Liability in the Time of a Pandemic

The Scope of Immunity Under the PREP Act

By Cortney Godin and Kaitlyn Hansen

Innovators, scientists, manufacturers, and healthcare workers around the world are battling to bring the COVID-19 pandemic under control. Litigation will surely follow.

On March 10, 2020, in response to the outbreak of COVID-19, the Secretary of the United States Department of Health and Human Services (HHS), Alex Azar (Secretary) issued a declaration invoking broad liability protections under the Public Readiness and Emergency Preparedness Act (the PREP Act) for certain individuals and entities engaged in the design, manufacture, testing, and administration of countermeasures to the emerging public health emergency. Public Readiness and Emergency Preparedness Act, codified at 42 U.S.C. §§247d-6d; Medical Countermeasures Against COVID-19 Declaration, 85 Fed. Reg.15,198 (Mar. 17, 2020)) (Declaration).

When the Declaration was issued, the world had been brought to an abrupt halt as COVID-19, an acute respiratory disease caused by the SARS-CoV-2 betacoronavirus, or a virus mutating from it, ravaged communities, stole lives, and immobilized economies. As a society, we were confronting immeasurable loss, and as a nation, we faced a healthcare system that was overwhelmed by a sudden influx of patients, strained for resources, and threatened with depleted reserves of protective equipment. In response to the crisis, manufacturers and innovators directed resources, and in some cases, they repurposed manufacturing operations entirely, to research, develop, and supply the products needed to counter and treat COVID-19. The Secretary's activation of the liability protections afforded by the PREP Act was intended to encourage and expediate these efforts, which may have otherwise been encumbered by the underlying threat of potential litigation.

While the innovators, scientists, healthcare professionals, life sciences companies, and others work fervently to develop and produce equipment, vaccines, and lifesaving medical treatments for COVID-19, plaintiffs' attorneys are preparing to chal-

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lenge the scope of immunity provided by the PREP Act. Accordingly, it is important for entities to understand the scope and limitations of the liability protections afforded by the act to minimize risk and operate, to the extent possible, within its parameters.

The PREP Act: Historical Background

Congress enacted the PREP Act in 2005, in response to the avian influenza. 42 U.S.C. §§§247d-6d. As mentioned, the PREP Act established a framework for providing immunity from claims that arise from the manufacture, development, distribution, administration, and use of medical countermeasures during a public health emergency. It simultaneously structured a no-fault system to compensate individuals for serious injuries directly caused by such countermeasures. 42 U.S.C. §§§247d-6d(a)-(d). When the act is invoked, certain covered persons are shielded from liability for losses "caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a 'covered countermeasure.'" 42 U.S.C. §§§247d-6d§(a)(1). The intent of the act is to encourage innovation and rapid treatment options when the country encounters a novel health threat. H.R. Rep. No. 151-164 (Dec. 18 2005) (Conf. Rep.); ***Public Health and Readiness Act***, U.S. Dep't Health & Human Svcs. (2020) *See also* Medical Countermeasures Against COVID-19 Declaration, 85 Fed. Reg.15,198, §§§I, II (Mar. 17, 2020).

The PREP Act authorizes the HHS Secretary to issue a declaration triggering the liability protections under the act when the Secretary determines that a disease or other threat to health "constitutes a public health emergency." 42 U.S.C. §§§247d-6d(b). Before the current crisis, declarations activating the immunity provisions of the PREP Act have been issued in response to a series of public health crises: Ebola, Zika Virus, H1N1, anthrax, acute radiation, smallpox, and botulinum toxin. Public Health and Readiness Act, *supra*.

Although the PREP Act has been criticized for restricting access to judicial relief, the act expressly provides a no-fault mechanism to compensate individuals, or estates of individuals, who sustain certain serious physical injuries or death "directly caused by" the administration or use of a covered countermeasure. 42 U.S.C. §§§247d-6e. Specifically, the Countermeasures Injury Compensation Program (CICP) is a fund established under the PREP Act and administered by the HHS that furnishes monetary damages, including unreimbursed medical expenses, lost-employment income, and survivor death benefits to eligible individuals. 42 U.S.C. §§§247d-6e; **Countermeasures Injury Compensation Program**, Health Resour. & Svcs. Admin.Under the Declaration.

Secretary Azar triggered the PREP Act immunity protections in connection with COVID-19 when he issued the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, on March 10, 2020. *See generally* Declaration, *supra*. Since the issuance of the original Declaration, the HHS has published amendments to the Declaration and advisory guidance to both clarify and broaden the liability protections conferred by the Declaration. HHS is likely to continue issuing such advisory guidances and amendments in the future. PREP Act Advisory Op. on March 10, 2020 Declaration, Dept. Health & Human Svcs. (Apr. 14, 2014) (Advisory Opinion; COVID-19 Declaration Amendment, 85 Fed. Reg. 21,012 (Apr. 15, 2020).

The scope of immunity afforded by the Declaration is broad, but it is not absolute. The liability protection applies to conduct by a "covered person," engaged in qualified activities, related to a "covered countermeasure," within the operative time period. The Declaration insulates such qualifying conduct from claims of death, personal injury, and loss or damage to property, sounding in either tort or contract. 42 U.S.C. §§§247d-6d(a); Advisory Op., *supra*.

During the effective period of the Declaration, the immunity provisions preempt conflicting state laws, prohibiting any state or state political subdivision from establishing, enforcing, or continuing laws or legal requirements that are different from or conflict with any sections of the PREP Act Declaration. 42 U.S.C. §§§247d-6d(b)(8). The immunity conferred under the Declaration applies only to claims that are within the jurisdiction of the United States. Declaration, *supra*, at §§XI.

Covered Persons

The Declaration provides immunity from liability only from conduct by "covered persons." Accordingly, to evaluate whether an entity will be eligible for immunity, it is necessary to first determine whether the entity qualifies as a "covered person." The term "covered persons" includes manufacturers, distributors, program planners, qualified persons, and their officials, agents, and employees and the United States, as each of those terms is broadly defined by the PREP Act. 42 U.S.C. §§§247d-6d(i)(2).

In response to the crisis, manufacturers and innovators directed resources, and in some cases, they repurposed manufacturing operations entirely, to research, develop, and supply the products needed to counter and treat COVID-19. The Secretary's activation of the liability protections afforded by the PREP Act was intended to encourage and expediate these efforts, which may have otherwise been encumbered by the underlying threat of potential litigation.

Specifically, the term "manufacturer" includes a contractor or subcontractor of a manufacturer; 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 all parents, subsidiaries, affiliates, successors, and assigns of a manufacturer. 42 U.S.C. §§§247d-6d (i)(4).

These statutory requirements for covered countermeasures are complex as drafted and as such have proved challenging for entities to interpret. As a result, manufacturers and other entities have asked the HHS to clarify the products that might qualify as covered countermeasures.

The term "distributor" extends to persons and entities involved in the distribution of biologics, or devices, "including but not limited to: manufacturers; re-packers; 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." 42 U.S.C. §§§247d-6d(i)(3).

"Program planner" refers to those in administration and government roles responsible for dispensing covered countermeasures. Specifically, "program planner" means the following:

> 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 [Declaration].

42 U.S.C. §§§247d-6d(i)(6).

Finally, the term "qualified person," when used with respect to the administration or use of a covered countermeasure, means "a licensed health professional or other individual who is authorized to prescribe, administer, or dispense" covered countermeasures "under the law of the State in which the countermeasure was prescribed, administered, or dispensed." 42 U.S.C. §§§247d-6d(i)(8). The act includes a provision that permits an "authority having jurisdiction" to extend the application of this term as needed. Specifically, the act provides that "qualified person" may also include a person within a category of persons identified as qualified in the Secretary's Declaration. 42 U.S.C. §§§247d-6d(i)(8)(B). In the context of COVID-19, the Declaration extended the scope of the term "qualified person" to include: "(a) [a]ny person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction… to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors, and volunteers, following a Declaration of an emergency[.]" Declaration, *supra*, at §§V. This expanded application of the term means, for example, that where the HHS issued guidance for licensed pharmacists allowing them to order and administer COVID-19 tests that the FDA authorized, such licensed pharmacists are "qualified persons" subject to the immunity provisions of the act. Advisory Op, *supra*, at 6.

Recommended Activities

Immunity from liability is afforded to covered persons only for "recommended activities." Declaration, *supra*, at §§VII. Such activities include the manufacture, testing, development, distribution, administration, and use of a countermeasure. *Id.* at §§III. The Declaration provides that the recommended activity must be related to a contract, arrangement, or agreement with the federal government or be authorized in accordance with the public health and medical response of an "authority having jurisdiction" to respond to the emergency. *Id.* at §§VII. Advisory guidance suggests that the HHS interprets these conditions broadly to include "1) activities that relate to any arrangement with the federal government, or 2) any activity that is part of an authorized emergency response at the federal, regional or state level." Advisory Op., *supra*, at 2. Accordingly, a recommended activity may qualify for immunity if it is authorized through guidance, requests for assistance, agreements, or other arrangements. *See id.*

Covered Countermeasures

The Declaration confers immunity from claims only insofar as they are caused by, arise out of, relate to, or result from the administration or use of "covered countermeasures." Advisory Op., *supra*, at 1 (citing 42 U.S.C. §§247d-6d(a)(1). To qualify as a "covered countermeasure," a product must fulfill two requirements delineated in §§VI of the Declaration and the Amended Declaration. First, the product must be an antiviral, drug, biologic, diagnostic, device, or any vaccine used to prevent, diagnose, treat, cure, or mitigate COVID-19 or "any device used in the administration of any such product, and all components and constituent materials of any such product." Declaration, *supra*, at §§VI. Second, the product must fall within one of the following four categories: (1) "qualified pandemic or epidemic products"; (2) "security countermeasures"; (3) drugs, biological products, or devices authorized for investigational or emergency use; or (4) any respiratory protective device approved by the National Institute for Occupational Safety (NIOSH) under 42 C.F.R. part 84, or any successor regulations." *See id. See also* Medical Countermeasures Against COVID-19 Declaration Amendment, 85 Fed. Reg. 21,012 (Apr. 25, 2020).

These statutory requirements for covered countermeasures are complex as drafted

and, as such, have proved challenging for entities to interpret. As a result, manufacturers and other entities have asked the HHS to clarify the products that might qualify as covered countermeasures. *See* Advisory Op., *supra*. In response to these inquiries and requests for advisory opinions, the HHS issued an omnibus Advisory Opinion on April 14, 2020. *See* Advisory Op., *supra*; Declaration, *supra*, at §§VI. The Advisory Opinion clarifies that "covered countermeasures" include the following: (1) "Any drug, device, or biological product that is approved, cleared, or licensed by the FDA… used to diagnose, mitigate, prevent, treat, cure, or limit the harm of COVID-19"; (2) "respirators that may not be medical devices," that "are NIOSH approved and subject to an EUA [emergency use authorization]"; or 3) "[a]ny drug, device or biological product authorized for emergency use with respect to COVID-19 under an EUA, described in [an emergency use instruction, abbreviated as EUI] issued by the CDC, or being researched under certain investigational provisions (i.e., IND, IDE) to treat COVID-19." *See* Advisory Op., *supra*, at 2–3; Declaration, *supra*, at §§VI. In addition, the advisory guidance provides that the term also includes "any device used in the administration of a covered countermeasure, and all components and constituent materials of a such countermeasures." *Id.*

While the Advisory Opinion recognizes that the number of products used for COVID-19 and approved, licensed, or cleared for such use are too numerous to list, the guidance includes links to two non-exhaustive lists of EUAs issued for COVID-19. *Id*. at 4. *See also* U.S. Food & Drug Admin., **FDA Combating COVID-19 with Therapeutics** (June 15, 2020); U.S. Food & Drug Admin., **FDA Combating COVID-19 with Medical Devices** (June 26, 2020).

The EUAs that are included in these lists relate to certain personal protective equipment (PPE), sterilization equipment, diagnostic tests, ventilators, and therapeutic drugs, among other things. In accordance with the terms of the Declaration, the products that are authorized under these EUAs for COVID-19 are covered countermeasures.

Although it is impractical to itemize each product that may qualify as a covered countermeasure, the categories of products discussed below are of particular interest to manufacturers' efforts to address shortages of protective equipment and ventilators and to provide therapeutic options for COVID-19 patients.

Face Masks and Face Coverings

The Declaration expressly provides that NIOSH-approved facemasks are covered countermeasures. In addition, the FDA has issued blanket EUAs both for certain imported disposable filtering facepiece respirators (referred to as "FFRs," or respirators) that are not NIOSH approved and certain other face masks and face coverings used for "source control" for members of the public, including healthcare personnel (HCP). *See* U.S. Food & Drug Admin., **Emergency Use Authorization** Letter for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (Mar. 28, 2020);U.S. Food & Drug Admin., **Emergency Use Authorization** Letter for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Imported from China (Apr. 3, 2020);U.S. Food & Drug Admin., **Emergency Use Authorization** Letter for Face Masks (non-surgical) (Apr. 24, 2020). To the extent that a non-NIOSH-approved facemask falls within the scope of one of these EUAs, it may qualify as a covered countermeasure.

Face Shields

The FDA has also issued an EUA that broadly authorizes the use of certain categories of face shields "when they are intended for use by HCP as PPE in healthcare settings in accordance with CDC recommendations to cover the front and sides of the face and provide barrier protection and meet the other requirements delineated in the authorization." *See* U.S. Food & Drug Admin., **Emergency Use Authorization** Letter for Face Shields by HCP as PPE (Apr. 13, 2020). Face shields that meet the requirements set forth in the EUA may also constitute covered countermeasures.

Ventilators and Ventilator Parts and Accessories

In response to concerns relating to the insufficient availability of FDA-cleared ventilators, the FDA issued an EUA for certain ventilators, ventilator tubing connectors, and ventilator accessories for use in the healthcare setting to treat COVID-19 patients. See U.S. Food & Drug Admin., **Emergency Use Authorization** Letter for Authorized Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories (Mar. 24, 2020). Unlike the EUAs for face masks and face shields, which provide a general authorization for certain categories of products, the EUA for ventilators, ventilator parts, and accessories specifically identifies each product that has met the criteria for safety, performance, and labeling set forth in the EUA, as determined by the FDA; thus, this EUA only applies to products that have been specifically authorized and identified in the EUA. *Id*.

Component Parts

The Declaration expressly provides that immunity extends to "components and constituent materials" of covered countermeasures. Declaration, *supra*, at §§VI.

Off-Label Use

It is noteworthy that the Declaration does not expressly mention off-label use, and to date, there has been no case law addressing whether off-label use qualifies as a covered countermeasure. In the absence of any authority or guidance on whether an off-label use would qualify as a "covered countermeasure," without additional regulatory action, manufacturers should continue to be cautious in communications or promotions that relate to unapproved uses of pharmaceutical products and medical devices.

"Reasonable Belief" as It Applies to "Covered Person" or "Covered Countermeasure"

While the terms "covered persons" and "covered countermeasures" are defined by the PREP Act and the ensuing Declaration, the Advisory Opinion instructs that a strict liability standard will not be imposed on entities with respect to the application of these terms. *See* Advisory Op. *supra*. Specifically, the opinion provides that a person or entity that does not otherwise qualify as a covered person, as the term is defined under the Declaration, may still be entitled to immunity from liability as long as the person or entity otherwise meets the requirements for immunity

and "*reasonably could have believed*" that they are a covered person. *See id*. at 7. Similarly, the guidance states that even if a product is not a covered countermeasure, a covered person or entity that otherwise meets the requirements for immunity under the PREP Act will not lose immunity "if the person or entity *reasonably could have believed* that the product was a covered countermeasure." *See id*. at 4 (emphasis added).

The "willful misconduct" exception to the PREP Act provides perhaps the most likely avenue for future litigation and interpretation. Accordingly, manufacturers should take steps to reduce exposure and support the application of the immunity afforded under the act.

For example, if a covered person purchases counterfeit tests for COVID-19 or respirators that appear to be authorized under an EUA, and the person takes "reasonable steps" to substantiate the authenticity of the products, the Declaration would still afford immunity to the purchaser against a claim that arises out of the use of the counterfeit product. *See id*.

It is important to consider that the "reasonable belief" standard sponsored in the Advisory Opinion represents the views of the HHS Office of the General Counsel only and does not otherwise constitute a final agency action or final order, nor does it have the force or effect of law, and it does not bind the HHS or the federal courts. Accordingly, to the extent that the guidance denotes a broader application of the liability protections than the letter of the PREP Act and the Declaration provide, such application remains vulnerable to future challenges and opposing interpretations by the courts.

Limitations to Immunity Conferred by the Declaration

The terms of the PREP Act and advisory guidance expressly address some of the well-defined limits of the immunity protections invoked by the Declaration.

Types of Claims

As an initial matter, as explained above, the types of claims that qualify for immunity are limited. 42 U.S.C. §§§247d-6d(a); Advisory Op., *supra*, at 2. The Declaration does not provide immunity against criminal, civil, or administrative federal enforcement actions, nor does it confer immunity for claims under federal law for equitable relief. *Id*.

Willful Misconduct Exception

The sole exception to immunity expressly carved out by the PREP Act is for acts of "willful misconduct." 42 U.S.C. §§§247d-6d(c). "Willful misconduct" means an "act or omission" that is taken "(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) 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." *See* 42 U.S.C. §§§247d-6d(c)(1). To prevail in such a case, the burden is on the plaintiff to prove by "clear and convincing evidence" both willful misconduct by each covered entity and that such misconduct caused death or serious injury. 42 U.S.C. §§§247d-6d(c)(3). It is significant that a claim for "willful misconduct" can only be brought against a manufacturer or distributor with respect to a covered countermeasure that is subject to regulation under either the PREP Act or by the Federal Food, Drug, and Cosmetic Act (FD&C Act), if (1) the HHS Secretary or the U.S. Attorney General has initiated an enforcement action with respect to the alleged willful misconduct; or (2) if an enforcement action has been initiated and subsequently terminated, or finally resolved without a covered remedy. 42 U.S.C. §§§247d-6d(c).

The "willful misconduct" exception to the PREP Act provides perhaps the most likely avenue for future litigation and interpretation. Accordingly, manufacturers should take steps to reduce exposure and support the application of the immunity afforded under the act. Specifically, because the PREP Act does not relieve entities from their obligation to comply with FDA regulations and requirements imposed by the FD&C Act, manufacturers should continue to use best practices and pay careful attention to all regulatory obligations, including, but not limited to, those relating to record keeping, labeling, good manufacturing practices, promotion, and post-marketing surveillance and reporting. In this same vein, manufacturers of covered countermeasures should take care to document the precautions that they take in the design, development, testing and manufacture of covered products. As FDA guidance, regulatory requirements, authorizations, and approvals related to COVID-19 are rapidly shifting, entities need to continue to exercise vigilance in keeping abreast of regulatory developments. In addition, pursuant to the guidance issued by the HHS, entities should document the "reasonable precautions" that they have taken with respect to covered countermeasures. Advisory Op., *supra*, at 2.

Effective Time Period

The immunity provisions triggered under the Declaration became effective retroactively on February 4, 2020, and they are currently set to expire on October 1, 2024. The Declaration provides for an additional twelve months of liability protection at the conclusion of the effective period to allow manufacturers to arrange for the disposition of covered countermeasures, and to enable covered persons to "take such other actions as are appropriate to limit the administration or use of covered countermeasures." Declaration, *supra*, at §§XIII. Manufacturers should remain mindful of this effective period and forward-thinking in terms of tracking products to facilitate the destruction or return of products when the effective period expires. Any products that remain in circulation after the expiration of the Declaration are no longer protected by the immunity provisions of the PREP Act.

Guidance from the Courts

The scope and magnitude of the current COVID-19 pandemic is beyond any

that our nation has faced since the PREP Act has been in existence. Accordingly, although the recent advisory guidance suggests that the immunity afforded by the act would have very broad application, case law interpreting the scope of the act is limited. The only insight that we have from the courts is gathered from three cases involving vaccines developed in response to the H1N1 health crisis in 2009. *Parker v. St. Lawrence County Public Health Department*, 102 A.D.3d 140 (N.Y. App. Div. 2012); *Casabianca v. Mount Sinai Medical Center*, No. 112790/10, 2014 WL 10413521 (N.Y. Sup. Ct. 2014); *Kehler v. Hood*, No. 4:11-CV-1416-FRB, 2012 WL 1945952 (E.D. Mo. 2012). While one of these courts found that the PREP Act conferred immunity to a claim involving the administration of a vaccine, another held that a claim for negligent failure to administer a countermeasure did not qualify for immunity under the act. In the third case, it was undisputed that the PREP Act afforded immunity to a vaccine manufacturer against failure-to-warn claims.

Parker is a state court case that involved claims against a county health department, alleging that the department's nurse administered an H1N1 vaccination to a child without parental consent. 102 A.D.3d at 140. The department moved to dismiss the case on the grounds that the plaintiff's claims were expressly preempted by the liability protections afforded under the PREP Act. *Id.* at 142. The lower court denied the motion to dismiss, agreeing with the plaintiff's argument that PREP Act immunity did not extend to a situation in which an entity administered a drug without consent. *Id*. On appeal, the appellate court rejected the plaintiff's argument and found that the immunity provisions of the PREP Act applied to the administration of a covered countermeasure, even in the absence of consent. *Id*. at 144. The court held that the plaintiff's negligence and battery claims were, therefore, preempted, concluding:

> Considering the breadth of the preemption clause, together with the sweeping language of the statute's immunity provision, we conclude 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, including one based upon a defendant's failure to obtain consent.

Id. at 143–44.

It is notable that in its ruling, the *Parker* court considered the fact that there were alternative avenues by which the plaintiff could recover damages under the PREP Act, including through the Countermeasure Injury Compensation Program (CICP), or a federal cause of action for willful misconduct. *Id*. at 144. It is possible that other courts may similarly find that the existence of a no-fault avenue for plaintiffs to recover damages under the PREP Act, is a compelling balance that permits the broad application of immunity.

Casabianca was another state court matter. In this instance, the case involved claims against a hospital for injuries allegedly sustained as a result of the hospital's failure to administer an H1N1 vaccine. 2014 WL 10413521 (N.Y. Sup. Ct. 2014). The decedent and subject of the action did not receive the H1N1 vaccine because he did not fit into one of the designated categories of "eligible individuals," when the vaccine was in short supply. *Id.* at *1. The defendant asserted a motion to dismiss premised on the fact that the immunity provisions of the PREP Act preempted the proffered causes of action. The plaintiff countered that the protections afforded by the PREP Act did not apply where the covered countermeasure was not administered. *Id*. at *2.

The *Casabianca* court agreed with the plaintiff and held that the PREP Act was not applicable to a decision not to treat since the PREP Act applied only to claims "resulting from the administration to or the use by an individual of a covered countermeasure." The court reasoned that the term "administration" extended "only to physical provision of a countermeasure to a recipient." *Id.* at *3. In support of its decision, the court cited the declaration invoking the PREP Act in the context of H1N1, which provided that "administration" of covered countermeasures included "physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures." Pandemic Influenza Vaccines Amendment, 77 Fed. Reg. 13,329, §§IX (Mar. 6, 2012) ("Secretary's Declaration for H1N1). The court relied on the HHS Secretary's interpretation of the term "administration":

> "administration" extends only to *physical provision of a countermeasure to a recipient*, such as vaccination or handing drugs to patients, *and to activities related to management and operation of programs and locations for providing countermeasures to recipients*, such as decisions and actions involving security and queuing, *but only insofar as those activities directly relate to the countermeasure activities*.… Under the Secretary's definition, these *liability claims are precluded if the claims allege an injury caused by physical provision of a countermeasure to a recipient, or if the claims are directly due to conditions of delivery distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites*.

2014 WL 10413521, at *3 (quoting Secretary's Declaration for H1N1) (emphasis in original); **77 Fed. Reg. 13,329**, §§IX (Mar. 6, 2012).

The current Declaration uses the same definition of "administration" as the declaration for H1N1 that was the subject of *Casabianca*. Accordingly, if followed by other courts for COVID-19-related claims, *Casabianca* raises potential liability issues for healthcare workers and hospitals alike. Specifically, due to shortages and rationing of COVID-19 tests, therapeutics, and vaccines, healthcare workers and hospitals that are required to determine which patients receive countermeasures may not be immune from claims that they negligently failed to administer such countermeasures. It seems, however, that even accepting the HHS interpretation of "administration" relied on by the *Casabianca* court, there remains a tenable argument that the PREP Act's immunity provisions should be applied more broadly to include claims relating to failure to treat due to shortages in treatments, tests, or supplies. Such claims would arguably fall within the ambit of "activities

related to management and operation of programs and locations for providing countermeasures to recipients, such as *decisions and actions involving security and queuing*, but only insofar as those activities directly relate to the countermeasure activities." Secretary's Declaration for H1N1, 77 Fed. Reg. 13,329, 13,333, §§IX (emphasis added)). In addition, an argument could also be made that the HHS interpretation of "administration" for the H1N1 declaration would not apply to the use of that term in the present Declaration.

In addition, it is compelling, that the PREP Act's broad immunity protections are balanced by both a no-fault mechanism for the payment of benefits when a covered countermeasure causes serious injury or death, and a procedure for pursuing damages for willful misconduct.

Kehler is the sole federal case to date that has provided any substantive discussion related to the PREP Act. The *Kehler* case involved claims against the prescribing physician and medical facility for negligent failure to obtain the plaintiff's informed consent before administering the H1N1 vaccine as well as third-party failure-to-warn claims against the vaccine manufacturer, Novartis Vaccines and Diagnostic, Inc. (Novartis). *Kehler v. Hood*, No. 4:11-CV-1416-FRB, 2012 WL 1945952 (E.D. Mo. 2012). The court dismissed the third-party claims against Novartis, holding that the manufacturer of the vaccine was "protected by the PREP Act and [was] absolutely immune from liability for any type of loss caused by the vaccine." *Id.* at *3. Further, the court found that there was no allegation that Novartis had engaged in willful misconduct "so as to bring its claim within the statute's only recognized exception to immunity." *Id.* The court remanded the claims against the doctor and the affiliated medical facility, finding that the plaintiffs' claims did not arise under federal law, but rather, raised state law claims of medical negligence. *Id.* at *4.

Concluding Considerations

Innovators, scientists, manufacturers, and healthcare workers are fighting a race against time in an attempt to bring the COVID-19 pandemic under control. As various strategies are used to counter the rapidly spreading illness, individuals from a wide range of industries and practices are researching, developing, building, and using products that will reach millions of people and undoubtedly save countless lives. Given the challenges that COVID-19 presents, however, in terms of transmission and exposure rates, medical complications, mortality, and evolving knowledge pertaining to treatment and mitigation of the illness, the possibility of adverse outcomes means that there will likely be litigation challenging the scope of the immunity afforded under the PREP Act.

There are multiple factors that support a broad application of the immunity provisions of the PREP Act. The PREP Act, and the Declaration invoking its protections as drafted, cast a broad net of liability protection with the intent of encouraging the rapid design, development, manufacture, and distribution of countermeasures to address the serious threat that the pandemic poses. Any decision that narrows the application of the immunity will necessarily affect the willingness of developers and manufacturers to participate in this expedited process. The Advisory Opinion, although not controlling, is certainly persuasive authority that supports a broad application of the act.

In addition, it is compelling, that the PREP Act's broad immunity protections are balanced by both a no-fault mechanism for the payment of benefits when a covered countermeasure causes serious injury or death, and a procedure for pursuing damages for willful misconduct. With that said, the case law interpreting the PREP Act's liability protections to date is extremely limited, and importantly, as yet, it has not substantively addressed the scope or application of the terms "covered person," "covered countermeasure," or "willful misconduct."

Finally, we know that innovation comes in many forms that potentially were not foreseen by the drafters of the PREP Act or the Declaration. Accordingly, as individuals and entities seek to address and contain this pandemic, there may be additional amendments, advisory guidance, and clarification relating to scope and application of the PREP Act and the Declaration. We encourage readers to keep abreast of this information.