The PREP Act: Defending Product Liability and Professional Liability Litigation Involving COVID-19 Countermeasures

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THE COVID-19 pandemic has raised numerous questions about liability exposure. As companies have raced to create products to combat COVID-19 (from vaccines to ventilators), and health care providers have likewise raced to care for and treat patients with and without these products, litigation risk for companies and providers is a critical topic.

The first and often foremost defense in the United States for any such potential litigation is the Public Readiness and Emergency Preparedness Act (the "PREP Act").[1] The PREP Act, enacted in 2005, provides broad immunity for manufacturers, distributors, and providers in lawsuits involving pandemic countermeasures after a declaration of a public health emergency. Thus, an understanding

[1] 42 U.S.C. §§ 247d-6d and 6e.

of the PREP Act is crucial in both assessing litigation risk and defending any litigation that may be filed. This article will provide an in-depth examination of the PREP Act in order to assist with both goals.

In order to understand the PREP Act, it is important to first provide the groundwork for the PREP Act by exploring its two key terms and those terms in the context of broader Food & Drug Administration ("FDA") law – which is the subject of the first part of this article. With this groundwork in place, the second part of this article will address the scope of PREP Act immunity, the sole enumerated exception to that immunity (for willful misconduct), and the compensation fund established by the PREP Act. With this foundation now in place, the third part of this article will address how the PREP Act specifically relates to the COVID-19 pandemic. This will involve a review of the COVID-19 PREP Act declaration of a public health emergency (the "Declaration"),[2] the various amendments to the Declaration,[3] and the advisory opinions on the Declaration and its

[2] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198-01 (March 17, 2020) ("*Declaration*").

[3] Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 21,012-02 (Apr. 10, 2020, published Apr. 15, 2020) ("*First Amendment*"); Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 35,100-01 (June 4, 2020, published June 8, 2020) ("*Second Amendment*"); Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 52,136-01 (Aug. 19, 2020, published Aug. 24, 2020) ("*Third Amendment*"); Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79,190-01 (Dec. 3, 2020, published 9, 2020) ("*Fourth Amendment*"); Fifth Amendment to Declaration Under the Public

amendments.[4] The final part of this article will review court decisions to date on the PREP Act.

I. Overview of the PREP Act and its Key Terms

To summarize the PREP Act in one sentence, the PREP Act provides a "covered person" nearly complete immunity from liability as to all claims "from the administration to or the use by an individual of a covered countermeasure," when there has been a declaration of a public health emergency.[5]

This summary demonstrates that there are two key definitions necessary to understand the nature and scope of the PREP Act, i.e., (i) a covered countermeasure and (ii) a covered person. In order to address the first definition, of a covered countermeasure, a brief overview of drug and device law is necessary.

A. Overview of FDA Law and Product Categories

Among other products, the FDA regulates drugs, biologics, and devices. A drug is a substance "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease."[6] Typically,

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Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 78,72-02 (Jan. 28, 2021, published Feb. 2, 2021) ("*Fifth Amendment*"); Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 9,516-01 (Feb. 11, 2021, published Feb. 16, 2021) ("*Sixth Amendment*"); Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 14,462-02 (Mar. 11, 2021, published Mar. 16, 2021) ("*Seventh Amendment*").

[4] Advisory Opinion on the PREP Act Declaration (Apr. 17, 2020, as modified on May 19, 2020) ("*First Advisory Opinion*"); Advisory Opinion 20-02 on the PREP Act Declaration (May 19, 2020) ("*Second Advisory Opinion*); Advisory Opinion 20-03 on the PREP Act Declaration (Oct. 23, 2020) ("*Third Advisory Opinion*"); Advisory Opinion 20-04 on the PREP Act Declaration (Oct. 23, 2020) ("*Fourth Advisory Opinion*") ; Advisory Opinion 21-01 on the PREP Act Declaration (Jan. 8, 2021) ("*Fifth Advisory Opinion*"); Advisory Opinion 21-02 on the PREP Act Declaration (Jan. 12, 2021) ("*Sixth Advisory Opinion*"). These advisory opinions are available at https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx (last visited on Apr. 5, 2021).

[5] 42 U.S.C. § 247d-6d(a)(1); *see also* Dupervil v. All. Health Operations, LCC, No. 20CV4042PKCPK, 2021 WL 355137, at *7 (E.D.N.Y. Feb. 2, 2021) ("In sum, the PREP Act … provides covered persons with immunity from suit for all claims of loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of covered countermeasures, which include certain drugs, biological products, and devices.").

[6] 21 U.S.C.A. § 321(g)(1); *accord* https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms (last visited on Mar. 23, 2021).

in order for a drug to be approved by the FDA, it must first go through an extensive investigational phase and then a rigorous review by the FDA.[7]

A biologic is very similar to a drug, except that a biologic is manufactured by a biological process, while a drug is manufactured by a chemical process.[8] Biologics include, for example, vaccines or blood derivatives that are used for "the prevention, treatment, or cure of a disease."[9] A biologic is licensed by the FDA after going through a similar process to the approval process for new drugs.[10]

A device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article … intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."[11] Depending upon the type of device, the device is either approved or cleared by the FDA.[12]

Thus, the FDA approves, licenses, and/or clears products to be used to cure, mitigate, prevent, or treat diseases. This FDA process is often lengthy and expensive.[13]

However, the FDA also has Emergency Use Authorization ("EUA") authority, which provides it with the ability to authorize drugs, biologics, and devices to combat a public health emergency when the Secretary of Health and Human Services (the "Secretary") declares a public health emergency.[14] The FDA can authorize products under its EUA authority that are either completely unapproved or that are already approved for other uses, but not for the use for which it is being authorized.[15]

B. Defining a Covered Countermeasure

With this short background on FDA law, we may examine the first of the two key terms of the PREP Act, a "covered countermeasure." In a nutshell, a covered countermeasure is a drug, biologic, or device that has been approved, licensed, cleared, in its investigation phase, and/or authorized by the FDA intended to combat a pandemic.[16]

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[7] 21 U.S.C. § 351, et seq.

[8] *See* https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms (last visited on Mar. 23, 2021).

[9] 42 U.S.C. § 262(i)(1).

[10] *E.g.*, 42 U.S.C. § 262.

[11] 21 U.S.C. § 321(h)(1)(B).

[12] *E.g.*, 21 U.S.C. § 360c; *see also* Riegel v. Medtronic, Inc., 552 U.S. 312, 316-317 (2008) (providing an overview of medical device regulatory law).

[13] *See, e.g.*, A PRACTICAL GUIDE TO FDA'S FOOD AND DRUG LAW AND REGULATION (Kenneth R. Pina & Wayne L. Pines, eds., 5th ed. 2014).

[14] 21 U.S.C. § 360bbb-3.

[15] 21 U.S.C. § 360bbb-3(a)(2).

[16] 42 U.S.C. § 247d-6d(i)(1) and (7).

Specifically, often using redundant language, the PREP Act defines a covered countermeasure as either a "qualified pandemic or epidemic product," a drug, biological, or device that is authorized under the FDA's EUA authority, or a National Institute for Occupational Safety and Health ("NIOSH") approved respiratory device.[17] A "qualified pandemic or epidemic product," in turn, is a drug, biological, or device that is used to diagnose, mitigate, prevent, treat, limit the harm, or cure a pandemic or epidemic.[18] It can also be a product used to prevent or mitigate the harm from a drug, biologic, or device combating the pandemic, or to enhance the benefits of such drugs, biologics, or devices.[19] However, in order to be a "qualified pandemic or epidemic product," the product must also be either (i) an FDA approved, cleared, or licensed product, (ii) a product that is going through the FDA investigational stage, or (iii) a product "authorized for emergency use" under the FDA's EUA authority.[20]

As the Office of General Counsel conveniently summed it up, for a product to be a qualified pandemic or epidemic product and fall under the PREP Act as to COVID-19, it:

> (1) must be used for COVID-19; and
> (2) must be
> (a) approved, licensed, or cleared by FDA;
> (b) authorized under an EUA;
> (c) described in an EUI [Emergency Use Instructions]; or
> (d) used under either an Investigational New Drug (IND) application or an Investigational Device Exemption (IDE).[21]

C. Defining a Covered Person

The second key term in the PREP Act is for a "covered person." The PREP Act broadly defines covered persons, which in short are the entities and people protected by the PREP Act. Covered persons largely fall into three broad

[17] 42 U.S.C. § 247d-6d(i)(1). The definition also includes drugs, biologics, or devices that fall within the definition of a security countermeasure if there has been a biological, chemical, or nuclear attack, *id.*; 42 U.S.C. § 247d-6b(Cc)(1)(B), which fortunately is not pertinent to the COVID-19 pandemic.

[18] 42 U.S.C. § 247d-6d(i)(7)(A)(i).

[19] 42 U.S.C. § 247d-6d(i)(7)(A)(ii) and (iii).

[20] 42 U.S.C. § 247d-6d(i)(7)(B).

[21] *First Advisory Opinion* at 4.

categories, (i) manufacturers and distributors of covered countermeasures, (ii) providers (termed as "a qualified person") who prescribe, administer, or dispense covered countermeasures, and (iii) governmental and similar entities (termed as a "program planner") who supervise or administer a program with respect to the administration or use of covered countermeasures.[22] This article will primarily focus on the first two categories.

The definition of a "manufacturer" includes contractors, subcontractors, suppliers, parents, subsidiaries, employees, and agents.[23] Similarly, the definition of a distributor means any person or entity engaged in distribution (as well as their employees), which includes everything from air carriers to retail pharmacies.[24]

The PREP Act's use of the term "qualified person" refers to either (i) "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 (ii) any other person identified in the declaration of a public health emergency that invokes the PREP Act.[25]

II. The Heart of the PREP Act – The Scope of Immunity, the Willful Misconduct Exception, and the Process Fund

The immunity conferred by the PREP Act is extraordinarily broad, but it is not without its limits. This section will first address the scope and limits of immunity under the PREP Act. Then, it will address the sole exception to immunity, willful misconduct. Finally, it will discuss the Covered Countermeasure Process Fund (the "Fund").

A. The Scope and Limits of Immunity

PREP Act immunity for a covered person applies "to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure."[26] With regards to causality, all that is required under the PREP Act is that the claim for loss "has a causal relationship with the administration to or use by an

[22] 42 U.S.C. § 247d-6d(i)(2) and (i)(6). This has been interpreted to include "private businesses, public and private transportation providers, public and private schools, and religious organizations" if they are supervising or administering a program that is administering or using a covered countermeasure. *Fourth Advisory Opinion* at 3.

[23] 42 U.S.C. § 247d-6d(i)(4).

[24] 42 U.S.C. § 247d-6d(i)(3).

[25] 42 U.S.C. § 247d-6d(i)(8).

[26] 42 U.S.C. § 247d-6d(a)(1).

individual of a covered countermeasure."[27]

A claim for loss, includes death, injury or illness, fear of injury or illness, and loss of or damage to property including business interruption.[28] There is "a rebut-able presumption that any administration or use … of a covered countermeasure shall have been for the category or categories of diseases" covered by a declaration, such as COVID-19.[29] The PREP Act also expressly preempts state law.[30]

By way of example of the breadth of the scope of immunity, in the Declaration, the Secretary stated

> that the PREP Act even precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control.[31]

However, immunity only applies if the countermeasure was administered or used during the effective period of the declaration.[32] Further, immunity only applies if the countermeasures "was administered or used for the category of diseases" in the declaration,[33] e.g., COVID-19. And, immunity can be limited by the means of distribution as specified in the declaration.[34]

B. The Willful Misconduct Exception

The "sole exception to the immunity" afforded by the PREP Act is for willful misconduct.[35] The PREP Act sets a very high bar for proving willful misconduct, and it sets out a number of procedural hurdles for such claims. Each issue is addressed in turn.

The willful misconduct exception only applies to claims for "wrongful death or serious physical injury."[36] The latter means an injury that is life threatening, results in permanent impairment of a body function, permanent damage to a body structure, or necessitates

[27] 42 U.S.C. § 247d-6d(a)(2)(B).
[28] 42 U.S.C. § 247d-6d(a)(2)(A).
[29] 42 U.S.C. § 247d-6d(a)(6).
[30] 42 U.S.C. § 247d-6d(b)(8).
[31] *Declaration*, 85 Fed. Reg. 15198-01 at 15,200.
[32] 42 U.S.C. § 247d-6d(a)(3)(A).
[33] 42 U.S.C. § 247d-6d(a)(3)(B).
[34] 42 U.S.C. § 247d-6d(a)(5).
[35] 42 U.S.C. § 247d-6d(d).
[36] 42 U.S.C. § 247d-6d(d)(2).

medical or surgical impairment to prevent such permanent impairment or damage.[37]

Willful misconduct is generally defined as "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."[38] The PREP Act explicitly states that willful misconduct is more stringent of a standard than negligence or recklessness.[39] Courts have not yet interpreted the definition and meaning of willful misconduct under the PREP Act.

With regard to manufacturers and distributors, the willful misconduct standard cannot be met unless there has also been a successful enforcement action by the Attorney General or FDA against the manufacturer or distributor.[40] Neither a mandatory recall nor a revocation of an EUA, alone, is sufficient to meet this rigorous requirement.[41]

If a plaintiff brings an action for willful misconduct, the exclusive jurisdiction is in the United States District Court for the District of Columbia.[42] The case is to be heard by a three-judge panel for all dispositive motions.[43] Before bringing an action, the plaintiff must first exhaust the remedies set forth in the Fund, addressed below.[44] And, if the plaintiff is entitled to compensation under the Fund, he or she must elect not to accept such compensation.[45]

A complaint for willful misconduct must be pleaded with particularity, be verified by the plaintiff, include medical records, and have an affidavit from a non-treating physician regarding causation.[46] Discovery is prohibited before a ruling on a motion to dismiss, and is curtailed even if the motion to dismiss is denied.[47] The plaintiff must prove willful misconduct by "clear and convincing evidence" and that such willful misconduct "caused death or serious physical injury."[48] And, should the plaintiff prevail, damages are reduced by collateral sources and noneconomic damages are limited.[49]

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[37] 42 U.S.C. § 247d-6d(i)(10).
[38] 42 U.S.C. § 247d-6d(c)(1)(A).
[39] 42 U.S.C. § 247d-6d(c)(1)(B).
[40] 42 U.S.C. § 247d-6d(c)(5).
[41] 42 U.S.C. § 247d-6d(c)(5)(B)(i) and (c)(5)(C)(ii).
[42] 42 U.S.C. § 247d-6d(e)(1).
[43] 42 U.S.C. § 247d-6d(e)(5).
[44] 42 U.S.C. § 247d-6e(d)(1).
[45] 42 U.S.C. § 247d-6e(d)(5).
[46] 42 U.S.C. § 247d-6d(e)(4).
[47] 42 U.S.C. § 247d-6d(e)(6).
[48] 42 U.S.C. § 247d-6d(c)(3).
[49] 42 U.S.C. § 247d-6d(e)(7) and (8).

C. The Covered Countermeasure Process Fund

As the PREP Act largely precludes tort remedies, it has created an administrative remedy for those injured by covered countermeasures. The PREP Act establishes "an emergency fund designated as the 'Covered Countermeasure Process Fund' for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure."[50] This is the exclusive remedy, except for a lawsuit under the willful misconduct standard addressed above.[51]

The compensation system for the Fund is generally based upon the compensation system for the Smallpox Emergency Personnel Protection Act,[52] and includes certain medical benefits,[53] compensation for lost employment income,[54] and a payment for death.[55] However, certain compensation is greater under the Fund than the Smallpox Emergency Personnel Protection Act.[56]

Although the PREP Act as applied to COVID-19 has been expanded to all routine childhood vaccinations, as discussed below, this expansion should not "be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program."[57] Compensation under the PREP Act is proper "only to the extent that injury compensation is not provided under that Program."[58]

Since its inception in 2010, as of April 1, 2021, the Fund has received a total of 701 claims for all of the various public health emergencies. 452 of those claims were ineligible for compensation, 210 of those claims are currently in the medical review process, and 39 of those claims were eligible for compensation. Of the 39 claims eligible for compensation, 10 of the claims did not have any compensable expenses or losses. Of the remaining 29 claims, the Department of Health & Human Services has paid out more than $6 million.[59]

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[50] 42 U.S.C. § 247d-6e(a). *See also* 42 C.F.R. § 110.1, *et seq*.; *First Advisory Opinion* at 8.
[51] 42 U.S.C. § 247d-6e(d)(4).
[52] 42 U.S.C. §§ 239, et seq. and 247d-6e(b)(2).
[53] 42 U.S.C. §§ 239c and 247d-6e(b)(2). *See also* 42 C.F.R. § 110.80.
[54] 42 U.S.C. §§ 239d and 247d-6e(b)(2). *See also* 42 C.F.R. § 110.81.
[55] 42 U.S.C. §§ 239e and 247d-6e(b)(2). *See also* 42 C.F.R. § 110.82.
[56] 42 U.S.C. § 247d-6e(b)(2) and (b)(3).
[57] *Third Amendment*, 85 Fed. Reg. 52,136-01 at 52,140.
[58] *Id.*
[59] https://www.hrsa.gov/cicp/cicp-data (last visited on Apr. 5, 2021).

The Fund only applies to those who suffered serious physical injury or death.[60] It only applies to those to whom the administration or use of the covered countermeasure falls within the Secretary's declaration of public health emergency.[61] This naturally leads to the discussion of the scope of the Declaration as to COVID-19, which is the subject of the next section of this article.

III. Overview of the Declaration, Subsequent Amendments, and Advisory Opinions

It is now appropriate to turn to the Declaration regarding COVID-19. After all, the PREP Act only applies if there has been a declaration of a public health emergency by the Secretary through publication in the Federal Register.[62]

The Declaration was made on March 10, 2020,[63] and this Declaration has been amended seven times since that date.[64] Both the Trump Administration and the Biden Administration have made amendments, and every amendment has expanded the protection provided under the PREP Act. This is not surprising, as the PREP Act itself states that an amendment cannot "retroactively limit the applicability of subsection (a) [i.e., the liability protections of the PREP Act] with respect to the administration or use of the covered countermeasure involved."[65] Of the various amendments, the fourth amendment contains the most changes, and it was significant enough to warrant a full restatement of the Declaration.[66]

As of April 1, 2021, the Office of the General Counsel has issued six advisory opinions on the PREP Act, the Declaration, and the amendments to the Declaration.[67] These advisory opinions are important, especially due to the fact that the Fourth Amendment to the Declaration stated that the Declaration "must be construed in accordance with the Advisory

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[60] 42 U.S.C. § 247d-6e(e)(3).
[61] 42 U.S.C. § 247d-6e(e)(2).
[62] 42 U.S.C. § 247d-6d(a)(1) and (b)(1).
[63] *Declaration*, 85 Fed. Reg. 15,198-01. The Declaration was made on March 10, 2020, but was published in the Federal Register on March 17, 2020. Accordingly, some sources refer to this as the March 10, 2020 Declaration while others refer to it as the March 17, 2020 Declaration. This article will refer to the date of the Declaration and subsequent amendments, as opposed to the publication date.
[64] *First Amendment*, 85 Fed. Reg. 21,012-02; *Second Amendment,* 85 Fed. Reg. 35,100-01; *Third Amendment,* 85 Fed. Reg. 52,136-01; *Fourth Amendment*, 85 Fed. Reg. 79,190-01; *Fifth Amendment*, 86 Fed. Reg. 7,872-02; *Sixth Amendment*, 86 Fed. Reg. 9,516-01; *Seventh Amendment*, 86 Fed. Reg. 14,462-02; *see also* 42 U.S.C. § 247d-6d(b)(4) (providing the statutory basis for amendments).
[65] 42 U.S.C. § 247d-6d(b)(4).
[66] *Fourth Amendment*, 85 Fed. Reg. 79,190-01.
[67] *First Advisory Opinion; Second Advisory Opinion; Third Advisory Opinion; Fourth Advisory Opinion; Fifth Advisory Opinion; Sixth Advisory Opinion*, *supra* note 4.

Opinions of the Office of the General Counsel," and those advisory opinions are "incorporate[d]" into the Declaration.[68] Nevertheless, the advisory opinions still continue to state that they are not final agency action and do not have the force or effect of law.[69]

This section will address key portions of the Declaration, the amendments, and the advisory opinions by examining the who, what, when, and where under the Declaration, the amendments, and the advisory opinions.

A. The Who – The Population and The Covered Persons

The population scope under the Declaration includes any person who uses or is administered the covered countermeasures.[70]

The Declaration originally included under "covered persons" the full list of regular covered persons under the PREP Act, and added any persons (including their agents, employees, contractors, and volunteers) authorized by the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, as well as any persons authorized under the FDA's EUA authority.[71] The first advisory opinion stated that as to covered persons,

> an entity or person that otherwise meets the requirements for PREP Act immunity will not lose that immunity—even if the entity or person is *not* a covered person—if that entity or person reasonably could have believed, under the current, emergent circumstances, that the person was a covered person.[72]

The definition of a covered person has been repeatedly expanded by subsequent amendments. In light of the COVID-19 pandemic causing a significant reduction in children's access to their routine childhood vaccines, the definition of covered persons was expanded in an amendment to include pharmacists providing the recommended childhood

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[68] *Fourth Amendment*, 85 Fed. Reg. 79,190-01 at 79,194-95. On a related note, the Fourth Amendment also incorporated authorizations issued by the Health and Human Services Office of the Assistant Secretary for Health.

[69] *E.g., Sixth Advisory Opinion* at 5.

[70] *Declaration*, 85 Fed. Reg. 15,198-01 at 15,203.

[71] *Declaration*, 85 Fed. Reg. 15,198-01 at 15,202-15,203 (citing 21 U.S.C. §§ 260bbb-3 and 260bbb-3a). The Declaration's definition of the Authority Having Jurisdiction is set forth in Section III.B., below.

[72] *First Advisory Opinion* at 7 (emphasis in original).

vaccinations for all diseases under certain guidelines.[73] And, the Declaration expanded its category of disease application to "not only COVID-19, … but also other diseases, health conditions, or threats that may have been caused by COVID-19, … including the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases."[74]

The definition of covered persons was further expanded to include healthcare personnel "using telehealth to order or administer" covered countermeasures.[75] Similarly, it was expanded for vaccinations to former health professionals whose licenses had expired within the last five years and health professionals licensed in different states.[76] The definition was also again expanded to include federal government employees, contractors, and volunteers who deliver, distribute, or dispense covered countermeasures.[77] And, any person who orders or administers an authorized COVID-19 vaccine falls under the PREP Act, regardless of whether the vaccine was ordered or administered to a person in a prioritized group.[78]

B. The What – The Scope of Covered Countermeasures and The Limitations on Distribution

This section reviews first the scope of covered countermeasures under the Declaration and its amendments and second the limitations on distribution under the Declaration and its amendments. The Declaration broadly defined covered countermeasures as:

> 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.[79]

The Declaration similarly broadly defined the administration of covered countermeasures.[80] This includes, by way of example, drugs

[73] *Third Amendment*, 85 Fed. Reg. 52,136-01.
[74] *Id.* at 52,141.
[75] *Fourth Amendment*, 85 Fed. Reg. 79,190-01 at 79,196.
[76] *Fifth Amendment*, 86 Fed. Reg. 7,872-02. This action also preempts state law to the contrary. *Id.* at 7,874.
[77] *Sixth Amendment*, 86 Fed. Reg. 9,516-01.
[78] *Sixth Advisory Opinion* at 2.
[79] *Declaration*, 85 Fed. Reg. 15,198-01 at 15,203.
[80] *Id*.

used to counteract COVID-19 vaccine reactions.[81]

Amendments have subsequently expanded these definitions. Respiratory protective devices approved by NIOSH have been added as a covered countermeasure.[82] The scope of covered countermeasures was further broadened to include products that "limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause."[83] As an amendment to the Declaration explained:

> [T]he COVID-19 pandemic has resulted in shortages of certain drugs and devices that the FDA has authorized. These drugs and devices may be used for COVID-19 and other health conditions. … Filling those shortages caused by COVID-19 reduces the strain on the American healthcare system by mitigating the escalation of adverse health conditions from COVID-19 and non-COVID-19 causes. And mitigating that escalation conserves limited healthcare resources—from personal protective equipment to healthcare providers—which are essential in the whole-of-Nation response to the COVID-19 pandemic.[84]

A subsequent amendment made explicit that there are situations where not administering a covered countermeasure can fall within the liability protections of the PREP Act.[85] The Amendment explained this as follows:

> For example, consider a situation where there is only one dose of a COVID-19 vaccine, and a person in a vulnerable population and a person in a less vulnerable population both request it from a healthcare professional. In that situation, the healthcare professional administers the one dose to the person who is more vulnerable to COVID-19. In that circumstance, the failure to administer the COVID-19 vaccine to the person in a less-vulnerable population "relat[es] to . . . the administration to" the

[81] *Third Advisory Opinion* at 7.
[82] *First Amendment*, 85 Fed. Reg. 21,012-02.
[83] *Second Amendment*, 85 Fed. Reg. 35,100-01 at 35,101.
[84] *Id.* at 35,101-35,102.
[85] *Fourth Amendment*, 85 Fed. Reg. 79,190-01 at 79,194 and 79,197.

> person in a vulnerable population.[86]

As such, an advisory opinion criticized court decisions such as *Lutz*, discussed below, which have held that "[t]here is simply no room to read [the PREP Act] as equally applicable to the non-administration or non-use of covered countermeasures."[87] The advisory opinion explained that the PREP Act extends immunity to anything "relating to" the administration of covered countermeasures. Thus, a covered person's "conscious decision not to use a covered countermeasure could relate to the administration of the countermeasure" providing for PREP Act immunity.[88] However, for example, "the failure to purchase any PPE … may not be sufficient to trigger the PREP Act."[89]

Also, the first advisory opinion explained that

> Congress did not intend to impose a strict liability standard on covered persons for determining whether a product is a covered countermeasure. Instead, we believe that a person or entity that otherwise meets the requirements for PREP Act immunity will not lose that immunity—even if the product is *not* a covered countermeasure—if that person or entity reasonably could have believed that the product was a covered countermeasure.[90]

The Declaration, however, was initially limited to distribution for covered countermeasures under either (i) broadly defined federal contracts or (ii) activities authorized in accordance with any Authority Having Jurisdiction as to the covered countermeasure.[91] With regards to the latter basis, there must also be a declaration of emergency that would indicate an immediate need to administer and use the covered countermeasure.[92] And, an Authority Having Jurisdiction is defined as "the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, state, or federal boundary lines) or functional (e.g.,

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[86] *Fourth Amendment*, 85 Fed. Reg. 79,190-01 at 79,197 (footnote omitted).
[87] *Fifth Advisory Opinion* at 4 (quoting *Lutz v. Big Blue Healthcare, Inc.*, 480 F. Supp.3d 1207, 1218 (D. Kan. 2020)) (alterations in original).
[88] *Fifth Advisory Opinion* at 4.
[89] *Id.*
[90] *First Advisory Opinion* at 4 (emphasis in original).
[91] *Declaration*, 85 Fed. Reg. 15,198-01 at 15,203.
[92] *Id*. The language of the Declaration itself is unclear on the extent that an EUA authorization falls within this definition.

law enforcement, public health) range or sphere of authority."[93] Public health guidance from an Authority Having Jurisdiction on covered countermeasures likely qualifies under the particular means of distribution as conferring PREP Act immunity if the covered person follows that public health guidance.[94]

Covered distribution channels have since been expanded to include private distribution channels as well.[95]

C. The When – The Effective Time Period

The effective date of the Declaration was February 4, 2020.[96] The time period for covered countermeasures under federal contracts extends to October 1, 2024, and the time period for covered countermeasures falling under the Authority Having Jurisdiction or private distribution channels lasts the length of the emergency declaration or October 1, 2024, which occurs first.[97] After the expiration of time, "an additional 12 months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, … and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures."[98]

D. The Where – The Geographic Area

The Declaration applies nationwide. The Declaration explains that "[l]iability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation."[99]

This geographic section of the Declaration was expanded in a subsequent amendment, and clarified in an advisory opinion, in light of multiple federal court decisions remanding COVID-19 PREP Act cases back to state court. As the amendment explained, "COVID-19 is a global challenge that requires a whole-of-nation response. There are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable* …, in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities."[100]

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[93] *Id*.
[94] *Fourth Advisory Opinion* at 4.
[95] *Fourth Amendment*, 85 Fed. Reg. 79,190-01 at 79,194 and 79,196-79,197.
[96] *Declaration*, 85 Fed. Reg. 15,198-01 at 15,198.
[97] *Declaration*, 85 Fed. Reg. 15,198-01 at 15,203; *see also* 42 U.S.C. § 247d-6d(a)(6) (PREP Act involves the "administration or use during the effective period" of the emergency declaration).
[98] *Declaration*, 85 Fed. Reg. 15,198-01 at 15,203.
[99] *Id*.
[100] *Fourth Amendment*, 85 Fed. Reg. 79,190-01 at 79,197.

By way of background, the *Grable* decision provides that even if only state law claims are pleaded, "in certain cases federal-question jurisdiction will lie over state-law claims that implicate significant federal issues."[101] To emphasize the point, the Fourth Amendment to the Declaration by the Secretary explained that "Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declarations,"[102] adding a footnote reminder that under the PREP Act, "[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection."[103]

In an advisory opinion, the Office of General Counsel also explained that the PREP Act expressly preempts state law. While the defense of "ordinary preemption" is not a basis for federal question jurisdiction supporting removal to federal court, "complete preemption" is a basis for federal question jurisdiction.[104] The advisory opinion stated that complete preemption occurs when a federal statute either establishes a federal cause of action as the only viable claim or vests exclusive jurisdiction in a federal court, and the "PREP Act does both."[105] The advisory opinion counsels federal courts to retain any PREP Act case removed to it, and first

> decide whether the immunity and preemption provisions apply; if they do not apply, then the court would try the case as it would a diversity case. If the court finds, though, that the PREP Act applies, it would dismiss the case or if death or serious physical injury proximately caused by willful misconduct is alleged, transfer it to the District Court for the District of Columbia.[106]

IV. Case Law under the PREP Act

Although the PREP Act was enacted in 2005, and there have been numerous declarations under the PREP Act,[107] there is a relative

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[101] Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg., 545 U.S. 308, 312 (2005).
[102] *Fourth Amendment*, 85 Fed. Reg. 79,190-01 at 79,198.
[103] *Fourth Amendment*, 85 Fed. Reg. 79,190-01 at 79,198 n. 25 (quoting 42 U.S.C. § 247d-6d(b)(7)).
[104] *Fifth Advisory Opinion* at 1-2.
[105] *Fifth Advisory Opinion* at 2.
[106] *Fifth Advisory Opinion* at 4-5.
[107] *Declaration*, 85 Fed. Reg. 15,198-01 (March 10, 2020) (COVID-19); Declaration Under the Public Readiness and Emergency Preparedness Act, 82 Fed. Reg. 21,819-01 (May 10, 2017) (organophosphorus poisoning and carbamate poisoning);

dearth of publicly available case law addressing the PREP Act. The vast majority of the PREP Act decisions as of early 2021 are wrongful death lawsuits against nursing homes or assisted living facilities ("facilities") when a patient allegedly contracted and succumbed to COVID-19 while at the facility. These decisions are collected in the footnote.[108]

Declaration Under the Public Readiness and Emergency Preparedness Act for Zika Virus Vaccines, 82 Fed. Reg. 10,365-01 (Feb. 10, 2017) (Zika virus); Declaration Under the Public Readiness and Emergency Preparedness Act, 80 Fed. Reg. 22,534-01 (Apr. 22, 2015) (Ebola therapeutics); Declaration Under the Public Readiness and Emergency Preparedness Act, 79 Fed. Reg. 73,314-01 (Dec. 10, 2014) (Ebola vaccines); Declaration Under the Public Readiness and Emergency Preparedness Act, 74 Fed. Reg. 50,968-03 (Oct. 2, 2009) (H1N1 influenza); Declaration Under the Public Readiness and Emergency Preparedness Act, 73 Fed. Reg. 78,362-01 (Dec. 22, 2008) (avian influenza); Declaration Under the Public Readiness and Emergency Preparedness Act, 73 Fed. Reg. 61,861-04 (Oct. 17, 2008) (avian influenza); Declaration Under the Public Readiness and Emergency Preparedness Act, 73 Fed. Reg. 61,864-01 (Oct. 17, 2008) (botulism); Declaration Under the Public Readiness and Emergency Preparedness Act, 73 Fed. Reg. 61,866-01 (Oct. 17, 2008) (acute radiation syndrome); Declaration Under the Public Readiness and Emergency Preparedness Act, 73 Fed. Reg. 61,869-01 (Oct. 17, 2008) (smallpox); Declaration Under the Public Readiness and Emergency Preparedness Act, 73 Fed. Reg. 58,239-01 (Oct. 1, 2008) (anthrax); Pandemic Countermeasures; Declaration Under the Public Readiness and Emergency Preparedness Act, 72 Fed. Reg. 4,710-02 (Jan. 26, 2007) (avian influenza).

[108] Schuster v. Percheron Healthcare, Inc., No. 4:21-CV-00156-P, 2021 WL 1222149 (N.D. Tex. Apr. 1, 2021); Cowan v. LP Columbia KY, LLC, No. 1:20-CV-00118-GNS, 2021 WL 1225965 (W.D. Ky. Mar. 31, 2021); Maltbia v. Big Blue Healthcare, Inc., No. 20-2607-DDC-KGG, 2021 WL 1196445 (D. Kan. Mar. 30, 2021); Gibbs v. Southeast SNF LLC, No. SA20CV01333JKPRBF, 2021 WL 1186626, (W.D. Tex. Mar. 30, 2021); Wright v. Encompass Health Rehabilitation Hospital of Columbia, Inc., No. CV 3:20-02636-MGL, 2021 WL 1177440 (D.S.C. Mar. 29, 2021); Ebony Stone v. Long Beach Healthcare Ctr., LLC, No. CV 21-326-JFW(PVCX), 2021 WL 1163572 (C.D. Cal. Mar. 26, 2021); Ivey v. Serrano Post Acute, LLC, No. CV2011773DSFSKX, 2021 WL 1139741 (C.D. Cal. Mar. 25, 2021); Martin v. Serrano Post Acute LLC, No. CV 21-187 DSF (SKX), 2021 WL 1146380 (C.D. Cal. Mar. 25, 2021); Lopez v. Life Care Centers of Am., Inc., No. CV 20-0958 JCH/LF, 2021 WL 1121034 (D.N.M. Mar. 24, 2021); Smith v. Colonial Care Ctr., Inc., No. 2:21-CV-00494-RGK-PD, 2021 WL 1087284 (C.D. Cal. Mar. 19, 2021); McCalebb v. AG Lynwood, LLC, No. 2:20-CV-09746-SB-PVC, 2021 WL 911951 (C.D. Cal. Mar. 1, 2021); Robertson v. Big Blue Healthcare, Inc., No. 220CV02561HLTTJJ, 2021 WL 764566 (D. Kan. Feb. 26, 2021); Saunders v. Big Blue Healthcare, Inc., No. 220CV02608HLTTJJ, 2021 WL 764567 (D. Kan. Feb. 26, 2021); Garcia v. Welltower OpCo Grp. LLC, No. SACV2002250JVSKESX, 2021 WL 492581 (C.D. Cal. Feb. 10, 2021); Lyons v. Cucumber Holdings, LLC, No. CV2010571JFWJPRX, 2021 WL 364640 (C.D. Cal. Feb. 3, 2021); *Dupervil*, 2021 WL 355137; Grohmann v. HCP Prairie Vill. KS Opco LLC, No. 20-2304-DDC-JPO, 2021 WL 308550 (D. Kan. Jan. 29, 2021); Goldblatt v. HCP Prairie Vill. KS OPCO LLC, No. 20-2489-DDC-KGG, 2021 WL 308158 (D. Kan. Jan. 29, 2021); Anson v. HCP Prairie Vill. KS OPCO LLC, No. 20-2346-DDC-JPO, 2021 WL 308156 (D. Kan. Jan. 29, 2021); Hatcher v. HCP Prairie Vill. KS OPCO LLC, No. 20-2374-SAC-JPO, 2021 WL 733326 (D. Kan. Jan. 27, 2021); Estate of Smith by & through Smith v. Bristol at Tampa Rehab. & Nursing Ctr., LLC, No. 8:20-CV-2798-T-60SPF, 2021

Of the remaining PREP Act cases, there is one against a vaccine manufacturer and a provider for an H1N1 vaccination (which interestingly is the only PREP Act case decision involving a manufacturer),[109] two against providers who either did or did not administer the H1N1 vaccination,[110] and one wage claim case during COVID-19 in which the PREP Act was asserted as a defense.[111]

The major two issues that arise in most of these cases are (i) whether the defendant is entitled to immunity under the PREP Act, and (ii) whether the defendant can remove the case under the PREP Act to federal court. These issues are often interrelated, as many courts have concluded that the lack of PREP Act immunity means that a facility cannot remove the case.[112] Each issue is addressed below.

A. Decisions on Immunity

On the issue of immunity, the only case involving a manufacturer will be addressed first. Second, this

WL 100376 (M.D. Fla. Jan. 12, 2021); Parker through Parker v. St. Jude Operating Co., LLC, No. 3:20-CV-01325-HZ, 2020 WL 8362407 (D. Or. Dec. 28, 2020); Gunter v. CCRC OPCO-Freedom Square, LLC, No. 8:20-CV-1546-T-36TGW, 2020 WL 8461513 (M.D. Fla. Oct. 29, 2020); Saldana v. Glenhaven Healthcare LLC, No. CV205631FMOMAAX, 2020 WL 6713995 (C.D. Cal. Oct. 14, 2020); Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC, No. 20CV1198, 2020 WL 6140474 (W.D. Pa. Oct. 16, 2020); Martin v. Serrano Post Acute LLC, No. CV 20-5937 DSF (SKX), 2020 WL 5422949 (C.D. Cal. Sept. 10, 2020); Fortune v. Big Blue Healthcare, Inc., No. 2:20-CV-2318-HLT-JPO, 2020 WL 4815097 (D. Kan. Aug. 19, 2020); Rodina v. Big Blue Healthcare, Inc., No. 2:20-CV-2319-HLT-JPO, 2020 WL 4815102 (D. Kan. Aug. 19, 2020); Lutz v. Big Blue Healthcare, Inc., 480 F. Supp.3d 1207 (D. Kan. Aug. 19, 2020); Campbell v. Big Blue Healthcare, Inc., No. 2:20-CV-2265-HLT-JPO, 2020 WL 4815082 (D. Kan. Aug. 19, 2020); Eaton v. Big Blue Healthcare, Inc., No. 2:20-CV-2291- HLT-JPO, 2020 WL 4815085 (D. Kan. Aug. 19, 2020); Long v. Big Blue Healthcare, Inc., No. 2:20-CV- 2263-HLT-JPO, 2020 WL 4815079 (D. Kan. Aug. 19, 2020); Jackson v. Big Blue Healthcare, Inc., No. 2:20-CV-2259-HLT-JPO, 2020 WL 4815099 (D. Kan. Aug. 19, 2020); Brown v. Big Blue Healthcare, Inc., No. 2:20-CV-2261-HLT-JPO, 2020 WL 4815078 (D. Kan. Aug. 19, 2020); Block v. Big Blue Healthcare, Inc., No. 2:20-CV-2262-HLT-JPO, 2020 WL 4815076 (D. Kan. Aug. 19, 2020); Baskin v. Big Blue Healthcare, Inc., No. 2:20-CV-2267-HLT-JPO, 2020 WL 4815074 (D. Kan. Aug. 19, 2020); Harris v. Big Blue Healthcare, Inc., No. 2:20-CV-2266-HLT-JPO, 2020 WL 4815098 (D. Kan. Aug. 19, 2020); Estate of Maglioli v. Andover Subacute Rehab. Ctr. I, 478 F. Supp.3d 518 (D. N.J. 2020). Most of the cases against HCP Prairie Village (in January 2021) and Big Blue Healthcare (in August 2020) were related cases in which the same judge issued nearly an identical opinion in each of multiple cases against the same defendant on the same day.

[109] Kehler v. Hood, No. 4:11CV1416 FRB, 2012 WL 1945952 (E.D. Mo. May 30, 2012).

[110] Parker v. St. Lawrence Cty. Pub. Health Dep't, 102 A.D.3d 140, 954 N.Y.S.2d 259 (N.Y. App. Div. 2012); Casabianca v. Mount Sinai Med. Ctr., Inc., 2014 NY Slip Op 33583(U), 2014 WL 10413521 (N.Y. Sup. Ct. Dec. 2, 2014).

[111] Haro v. Kaiser Found. Hosps., No. CV 20-6006-GW-JCX, 2020 WL 5291014 (C.D. Cal. Sept. 3, 2020).

[112] *See, e.g., Grohmann*, 2021 WL 308550; *Lutz*, 480 F. Supp.3d 1207.

section of this article will discuss the immunity decisions involving the H1N1 vaccine. Third, this section will review the immunity decisions involving facilities. Finally, this section will address the outlier case of a wage claim lawsuit and the PREP Act.

As of early 2021, the only decision under the PREP Act involving a manufacturer, *Kehler v. Hood*, involved the H1N1 vaccine. In *Kehler*, the plaintiff sued his doctor and her employer for failing to warn him of the increased risk he faced from an H1N1 vaccine.[113] The doctor and employer brought third party product liability claims against the vaccine manufacturer, who removed the case to federal court based upon federal officer removal statute.[114] As there was no dispute that the manufacturer fell under the PREP Act, and as there were no claims for willful misconduct, the federal court dismissed the claims against the manufacturer for lack of jurisdiction.[115] Having done so, the *Kehler* court granted the motion to remand by the plaintiff of the claims against the doctor and her employer, as the court found there was no federal question jurisdiction.[116]

There are two decisions involving the provision of the H1N1 vaccine that did not involve a manufacturer. In *Parker v. St. Lawrence*, the parents of a kindergartener who was vaccinated without their permission brought negligence and battery claims against the public health department who administered the vaccine.[117] The trial court granted the defendant's motion to dismiss based on the PREP Act, and the New York Appellate Division affirmed. The appellate court held "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."[118] On the other hand, a trial court in New York decided in *Casabianca* that the failure to give the H1N1 vaccine was not the administration of a covered countermeasure under the PREP Act because the vaccine was never given, so the PREP Act did not apply.[119] The Office of General Counsel has bluntly stated that this decision "was wrong."[120]

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[113] *Kehler*, 2012 WL 1945952, at *1–2.
[114] *Id.* In at footnote, the Court rejected without analysis the plaintiff's contention that this federal officer removal was improper. *Id.* at *3, n. 4.
[115] *Id.* at *2-3.
[116] *Id.* at *3-4.
[117] *Parker*, 102 A.D.3d 140, 954 N.Y.S.2d 259.
[118] *Id.* at 144.
[119] *Casabianca*, 2014 WL 10413521.
[120] *Fourth Advisory Opinion* at 7.

There have been a number of facility cases in which courts have considered whether the PREP Act bars the action. In *Garcia*, the court determined that plaintiff's allegations of insufficient PPE and insufficient training on PPE fell squarely within the PREP Act, and mandated dismissal of the facility.[121] However, multiple courts have reached the opposite conclusion, usually based upon the argument that the complaint alleges a lack of use of covered countermeasures.[122] In perhaps the most interesting analysis, the *Grohmann* court stated that while allocation determinations based upon scarcity fall within the PREP Act, this case did not allege that. Rather, as the *Grohmann* decision described, the case facts reflect "the difference between (1) robbing Peter *and* paying Paul, and (2) robbing Peter *to* pay Paul—or more precisely: not paying Peter in order to pay Paul."[123]

In a very different context from all other cases discussed in this article, a federal court found that minimum wage claims by employees of a health care provider are not preempted by the PREP Act, as the minimum wage claim was not causally connected to the health care provider's covered countermeasures.[124]

B. Decisions on Removal

One of the largest issues under the PREP Act is whether the Defendant can remove a case implicating the PREP Act to federal court. For product liability claims involving the PREP Act, in most cases the manufacturer or distributor will be able to remove the case under diversity jurisdiction. And, considering that the PREP Act covers telehealth,[125] there may be some provider cases that can also be removed under diversity jurisdiction.

However, for cases in which there is no diversity jurisdiction, there are three possible removal bases. First, there is substantial federal question under *Grable*. Both the Fourth Amended Declaration and an Advisory Opinion state that this is a proper basis for removal in cases implicating the PREP Act. [126] Nevertheless, several courts have rejected this as a basis for removal in the PREP Act facility cases.[127]

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[121] *Garcia*, 2021 WL 492581.

[122] *See e.g.*, *Dupervil*, 2021 WL 355137; *Grohmann*, 2021 WL 308550; *Hatcher*, 2021 WL 733326; *Sherod*, 2020 WL 6140474; *Lutz*, 480 F. Supp.3d 1207.

[123] *Grohmann*, 2021 WL 308550, at *10 (emphasis in original).

[124] *Haro*, 2020 WL 5291014.

[125] *Fourth Amendment*, 85 Fed. Reg. 79,190-01 at 79,196.

[126] *Fourth Amendment*, 85 Fed. Reg. 79,190-01 at 79,197; *Fifth Advisory Opinion* at 4-5.

[127] *Lyons*, 2021 WL 364640; *Dupervil*, 2021 WL 355137; *Saldana*, 2020 WL 6713995, at *3.

Second, there is complete preemption. The Office of General Counsel has opined that the PREP Act creates complete preemption,[128] and the *Garcia* decision is in accord.[129] However, other courts have reached the opposite result, though some of these decisions either predate the advisory opinion or do not reference it.[130]

Third, there is federal officer removal. The *Kehler* decision found this was a proper basis for removal for a vaccine manufacturer.[131] However, other courts have rejected this as to facilities.[132]

Even if a case is not removed, the defendant can still raise the defense of the PREP Act. After all, the only appellate case so far on the PREP Act involves a state court decision dismissing an action under the PREP Act.[133] And many courts have made it clear that their respective decisions on a motion for remand do not decide the applicability of the PREP Act, but rather only the propriety of the federal court hearing the case.[134]

V. Conclusion

The PREP Act creates a robust (and often complete) defense to lawsuits involving countermeasures to combat COVID-19. A careful review of the PREP Act, the Declaration and its amendments, and the case law interpreting the PREP Act is key to both (i) understanding liability risk and (ii) defending cases that may involve the PREP Act.

While the PREP Act largely speaks for itself, product liability risk can be lowered (or at least more accurately assessed) by confirming that products are considered covered countermeasures under the

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[128] *Fifth Advisory Opinion* at 2.
[129] *Garcia*, 2021 WL 492581.
[130] *Lyons*, 2021 WL 364640; *Dupervil*, 2021 WL 355137; *Estate of Smith*, 2021 WL 100376; *Parker*, 2020 WL 8362407.
[131] *Kehler*, 2012 WL 1945952, at *3 n. 4; *see also* Fields v. Brown, No. 6:20-CV-00475, 2021 WL 510620, at *2 (E.D. Tex. Feb. 11, 2021) (federal officer removal proper in a non-PREP Act COVID-19 case against a meat packing plant).
[132] *Lyons*, 2021 WL 364640; *Dupervil*, 2021 WL 355137; *Saldana*, 2020 WL 6713995, at *3.
[133] *Parker*, 102 A.D.3d 140, 954 N.Y.S.2d 259.
[134] *E.g., Estate of Maglioli*, 478 F. Supp.3d at 533; *Kehler*, 2012 WL 1945952, at *3-4.

PREP Act. While many COVID-19 diagnostic tests have been authorized by the FDA and are thus covered countermeasures, laboratory developed tests for COVID-19 that do not go through the authorization process may not be covered by the PREP Act.[135] Similarly, it behooves manufacturers to ensure that their EUA products are properly labeled to stay within the scope of the authorization.

Providers can reduce litigation risk by memorializing in medical records the use of covered countermeasures – and referring to them as such (or as pandemic products). Similarly, if a provider decides not to use a covered countermeasure, charting that decision may be helpful to demonstrate that the provider made a conscious decision not to use a covered countermeasure.[136]

From a litigation defense standpoint, raising the PREP Act immediately in any litigation is key. As the PREP Act provides the Secretary with broad powers regarding the declaration of a public health emergency, a careful review of the declaration, its amendments, and the advisory opinions are critical in demonstrating PREP Act immunity. The PREP Act should warrant the dismissal of most product liability and medical malpractice claims in the United States that involve covered countermeasures that combat COVID-19.

[135] https://www.hhs.gov/coronavirus/testing/recission-guidances-informal-issuances-premarket-review-lab-tests/index.html (last visited on Mar. 23, 2021).

[136] *See Fifth Advisory Opinion* at 4.