use by the U.S. Food and Drug Administration (FDA).

In this article, we provide a basic overview of several federal statutes that provide, or may provide, defenses to product 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 We focus primarily on the Public Readiness and Emergency Preparedness Act (PREP Act), originally enacted in 2005, which provides immunity for claims of loss arising from certain activities triggered by a special declaration of emergency issued by the Secretary of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 U.S. Department of Health and Human Services (HHS). The HHS Secretary issued such a declaration in connection with the COVID-19 pandemic on March 17, 2020 (the PREP Act COVID-19 Declaration) and amended that declaration in April 2020. We then address the implied conflict preemption defense 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 FDA to issue emergency use authorizations (EUAs) in a declared public health emergency, either for previously unapproved medical products, or for unapproved uses of approved medical products in certain emergencies. Finally, we briefly discuss the unsettled 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. *See* Congressional Res. Serv., ***The Defense Production Act of 1950: History, Authorities, and Considerations for Congress*** 1–2 (updated Mar. 2, 2020)

This overview is only a starting point for understanding the product 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 products potentially related to the COVID-19 crisis to consult its counsel regarding product liability litigation issues and risk-mitigation strategies.

The PREP Act

The PREP Act, as mentioned above, authorizes the HHS Secretary to issue a special emergency declaration offering immunity against claims of loss arising from certain activities related to the emergency. The HHS Secretary, as previously stated, issued such a required declaration with respect to the COVID-19 pandemic in early March. 85 Fed. Reg. 15,198, PREP Act COVID-19 Declaration (Mar. 17, 2020). The HHS Secretary then amended the declaration in April. 85 Fed. Reg. 21,012 (April 15, 2020).

PREP Act Immunity

The PREP Act authorizes the HHS Secretary to issue a declaration under the act that will provide immunity from liability, except for "willful misconduct," for certain tort claims. In general, the immunity extends to "covered persons" for 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 depends on the terms and definitions of the specific declaration issued by the HHS Secretary.

The PREP Act COVID-19 Declaration 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 Fed. Reg. at 15,201.

Assuming that an entity is participating in one of those "recommended activities," the scope of liability immunity is tied to four basic inquiries: (1) whether the entity seeking immunity is a "covered person"; (2) whether the product is a "covered countermeasure" that meets the relevant regulatory requirements; (3) whether there are any limitations on the immunity provided by the PREP Act; and (4) whether there was willful misconduct.

Covered Persons

The PREP Act COVID-19 Declaration provides that the "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 Fed. Reg. at 15,201.

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." 42 U.S.C. §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, covered-person categories, the PREP Act COVID-19 Declaration provides that the following are "covered persons":

- "[a]ny person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction [essentially any local, state, tribal, or federal government entity with authority and responsibility to respond to incidents.]… to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency";
- "[a]ny 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 Federal Food, Drug, and Cosmetic Act, as amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 [PAHPRA]); and
- "[a]ny person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act."

85 Fed. Reg. at 15,201–02.

Covered Countermeasures

"Covered countermeasures" under the amended PREP Act COVID-19 Declaration include the following:

> any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective 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 Fed. Reg. at 21,014.

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 that a "covered countermeasure" is a "qualified pandemic or epidemic product," a "security countermeasure," a "drug, biological product, or device," or a "respiratory protective device," defined and subject to further regulation.

- A **"qualified pandemic or epidemic product"** 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. 42 U.S.C. §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);
- A **"security countermeasure"** means a drug, biological product, or device that the Secretary of Homeland Security determines to be (1) a necessary 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," "biological product,"** and **"device"** in the PREP Act incorporate the definitions in the Federal Food, Drug, and Cosmetic Act (FD&C Act). 21 U.S.C. §321(g)(1) (drug); 42 U.S.C. §262(i) (biological product); 21 U.S.C. §321(h) (device). All three must be authorized for emergency use in accordance with section 564, 564A, or 564B of the FD&C Act. §247d(i)(1)(C).
- A **"respiratory protective device"** seems to mean respirators, not ventilators, and they must be determined to be a priority for use during a public health emergency and approved by the National Institute for Occupational Safety and Health under applicable regulations. 42 U.S.C. §247d(i)(1)(D). (This is discussed more below.)

There is some nonbinding administrative guidance on the subject of "covered countermeasures." The General Counsel for the Department of Health and Human Services (HHS General Counsel) has issued an omnibus advisory opinion, which describes what the HHS General Counsel believes to be the scope of the PREP Act immunity under the PREP Act COVID-19 Declaration. *See* Advisory Op., Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act, April 17, 2020, as Modified on May 19, 2020 (OmnibusCOVID-19 Advisory Opinion). The opinion addresses what constitutes a "covered countermeasure" in two significant ways.

First, it contains links to lists of "covered countermeasures" that are subject to an EUA. *See* U.S. Food & Drug Admin., ***FDA Combating COVID-19 with Medical Devices*** (updated June 8, 2020); U.S. Food & Drug Admin., ***FDA Combating COVID-19 with Therapeutics*** (updated May 11, 2020). This provides a helpful way to cross-check any independent analysis with the agency's view of what products are protected under the PREP Act.

Second, it is the opinion of the HHS General Counsel that a "covered person" who otherwise complies with the requirements of the PREP Act will not lose immunity—even if the product is not a "covered countermeasure"—as long as the "covered person" could have reasonably believed that the product was a "covered countermeasure." COVID-19 Omnibus Advisory Op., *supra*, at 4–5. The basis for this opinion is the HHS General Counsel's interpretation that "Congress did not intend to impose a strict liability standard on covered persons for determining whether a product is a covered countermeasure."

Id. The opinion also states that a person or entity who otherwise complies with requirements for the PREP Act immunity would not lose that immunity on the basis of not being a "covered person," again, as long as the person or entity could have reasonably believed that it was a "covered person." *Id.* at 7. While the opinion does not have the force and effect of law, it nevertheless provides helpful guidance for companies attempting to minimize their litigation risk. *Id.* at 1.

Limitations on Immunity

The HHS Secretary has the authority to place limitations and conditions on the immunity afforded by the PREP Act. 42 U.S.C. §247d-6d(a)(3–5). He included some such limitations in the PREP Act COVID-19 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) "[a]ctivities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency." 85 Fed. Reg. at 15,202.

The first activities category is the cleanest way to ensure that the PREP Act immunity is not limited because it appears to cover a wide variety of federal agreements. The second activities 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 that 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 COVID-19 Declaration also states that the immunity applies regardless of where a "covered countermeasure" is used, regardless of who uses it, as long as the use occurs within the effective time period for the liability immunity. 85 Fed. Reg. at 15,202. According to the online "PREP Act Q&A," immunity under the statute should apply to all domestic claims over which the United States has jurisdiction and may apply to some foreign claims if they have a link to the United States that makes it reasonable to apply U.S. law. *See* ***PREP Act Q&As***, U.S. Dep't Health & Human Servs.

Effective Time Period and the PREP Act Declaration Amendment

The recently passed Families First Coronavirus Response Act, Pub. L. 116-127 (Mar. 18, 2020), and the Coronavirus Aid, Relief, and Economic Security Act, Pub. L. 116-136 (Mar. 27, 2020), added to and amended the "covered countermeasure" definition to include a "personal respiratory protective device." 42 U.S.C. §247d(i)(1)(D). This countermeasure category appears to apply to respirators, a type of personal protection equipment for health-care workers, and not ventilators, which are used for patient care. The original PREP Act COVID-19 Declaration, however, did not mention such devices. As noted above, the HHS Secretary amended the PREP Act COVID-19 Declaration in April, and he specifically included respiratory protective devices in the definition of "covered countermeasures." 85 Fed. Reg. 21,012.

Be aware, however, that the amendment includes an effective time period for immunity that differs from the effective time period for all other "covered countermeasures." The immunity for respiratory devices begins on March 27, 2020, and extends through October 1, 2024. 85 Fed. Reg. at 21,014. The immunity for other "covered countermeasures" begins on February 4, 2020, and extends through October 1, 2024. *Id.* Thus, for respiratory protective devices manufactured before March 27, 2020, it would be safest to ensure that such devices fit under another category of "covered countermeasures" such as a "device" or a "qualified pandemic product."

Also note that if any "covered countermeasure" is administered or used in accordance with "the public health and medical response of the Authority Having Jurisdiction" (discussed above, in the "Limits on Immunity" section), then the effective time period begins with the relevant emergency declaration and lasts until either October 1, 2024, or the final day on which the emergency declaration is in effect, whichever occurs first. 85 Fed. Reg. at 21,014. There are an additional twelve months after the expiration of the effective time period during which the immunity will apply, during the wind down of the use of "covered countermeasures." 85 Fed. Reg. at 15,202.

Willful Misconduct

As noted, the only exception to the immunity afforded by the PREP Act, assuming that 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 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 do the following: (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 nontreating physician affidavit substantiating the claim, as well as certified medical records documenting injury and causation. §247d-6d(e)(3) & (4).

Limiting the exception 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" as long as (1) neither the HHS Secretary nor the Attorney General has initiated an enforcement action with respect to such

act or omission; or (2) 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 a claim for willful misconduct under the PREP Act because the claim had to be brought in the U.S. District Court for the District of Columbia).

Apart from the statutory cause of action, it is also noteworthy that those who are injured or are fatally injured by "covered countermeasures" may seek compensation from the "Countermeasures Injury Compensation Program." The program was created and authorized by the PREP Act COVID-19 Declaration and 42 U.S.C. §247d-6e "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 Fed. Reg. at 15,201.

PREP Act Express Preemption

In addition to the immunity that 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) are different from or conflict with requirements under the PREP Act; and (2) relate to, among other things, the development, manufacture, and distribution of a "covered countermeasure." 42 U.S.C. §247d-6d(b)(8). The COVID-19 Omnibus Advisory Opinion states that the PREP Act's express preemption section compliments the immunity provided elsewhere in the statute. The opinion points out, for example, that PREP Act immunity does not expressly cover local laws, whereas PREP Act preemption would, in the agency's view, preempt such laws. COVID-19 Omnibus Advisory Op., *supra*, at n.2.

Consistent with the COVID-19 Omnibus Advisory Opinion, courts have broadly interpreted PREP Act preemption 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 securing 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, "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.

Potential Implied Preemption for Claims Arising from Public Health Service Act Emergency Use Authorization Activities

The PREP Act COVID-19 Declaration specifically references "emergency use authorizations" (EUAs) in defining "covered persons." 85 Fed. Reg. at 15,201–02. So does the PREP Act itself, requiring that "covered countermeasures" fall within certain defined categories, one of which encompasses drugs, biological products, or medical devices subject to an EUA. *See id.* 42 U.S.C. §247d-6d(i)(1)(C). To the extent that a company obtains an EUA to produce or distribute a medical product qualifying as a "covered countermeasure" under the PREP Act COVID-19 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 COVID-19 Declaration, then those activities would likely fall under the PREP Act's broad immunity provisions.

The FDA has issued several nonbinding guidance documents with respect to EUAs for medical products meant to combat COVID-19, and any company considering seeking an EUA for such a product, or operating pursuant to one, should become thoroughly familiar with these documents. *See, e.g.*, ***COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders***, U.S. Food & Drug Admin. (current as of June 17, 2020).

But what about a hypothetical medical product governed by an EUA that for whatever reason does *not* qualify as a "covered countermeasure"? The implied conflict preemption may offer protection from product liability claims for such a medical product. The underlying premise of this doctrine, stated at its simplest, is that state law cannot require an actor to do something that federal law forbids. *See generally* U.S. Const. art. IV, §2 (stating that federal law is "the supreme Law of the Land[.]"). This straightforward principle unfortunately splinters into myriad, complex legal issues and turns heavily on product- and case-specific factors. Accordingly, a full discussion of implied preemption as it may apply to EUA-covered medical products is beyond the scope of this article, but the following synopsis is designed to introduce the basic concepts of this doctrine.

The FDA's Role and the Concept of Federal Preemption

First, some very basic background. The FDA is the agency within the HHS that regulates drugs, medical devices, and biological products (e.g., vaccines) through, respectively, the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), and the Center for Biologics Evaluation and Research (CBER). It conducts this regulatory function in accordance with federal statutes and through regulations that it promulgates to implement those statutes. For purposes of federal preemption, the FDA's regulations generally have the force of federal law, as may certain other actions by the agency, such as rejecting a manufacturer's proposed change to a product's warnings or design.

As noted above, when federal law and state law directly conflict, the latter is preempted and must yield to the former. And even if there is no federal statutory pro-

vision expressly preempting state law (as there is in the PREP Act), a federal law may have an implied preemptive effect. A state law requirement is impliedly preempted if it would be impossible for an actor to comply unilaterally with it without violating federal law (often called "impossibility" preemption), or when enforcement of the state law requirement would pose an obstacle to the purposes and objectives of Congress (often called "obstacle" or "purposes and objectives" preemption). *See*, *e.g.*, *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2012) (addressing impossibility preemption); *Wyeth v. Levine*, 555 U.S. 555, 568, 573–74 (2009) (addressing impossibility and obstacle preemption).

Critically, state law in this context includes common law tort doctrines "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 because 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 such a generic drug company would have violated federal law by changing the label without prior FDA authorization, the Supreme Court has found that such a state law failure-to-warn claim conflicted with and was impliedly preempted by federal law. *Mensing*, 564 U.S. at 617.

Implied conflict preemption also may apply when federal law permits an actor to distribute a regulated product, but state law prohibits the distribution of that product. In litigation, this conflict could arise when, for example, the plaintiff does not or cannot, for some reason, argue that a product should have been redesigned or accompanied by different warnings, and instead, the plaintiff asserts that it is too dangerous to be sold at all; that is, its risks outweigh its benefits overall. In a case involving 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.").

Implied Conflict Preemption and Emergency Use Authorizations

The Public Health Service Act (PHSA), as amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, (PAHPRA), as mentioned above, authorizes the FDA, among other things, to issue EUAs 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)(1)(C). The HHS Secretary issued this declaration, which is different from the PREP Act Declaration, on January 31, 2020.

In a guidance document dated January 2017, the FDA provided its views on the scope of the agency's authority with respect to EUAs after declaring a public health emergency under PAHPRA. *See* U.S. Food & Drug Admin., ***Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*** (Jan. 2017)(EUA guidance) (note that the FDA currently provides the EUA guidance as a primary resource on its webpage addressing EUAs, although the guidance itself contains an expiration date of August 31, 2019. *See* ***Emergency Use Authorization***, U.S. Food & Drug Admin. (current as of June 16, 2020)).

According to the EUA guidance, the FDA's authority to issue EUAs "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." EUA guidance, *supra*, at 4. Among these emergencies are "emergency infectious disease threats." *Id.* at 1. The EUA guidance, as with other FDA guidance documents, is nonbinding on the FDA and the public, and it "does not establish any rights for any person." *Id.* Nonetheless, in the EUA guidance, the FDA expressed its views on implied preemption when state law requirements "governing the shipment, holding, dispensing, administration, or labeling of unapproved medical devices or approved medical devices for unapproved uses" apply to a medical product governed by an EUA. *Id.* at 39. As noted above, such requirements may include state law tort doctrines imposing obligations on product manufacturers, such as a duty to sell a safely designed and manufactured product with adequate warnings and instructions for its use.

The FDA stated its belief that "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 section 564." *Id.* at 40. These different or additional state and local requirements, the FDA found, stand as obstacles to the implementation of Congress' purposes and objectives. *Id.* In other words, the FDA invoked the doctrine of obstacle preemption to express its view that a state could not hold a company liable for failing to take an action not required under the EUA (e.g., adding a warning or using a different component part).

The likelihood that a court would defer to the FDA's views on the preemptive effect of its actions in a product liability lawsuit is unclear and governed by complex and ambiguous legal precedents. *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 576–77 (2009) (rejecting the FDA's position that obstacle preemption applied and stating that while agencies "have a unique understanding of the statutes they administer," the "weight we accord the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness"). And the extent to which obstacle preemption remains a viable doctrine at all has been much discussed in recent years. *See, e.g.*, James Beck, ***Viewing Buckman as a Logical Contradiction Decision***, Drug & Device Law blog (Nov. 4, 2019), (noting Justice Thomas's and possibly Justice Gorsuch's "doctrinal disdain" for obstacle preemption). *See Kansas v. Garcia*, 140 S. Ct. 791, 807, 206 L. Ed. 2d 146 (2020) (Thomas, J., concurring) ("[W]e should explicitly abandon our 'purposes and objectives' pre-emption jurisprudence.").

Nonetheless, the FDA's position in the EUA guidance on obstacle preemption makes sense, and courts might find it persuasive, given the special circumstances of a public health emergency. The very existence of an EUA presupposes that the federal government has declared such an emergency and that the FDA, acting under its delegated authority, has determined that the emergency requires the rapid distribution of medical products outside the normal regulatory scheme. It arguably interferes with Congress' intent if the fifty states may freely second-guess the FDA's decision-making in such a situation by permitting juries to impose state law liability after-the-fact with respect to a product that complied with an EUA. It also arguably creates disincentives for companies to use the EUA process to provide needed products during a crisis, especially companies new to medical products.

On the other hand, Congress has provided express, statutory immunity and preemption for medical products covered under the PREP Act, including products subject to EUAs. If a product subject to an EUA falls outside those PREP Act liability protections, courts might be reluctant to agree with the FDA on the applicability of obstacle preemption. In *Levine*, for example, the Supreme Court pointed to the absence of express statutory preemption in rejecting implied obstacle preemption and declining to defer to the FDA's position that state tort suits challenging the adequacy of FDA-approved, brand-name prescription drug labels posed an obstacle to Congress' purposes and objectives. *Levine*, 555 U.S. at 574 ("If Congress though state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70-year history.").

Finally, putting aside obstacle preemption and the complicated issue of judicial deference to agency views, impossibility preemption may also provide a potential defense in the context of EUAs. Its potential application will be highly product and fact specific, but one key, initial question provides a useful analytic framework: Could a company *unilaterally* have taken the action that the plaintiff claims was required by state tort law without first seeking permission from the FDA? If the answer is "no," impossibility preemption may provide a viable defense. *Compare Levine*, 555 U.S. at 572 (rejecting impossibility preemption where a federal regulation allowed brand-name drug companies to make unilateral changes to drug labels absent "clear evidence" that the FDA would have rejected the change), *with Mensing*, 564 U.S. at 618 (finding a failure-to-warn claim was barred by impossibility preemption because generic drug companies could not make unilateral changes to label, and so, "[i]f the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law").

The answer to the unilateral action question will turn, in part, on the specificity with which the EUA dictates the design, manufacture, and labeling of the medical product, and the extent of the company's ability, under the terms of the EUA or other applicable FDA rules, to make changes without first seeking FDA approval. Bear in mind that when it comes to interpreting the scope of what regulated companies can and cannot do under FDA regulations, as opposed to the preemptive effect of FDA actions, the Supreme Court has accorded the FDA's views much greater deference. *See, e.g.*, *Mensing*, 564 U.S. at 613 (stating with respect to whether FDA regulation allowed unilateral label changes, the "FDA's views are controlling unless plainly erroneous or inconsistent with the regulations or there is any other reason to doubt that they reflect the FDA's fair and considered judgment") (quotation and internal quotation marks omitted).

In sum, implied conflict preemption is a difficult defense to establish, but it is worth analyzing. If it arguably applies, it will be worth asserting and preserving.

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 or she deems is necessary for the national defense. 50 U.S.C. §4511(a). In one example, President Trump recently used this power to instruct the HHS Secretary to require GM to accept, perform, and prioritize contracts or orders for the numbers of ventilators that the HHS Secretary determined to be appropriate. *See* **Mem. on Order Under the Defense Production Act Regarding General Motors Company,** Mar. 27, 2020.

Compliance with an order under the DPA is partly 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 (establishing monetary fines or up to a year in prison).

Similar to the PREP Act, the DPA also has a provision providing immunity from liability for any act or failure to act that results directly or indirectly from compliance with a rule, regulation, or order issued under 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, it applies only to strict product liability, not to other actions arising under 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.

An Eye to the Future

No one can predict how the COVID-19 pandemic will affect the legal landscape, including how courts across the country will grapple with novel claims and defenses. But companies that develop, manufacture, and distribute medical products designed to combat the COVID-19 pandemic would be wise to implement risk-mitigation strategies early, including carefully evaluating the range of directly applicable or potentially applicable statutory, regulatory, and common law defenses.