FEDERAL HEALTHCARE WORKER IMMUNITY PURSUANT TO COVID-19 PREP ACT DECLARATION

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I. INTRODUCTION

On March 10, 2020, the United States Secretary of Health and Humans Services ("HHS Secretary") issued a Declaration[1] for Medical Countermeasures Against COVID-19 (the "Declaration") pursuant to the Public Readiness and Emergency Preparedness Act (the "PREP Act") effective February 4, 2020.[2] Enacted in 2005, the PREP Act provides tort liability immunity to certain individuals and entities against any claim of loss during a pandemic or epidemic.[3] The United States has previously invoked the PREP Act in response to the Avian Flu outbreak, the H1N1 pandemic, and the Ebola Virus outbreak. In this instance, the HHS Secretary issued the Declaration to amend the PREP Act to assist the United States in its battle against COVID-19.

To date, thousands of lawsuits have been filed related to the COVID-19 pandemic, and over 100 have been filed in relation to medical or health services. The PREP Act will play a large role in many of those lawsuits. This article is intended to explain which individuals or entities qualify for PREP Act immunity, what actions are covered by PREP Act immunity, and the scope of immunity provided. It describes the procedural challenges a plaintiff who seeks to circumvent PREP Act immunity faces. Finally, it also outlines how a defendant can utilize the PREP Act's

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[1] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020), *amended by* 85 Fed. Reg. 21012 (Apr. 15, 2020), 85 Fed. Reg. 35100 (Jun. 8, 2020), 85 Fed. Reg 52136 (Aug. 24, 2020), 85 Fed. Reg. 79190 (Dec. 9, 2020), and 85 Fed. Reg. 7872 (February 2, 2021) (herein referred to as "the Declaration"). The Original Declaration was dated March 10, 2020, published in the Federal Register on March 17, 2020, and retroactively effective from February 4, 2020.

[2] Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C.A. §§ 247d-6d, 247d-6e (West 2020).

[3] 85 Fed. Reg. at 15198.

statutory framework in defending against COVID-19 related lawsuits, including motions to be filed, defenses to be raised, and necessary discovery needed to support immunity.

II. THE PREP ACT

The PREP Act authorizes the Secretary of HHS to provide targeted civil immunity to individuals and businesses during a declared public health emergency. It is just one component of the national emergency response framework, and more specifically the Public Health Service Act.[4] That framework enables the Secretary of HHS to declare that a public health emergency exists, and to take such action as may be appropriate to lead the national response.[5] To that end, the secretary is empowered to, among other things, maintain the Strategic National Stockpile, to implement the National Disaster Medical System, to establish and maintain a Medical Reserve Corps, to provide support to state and local governments, modify CMS conditions of participation, modify HIPAA sanctions.[6]

Historically, the PREP Act was intended to protect vaccine and drug manufacturers from financial risk related to tort liability in the event of a federally declared public health emergency. It was drafted to encourage the rapid production of vaccines, drugs, and medical devices necessary to protect Americans from a potential public health threat. To alleviate the financial risk related to tort liability, the PREP Act provides immunity against tort claims for "covered persons" involved in "recommended activities" for "covered countermeasures."[7]

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[4] 42 U.S.C. § 201, *et seq.*

[5] 42 U.S.C. § 247d.

[6] *See generally*, §§ 247d through 247d-10; HHS, Office of the Assistant Secretary for Preparedness, *Public Health Emergency Declaration*, https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx (last visited September 23, 2020).

[7] 42 U.S.C.A. § 247d-6d (a)(1); *see* Sen. Hatch, 151 Cong. Rec. 167, pp. S14237-38 (Dec. 21, 2005) ("There should be no doubt that the sole intention of the principal drafters of this legislation is to help devise a system that will increase the readiness of our country to respond to bioterrorist or natural public health threats… Integral to this system and to our national security is the too often-maligned pharmaceutical industry… [I]n the last several decades product liability exposure has drastically reduced our domestic vaccine production capability.")

In response to the COVID-19 pandemic, on March 10, 2020, the Secretary of HHS issued a Declaration invoking PREP Act immunity.[8] As set forth below, this Declaration defined the terms "covered person," "recommended activities," and "covered countermeasures" to provide as broad a scope of immunity as possible in response to a disease about which little was known and for which there were no vaccines. Thus, the Declaration essentially employed the full scope of authority afforded to the Secretary under the PREP Act.

Since its initial publication, the Declaration has been amended on six occasions, each time expanding the scope of immunity. First, on April 10, 2020, the Secretary expanded the definition of "covered countermeasures" to include "respiratory protective devices" that are NIOSH-approved.[9] This amendment coincided with the passage of the CARES Act, which expanded the statutory definition of "covered countermeasure" under the PREP Act in the same manner.[10] Second, on June 4, 2020, the Secretary further amended to clarify that the original Declaration was intended to use the full breadth of authority under the Act.[11] Specifically, it amended the definition of "covered countermeasure" under the Declaration to include products that are used "to limit the harm that COVID-19 … might otherwise cause," since that language had been inadvertently omitted.[12]

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[8] 85 Fed. Reg. 15198.

[9] 85 Fed. Reg. 21012 (Apr. 15, 2020) (dated April 10, 2020; published April 15, 2020; retroactively effective as of March 27, 2020). .

[10] (Pub. L. 116–136, div. A, title III, § 3103; 134 Stat. 361) (enacted Mar. 27, 2020)

[11] 85 Fed. Reg. 35100 (Jun. 8, 2020) (dated June 4, 2020; published June 8, 2020; retroactively effective as of February 4, 2020).

[12] *Id.* In the Preamble to the amendment, the Secretary explained that the intent was to ensure that the full breadth of products meeting the definition of "qualified pandemic and epidemic products," which is a sub-category of "covered countermeasures," were afforded coverage under the Act. Thus, it would include, for example, products meant to address side-effects of COVID-19 therapeutics, or residual effects of a COVID-19 infection, even if there is no active COVID-19 infection at the time of use. Notably, such additional products must still fit within the specified categories of products to which the PREP Act applies, addressed below, to wit: antivirals, other drugs, biologics, diagnostics, respiratory protective devices, other devices, and vaccines.

Third, on August 19, 2020, the Secretary amended the Declaration to afford PREP Act protections to licensed pharmacists, and interns acting under the pharmacists' supervision, who administer vaccines recommended by the Advisory Committee on Immunization Practices.[13] The Secretary also expanded the "category of disease, health condition, or threat" to include "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."[14]

Fourth, on December 3, 2020, the Secretary amended the PREP Act to clarify that the Declaration must be construed in accordance with the Department of Health and Human Services Office of the General Counsel Advisory Opinions and incorporated the Opinions into the Declaration by reference.[15] The Secretary also incorporated authorizations that the HHS Office of the Assistant Secretary of Health for Health has issued as an Authority Having Jurisdiction; added additional category of Qualified Persons to include healthcare personnel using telehealth to order or administer Covered Countermeasures in a state other than the state where the healthcare personnel are permitted to practice; modified the training requirements for certain licensed pharmacists and pharmacy interns to administer COVID-19 vaccinations; made explicit that Section VI of the Declaration covers all qualified pandemic and epidemic products under the PREP Act; and added a third method of distribution to include private distribution channels.[16] Further,

[13] 85 Fed. Reg 52136 (Aug. 24, 2020) (dated August 19, 2020; published August 24, 2020; effective as of August 24, 2020).

[14] *Id.* Interestingly, the amendment does not appear to require that the vaccine be for COVID-19, but rather only that it be a recommended vaccine for persons from the ages 3 to 18 years. If this is indeed the intended purpose, it appears that the Secretary perceived that the COVID-19 pandemic led to a decrease in immunizations for *other* diseases, perhaps de to public mistrust in vaccinations generally, or due to decreased outdoor activities in general.

[15] 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. 79190 (Dec. 9, 2020) (herein, "the Fourth Amendment to the Declaration")

[16] *Id.*

the December 3, 2020 Amendment made explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration's immunity provisions and reiterated that there are substantial federal legal and policy issues, and substantial federal legal and policy interests, in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities.[17]

Finally, on February 2, 2021, the Secretary amended the Declaration to add two additional categories of "covered persons" under the PREP Act, allowing (1) healthcare providers who are actively licensed in any State, and (2) physicians, registered nurses, and practical nurses whose licenses expired within the past five years, to prescribe, dispense, and/or administer COVID-19 vaccines in *any* State or jurisdiction where the PREP Act applies.[18] In identifying two additional categories of "covered persons," the Secretary recognized an urgent need to significantly expand the pool of available vaccinators in order to effectively respond to the pandemic, particularly as a vaccines are made more widely available in the coming months.[19] The Secretary specifically noted two purposes achieved by the Fifth Amendment's identification of two additional categories of "covered persons" under the Act.[20] First, the healthcare professionals added as qualified persons by the Fifth Amendment will be afforded liability protections under the PREP Act.[21] Second, any

[17] *Id.*

[18] Fifth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 86 Fed. Reg. 7872 (Feb. 2, 2021) (herein, "the Fifth Amendment").

[19] *Id*. at 7873.

[20] *Id*.

[21] *Id*.

State law that would otherwise prohibit these healthcare professionals from prescribing, dispensing, or administering COVID-19 vaccines is preempted.[22]

Ultimately, under the current COVID-19 Declaration, immunity applies if the following criteria are met: (1) the defendant is a "covered person"; (2) the defendant was engaging in a "recommended activity"; (3) the recommended activity involved a "covered countermeasure"; and (4) there is a causal nexus between the claim and the recommended activity. These criteria are addressed in turn below.

1. "Covered Person"

The first criterion for PREP Act immunity is that the individual or entity be a "covered person." That phrase is defined as a person or entity that is a (1) "manufacturer," (2) "distributor," (3) "program planner," (4) "qualified persons," and (5) their officials, agents, and employees.[23] Most relevant to hospitals, long term care facilities, and healthcare professionals is a "qualified person," which encompasses almost all health care providers. Specifically, the PREP Act defines a qualified person as 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.[24] Additionally, as related to the administration of COVD-19 vaccines specifically, the Fifth Amendment to the PREP Act recognizes actively licensed healthcare providers and physicians, registered nurses, and practical nurses whose licenses expired within the past five years as qualified persons who may prescribe, dispense, or administer COVID-19 vaccines as Covered Countermeasures in any State.[25]Also

[22] *Id*.

[23] 42 U.S.C.A. § 247d-6d(i)(2); *see also* 85 Fed. Reg. at 15199. The phrase is also defined to include the United States government.

[24] 42 U.S.C.A. § 247d-6d(i)(6), (8).

[25] *See* 86 Fed. Reg. at 7872-75 (amending section V of the Declaration).

relevant for hospitals, long term care facilities, and healthcare professionals is a "program planner," which is a 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.[26] Notably, the Declaration further clarifies that "a private sector employer or community group or other 'person' can be a program planner when it carries out the described activities."[27] The PREP Act also includes public or private corporations and entities in its definition of a "person."[28] Additionally, under the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), PREP Act immunity was extended to volunteer healthcare workers.[29] Therefore, it is likely that a majority of hospitals, facilities, and their healthcare providers satisfy the definition of a covered person.

Recently, in response to a private request, the General Counsel to the Secretary of HHS issued a Response Letter in which he stated that "senior living communities are 'covered persons' under the PREP Act when they provide a facility to administer or use a covered countermeasure …"[30] He explained that a senior living community would meets the definition of "program planner" when it "supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or

[26] 42 U.S.C.A. § 247d-6d(i)(6).

[27] 85 Fed. Reg. at 15,202; *see also* Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act, HHS, (Apr. 14, 2020), https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-april-14-2020.pdf (herein referred to as "the Advisory Opinion").

[28] 42 U.S.C.A. § 247d-6d(i)(5).

[29] Coronavirus Aid, Relief and Economic Security Act (CARES Act), S. 3548, 116th Cong. (2020).

[30] Charrow, Robert, Letter to Thomas Baker, August 14, 2020, (herein, the "Response Letter") (available upon request).

epidemic product, including by 'provid[ing] a facility to administer or use a Covered Countermeasure in accordance with' the Declaration."[31] He further acknowledged that a senior living community could also be a "qualified person" to the extent that it is authorized under Federal, State, or local law to engage in the countermeasure activities at issue.[32]

Even if an individual or entity does not meet the definition of a "covered person," immunity under the PREP Act may still be available. According to the Secretary, "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."[33] For example, suppose a hospital allows its licensed physicians to order covered countermeasures for its patients. Notwithstanding the hospital's reasonable-compliance measures to ensure current licensure, it later learns that one of its physicians inadvertently allowed his license to expire. Under these circumstances, the hospital would still be immune against a lawsuit relating to the COVID-19 covered countermeasure ordered by the physician.[34]

2. "Recommended Activities"

The second criterion for PREP Act immunity is that the individual or entity be involved in "recommended activities." The Declaration defines this phrase as the manufacture, testing, development, distribution, administration and use of one or more Covered Countermeasures.[35] This definition has also been clarified to include any arrangement with the federal government or

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[31] *Id.*

[32] *Id.*, at note 3.

[33] The Advisory Opinion. However, neither the Declaration nor the PREP Act expressly provide for such a safeguard.

[34] *Id.*

[35] 85 Fed. Reg. 15198, at 15201.

any activity that is part of an authorized emergency response at any level of government.[36] These activities can be authorized through guidance, requests for assistance, agreements, or other arrangements.[37]

Additionally, the Fourth Amendment to the Declaration expands immunity to any covered countermeasure, even if it is not related to any federal agreement or authorized by a local health response.[38] Thus, coverage under the PREP Act still applies even if a state or local authority has not declared a state of emergency.[39]

For hospitals, long term care facilities, and healthcare professionals, the most common category of "recommended activity" would be "administration." While it is undefined in the PREP Act, the Declaration defines "administration" as (1) "the physical provision of countermeasures to recipients"; (2) "activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients"; (3) "management and operation of countermeasure programs"; or (4) "management of operation of locations for purpose of distributing and dispensing countermeasures."[40] Thus, coverage under the PREP Act extends not only to the physical provision of a countermeasure to a recipient, but also 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 that are directly related to countermeasure delivery.[41] For example, in the preamble to the Declaration, the Secretary explains that immunity would extend to a claim for malpractice alleging that a health provider proscribed

[36] The Advisory Opinion.

[37] *Id.*

[38] 85 Fed. Reg. 79190.

[39] The Advisory Opinion.

[40] 85 Fed. Reg. 15198, at 15200 (emphasis added).

[41] *Id.*

the wrong dose of a drug, and to claims alleging a slip-and-fall injury or vehicle collision at a covered countermeasure dispensing location where the plaintiff claims of lax security or chaotic crowd control.[42]

This broad definition of "administration" has only been examined by the courts in limited settings and has not been directly analyzed in conjunction with the Fourth Amendment to the Declaration, so it is not entirely clear how far it extends beyond the "physical provision" of countermeasures. Arguably, it would encompass decisions and protocols with respect to infection control within a facility generally, since any such decisions would be closely related to the use and distribution of PPE and other countermeasures within the facility. This interpretation is supported by HHS Advisory Opinion 20-04 released on October 23, 2020 and the Fourth Amendment to the Declaration issued on December 3, 2020.[43] Specifically, Advisory Opinion 20-04 confirms that "use" and "administration" of countermeasures go well beyond just physical distribution of tangible countermeasures. HHS explained:

> 'Administration' also encompasses '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.'[44]

Advisory Opinion 20-04 stresses the breadth of the PREP Act's application to the "administration and use" of Covered Countermeasures, such as diagnostic testing and Personal Protective Equipment (PPE), by "program planners," and also clarifies the applicability of case law that other district courts have relied upon in remanding PREP Act cases based on claims of inaction or non-

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[42] *Id.*

[43] Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and The Secretary's Declaration Under the Act, HHS, (Oct. 22, 2020) (herein referred to as "Advisory Opinion 20-04").

[44] *Id.*

use.[45] The new Amendment and Advisory Opinions have not been considered in the recent remand orders.

In remanding COVID-19 claims alleging non-use of covered countermeasures, prior district courts have relied in part on *Casabianca v. Mount Sinai Medical Center*[46] and held that for the purposes of establishing subject matter jurisdiction, the PREP Act did not apply to claims of inaction.[47] However, Advisory Opinion 20-04 explained that:

> **The [*Casabianca*] court was wrong**. As the [*Casabianca*] court acknowledged, 'administration' is broader than the 'physical provision of a countermeasure to a recipient.' 'Administration' also encompasses '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.'[48]

Based on Advisory Opinion 20-04, restrictions on visitation taken to prevent the spread of COVID-19 would also be closely related to the use and distribution of countermeasures such as PPE. The term "administration" may also encompass the "monitoring" of a patient who has been exposed to COVID-19, since that would be part of the management and operation of an infection control protocol and of the location as a whole.

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[45] HHS Advisory Opinions are entitled to the *Skidmore* deference of "respect." *Christensen v. Harris County*, 529 U.S. 576 (2000)

[46] 1014 N.Y. Slip. Op. 33583(U), 2014 WL 10413521, at *1 (N.Y. Sup. Dec. 12, 2014).

[47] *Eaton v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.*, Case No. 2:20-cv-2291-HLT-JPO; *Fortune v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.*, Case No. 2:20-cv-2318-HLT-JPO; *Long v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.*, Case No. 2:20-cv-2263-HLT-JPO; *Campbell v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.*, Case No. 2:20-cv-2265-HLT-JPO; *Rodina v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.*, Case No. 2:20-cv-2319-HLT-JPO; *Brown v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.*, Case No. 2:20-cv-2261-HLT-JPO; *Block, Stephanie v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.*, Case No. 2:20-cv-2262-HLT-JPO; *Block, Deidra v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.*, Case No. 2:20-cv-2264-HLT-JOP; *Baskin v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.*, Case No. 2:20-cv-2267-HLT-JPO; *Harris v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.*, Case No. 2:20-cv-2266-HLT-JPO; *Lutz v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.*, No. 20-cv-2316-HLT-JPO; *Jackson v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.*, No. 2:20-cv-2259-HLT-JPO. .

[48] Advisory Opinion 20-04 at 7.

On December 3, 2020, HHS issued the Fourth Amendment to the Declaration incorporating by reference all Advisory Opinions into the Declaration itself and emphasizing that the Declaration and the PREP Act should be interpreted in accordance with the same.[49] Pointedly, the Fourth Amendment clarifies that liability immunity under the PREP Act will extend to situations of non-use or non-administration of covered countermeasures to a particular individual if that non-use or non-administration was part of a plan for systemic use or administration by a "covered person" (e.g., due to limited availability of resources).[50] It explains that, for example, if there are limited countermeasures, "*not* administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute 'relating to . . . the administration to . . . an individual' under 42 U.S.C. 247d-6d."[51] It further explains that "[p]rioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections."[52] Accordingly, the PREP Act can apply to multiple "non-use" situations concerning Covered Countermeasures. On the other hand, plaintiffs will argue that these activities do not necessarily involve the use of any countermeasure products, so they are beyond the reach of the PREP Act.[53] They may also attempt to circumvent the PREP Act by alleging negligent conduct taken ***before*** the administration of a covered countermeasure, such as failure to obtain informed

[49] 85 Fed. Reg. 79190. The Fourth Amendment formally incorporates all HHS's Advisory Opinions related to COVID-19 and the PREP Act into its initiating March 10, 2020 Declaration. *See Id.* at 5, *see also,* It specifically states that "[t]his Declaration must be construed in accordance with the Advisory Opinions of the Office of the General Counsel (Advisory Opinions). I incorporate those Advisory Opinions as part of this declaration." *See id*. at 15 (internal footnote omitted). It is now beyond question that these Advisory Opinions must be given Chevron "controlling weight." *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843–44 (1984); *see also* Fourth Amendment Four, p. 15 ("This Declaration is a 'requirement' under the PREP Act").

[50] 85 Fed. Reg. 79190, at 79194-79197.

[51] *Id.*

[52] *Id.*

[53] This is currently the subject of debate in several pending lawsuits, and there has been no definitive ruling to date outside of remand orders. *See infra,* Part 3.

consent, failure to consult a specialist prior to the administration of a covered countermeasure, and/or failure to consider plaintiff's unique co-morbidities prior to the administration of a covered countermeasure.[54]

Hospitals and long term care facilities may also find protection under the phrases "use" and "distribution." For example, when a facility dispenses covered countermeasures (such as PPE and hand sanitizer) to staff and patients or residents, that would arguably qualify as "use" or "distribution" of countermeasures for purposes of PREP Act immunity.[55] Thus, if a plaintiff claims that the facility did not provide enough PPE, or provided the wrong PPE, or improperly trained and supervised staff with respect to using PPE, those claims would be barred by the PREP act.

3. "Covered Countermeasures"

The third criterion of immunity under the PREP Act is that the recommended activity involve a "covered countermeasure." Under the Declaration, as amended, a covered countermeasure is specifically defined as:

> [(1) A]ny antiviral, any other drug, any biologic, any diagnostic, any respiratory protective device, any other device, or any vaccine, used
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> a. to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or
>
> b. to limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause; or
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> (2) any device used in the administration of any such product, and all components and constituent materials of any such product.[56]

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[54] However, case law from prior invocations of the PREP Act in response to H1N1 would caution against this. For example, in *Parker v. St. Lawrence County Public Health Dept.*, 102 A.D.3d 140 (3d Dep't 2012), the court held that the PREP Act barred an action alleging the failure to obtain parental consent prior to administration of a H1N1 vaccine.

[55] This issue is also being litigated.

[56] 85 Fed. Reg. 35100, at 35102.

The Declaration also requires that a covered countermeasure be: (1) a qualified pandemic or epidemic product, (2) a security countermeasure, (3) a drug, biological product, or device that is authorized for emergency use in accordance with the Federal Food, Drug, and Cosmetic Act, or (4) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health. Each of these covered countermeasures is further defined in the PREP Act.[57]

A "qualified pandemic or epidemic product" is defined as a drug, biological product, or device that is a product manufactured, used, designed, developed, modified, licensed or procured to (1) diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic, or (2) limit the harm such pandemic or epidemic might otherwise cause.[58] The term also includes (1) a product manufactured, used, developed, modified or procured to diagnose, mitigate, prevent, treat, or cure a serious life threatening disease or condition, or (2) a product or technology intended to enhance the use of a drug, biological product, or device.[59] However, these two products must also have either (1) U.S. Food and Drug Administration ("FDA") approval, (2) exemption under the Federal Food, Drug, and Cosmetic Act as the object for research, or (3) authorization for emergency use under an Emergency Use Authorization (EUA).[60] Additionally, pursuant to the CARES Act, Approved Respiratory Protective Devices are also considered a covered countermeasure for purposes of PREP Act immunity.[61]

Therefore, any drug, device, vaccine or biological product used to diagnose, treat, mitigate, prevent, or cure COVID-19 is a covered countermeasure if it is authorized under an EUA or has

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[57] 42 U.S.C.A. § 247d-6d(i)(1), (9).

[58] 42 U.S.C.A. § 247d-6d(i)(7).

[59] 42 U.S.C.A. § 247d-6d(i)(7); *see also* the Advisory Opinion.

[60] 42 U.S.C.A. § 247d-6d(i)(7); *see also* the Advisory Opinion.

[61] CARES Act, S. 3548, 116th Cong. (2020) (adding the inclusion of a respiratory protective device that is approved by the National Institute for Occupational Safety and Health and that is determined by a priority for use during a public health emergency declared under the PHSA).

FDA approval, clearance or licensing, as well as any NIOSH-approved respiratory protective device.[62] Moreover, like the "covered person" definition, a person or entity that establishes the requirements for PREP act immunity will not lose immunity—even if the product is ***not*** a covered countermeasure—if that person or entity reasonably believed that it was administering a covered countermeasure.[63] Thus, a covered person who takes reasonable steps to confirm EUA authorization and substantiates the authenticity of a product would be entitled to immunity even if the product turns out to be counterfeit.[64]

Under the COVID-19 Declaration, the products that qualify as "covered countermeasures" are too numerous to list, since they include any drug or device approved by the FDA,[65] or covered by an EUA.[66] However, by way of example, covered countermeasures would include the following:

a. Vaccines[67]

b. COVID-19 Protein Antigen Test[68]

c. Personal protective equipment (PPE);[69]

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[62] *See* 85 Fed. Reg. 35100, at 35102; the Advisory Opinion.

[63] The Advisory Opinion. Again, however, neither the Declaration nor the PREP Act expressly provide for such a safeguard.

[64] The Advisory Opinion.

[65] *See* generally, 21 CFR Ch 1, and with respect to devices, Subchapter H thereof.

[66] The FDA also maintains a list of specific products that are covered by EUAs in response to the COVID-19 pandemic: U.S. Food and Drug Administration, Emergency Use Authorizations, https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd. *See also* Advisory Opinion.

[67] *Id*. Currently, the Pfizer and Moderna Vaccines are the only two approved by the FDA pursuant to an Emergency Use Authorization.

[68] *Id.* A variety of these tests have received an EUA, the most recent was as of as of January 5, 2021, the variations in the EUAs in this regard account for the various entities who have submitted an application for their specific test.

[69] *See, e.g.*, 21 CFR §§ 21 CFR 878.4040 (surgical apparel), 880.6250 (non-powdered patient examination gloves), 880.6256 (examination gowns). The extensive amount of EUAs pertinent to PPE are available here: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas.

d. N95 respirators;[70]

e. Hand sanitizer;[71]

f. General purpose disinfectants;[72]

g. COVID-19 test kits;[73]

h. Thermometers;[74] and

i. Pulse oximeters.[75]

Furthermore, the Fourth Amendment to the Declaration makes "explicit that Section VI [of the Declaration] covers **all** qualified pandemic and epidemic products under the PREP Act."[76] Taken together, these authorities confirm that "covered countermeasures" clearly covers, among other things, *all* qualified pandemic and epidemic products under the PREP Act, including products used for conditions caused by any other product used for COVID-19.[77]

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[70] N95 masks were authorized for emergency use by the FDA's March 2, 2020 Emergency Use Authorization (EUA) issued pursuant to Section 563 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3) (*see* Policy Statement, March 11, 2020, available at: https://www.fda.gov/media/136023/download; Policy Statement, March 28, 2020, available at: https://www.fda.gov/media/135763/download).

[71] Over-the-counter hand sanitizer is a "drug" regulated by the FDA. *See generally,* FDA Briefing Document: Nonprescription Drugs Advisory Committee Meeting, Mar. 11, 2020, available at: https://www.fda.gov/media/135559/download; Temporary Policy for Preparation of Certain Alcohol-based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry, Mar. 2020, available at: https://www.fda.gov/media/136289/download; Topical Antiseptic Products: Hand Sanitizers and Antibacterial Soaps, FDA, last updated June 18, 2020, available at: https://www.fda.gov/drugs/information-drug-class/topical-antiseptic-products-hand-sanitizers-and-antibacterial-soaps; 82 FR 60474 (final rule for health care antiseptic products); 84 FR 14847 (final rule for consumer antiseptic products). *See also* 7 C.F.R. § 3201.18.

[72] 21 CFR § 880.6890 (defined as " germicide intended to process noncritical medical devices and equipment surfaces"). *See also* Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, FDA, March 2020, available at: https://www.fda.gov/media/136533/download.

[73] *See* FDA Combating COVID-19 with Medical Devices, FDA, last updated Aug. 4, 2020, available at: https://www.fda.gov/media/136702/download.

[74] *See, e.g.,* 21 CFR §§ 880.2200, 880.2900, 880.2910, 880.2920, 880.2930.

[75] 21 C.F.R. § 870.2700.

[76] 85 Fed. Reg. 79190, at 79191-79193.

[77] *Id.*

Following the Fourth Amendment to the Declaration, the Department of Health and Human Services issued Advisory Opinion 21-01 regarding the scope of the PREP Act's preemption provision.[78] While Advisory Opinion 21-01 focused on the issue of preemption, it further discussed issues arising in recent lawsuits alleging that covered persons declined to use a covered countermeasure.[79] The General Counsel for DHHS noted "a growing number of suits related to the use or non-use of covered countermeasures against COVID-19, including PPE," as well as a trend of cases being filed in state courts alleging state law-based torts, defendants filing removal petitions, and plaintiffs responding with remand motions.[80] Not only does the DHHS Advisory Opinion 21-01 interpret the PREP Act as a "complete preemption" statute, but it further recognizes that certain non-actions may fall within the definition of "covered countermeasures."[81] The General Counsel's interpretation of the covered countermeasure analysis focuses on "the plain language of the PREP Act, which extends immunity to anything 'related to' the administration of a covered countermeasure," explaining that prioritization, allocation, or other instances of non-use or refusal to administer therapeutic likely fall within that category, absent wanton and willful conduct.[82]

4. Causal Nexus:

The fourth criterion for PREP Act immunity is that the claim sought to be preempted must have some causal connection to the use or administration of a covered countermeasure. The Act applies to all claims "caused by, arising out of, relating to, or resulting from the administration to

[78] *See* Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act and The Secretary's Declaration Under the Act, DHHS, (Feb. 8, 2021) (herein referred to as "Advisory Opinion 21-01").

[79] *Id*.

[80] *Id*.

[81] *Id*. at 2-4.

[82] *Id*. at 3-4.

or the use by an individual of a covered countermeasure," i.e., any claim "that has a causal relationship with the … distribution, … purchase, … dispensing, prescribing, administration, … or use of" a countermeasure.[83]

As noted above, the phrase "administration" has a broad definition that extends beyond the physical provision of countermeasures to recipients. Thus, in the preamble to the Declaration, the secretary explains that the PREP Act would provide immunity to "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" but would not apply to a "slip and fall with no direct connection to the countermeasure's administration or use."

Determining the degree of causal nexus required under the PREP Act will require many case-by-case determinations. On one end of the spectrum will be cases involving complications from a drug or vaccine that was administered to the plaintiff, as well as cases in which the plaintiff alleges that that the wrong dose was provided. In such instances, the PREP Act would easily apply because the injury would flow directly from the countermeasure itself. On the other end of the spectrum are cases where the presence of countermeasures is completely ancillary to the central allegation. For example, if the claim is that a staff member physically assaulted a patient, and it turns out the staff member happened to be wearing a surgical mask at the time, the PREP Act would not apply to a claim for battery.

One scenario falling somewhere in the middle of that spectrum occurs when a plaintiff alleges that the infection control practices at a facility were negligent, but the Complaint does not expressly refer to any countermeasures. For example, a plaintiff may claim that a facility had negligent visitation policies, or failed to enforce social distancing, and that the plaintiff contracted

[83] 42 U.S.C.A. § 247d-6d(a)(1), (2)(B).

COVID-19 as a result.[84] In such instances, the defense should argue that those measures were "directly related to" the use of covered countermeasures, and that they involved the "management and operation" of a location where countermeasures were being administered, thus falling under the definition of "administration," even though those specific activities do not necessarily involve the use of any countermeasure products. In such instances, it may be necessary to offer evidence to show that the decisions with respect to visitation and social distancing were related to countermeasures (e.g., by demonstrating that the availability of PPE and other countermeasures factored into when, whom, and how many visitors would be allowed), that social distancing was to be practiced in connection with the use of PPE, and that those measures were just individual aspects of a larger infection control program that involved the systemic use of PPE, thermometers, hand sanitizers, and other countermeasures.

5. Other Requirements:

There are also additional requirements for immunity under the PREP Act and the Declaration beyond those set forth above. However, they will be easily satisfied in many cases.

First, the Declaration sets forth the "effective period" during which immunity attaches to a "recommended activity."[85] For activities with respect to NIOSH-approved "respiratory protective devices," this time period is from March 27, 2020, to October 1, 2024 (unless the Secretary terminates the Declaration before then).[86] For all other countermeasures, this time period is from February 4, 2020, until October 1, 2024 (again, unless the Secretary terminates the Declaration

[84] Of course, even if the PREP Act did not apply to such claims, the plaintiff would need to establish that a standard of care existed during the pandemic, and that they contracted the disease from a breach of that standard of care. This will be problematic in cases involving the early days of the pandemic and in cases where the source of infection is unknown or cannot be proved with any degree of professional certainty.

[85] *See* 42 U.S.C.A. §§ 247d-6d(a)(3)(B), 247d-6d(b)(2)(B).

[86] 85 Fed. Reg. 21012, at 21014.

Before then).[87] For countermeasures and activities that are authorized solely by a State or local emergency response, immunity attaches for the duration of that declared State or local emergency.[88]

Second, the countermeasure must be used or administered for the "category of disease, health condition, or threat" specified by the Secretary.[89] However, the Declaration broadly provides that countermeasures are recommended for "COVID-19 caused by SARS-CoV-2 or a virus mutating therefrom."[90] More recently, the Secretary expanded this category even further to include "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."[91] Moreover, if the countermeasure is used or administered during the "effective period," there is a rebuttable presumption that it was used or administered for the category of disease, health condition, or threat specified by the Declaration.[92]

Third, the Declaration specifies that immunity attaches only for activities with respect to countermeasures that are obtained through a "particular means of distribution."[93] However, in this regard, the Declaration broadly affords immunity to any recommended activity that is "related to … federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or [the applicable state or local emergency response]."[94] The Fourth Amendment to the Declaration clarified that immunity

[87] *Id.*

[88] *Id.*

[89] *See* 42 U.S.C.A. §§ 247d-6d(a)(3)(A), 247d-6d(b)(2)(A).

[90] 85 Fed. Reg. 15198, at 15202.

[91] 85 Fed. Reg. 52136, at 52141 (effective Aug. 24, 2020).

[92] 42 U.S.C.A. § 347d-6d(a)(6).

[93] 42 U.S.C.A. § 247d-6d(b)(2)(E).

[94] 85 Fed. Reg. 15198, at 15202.

applies to any covered countermeasure, even if it is not related to any federal agreement or authorized by a local public health response.[95] Thus, immunity will attach as long as the countermeasure was obtained through any "transaction" or any other legal means of procurement.[96]

Fourth, the PREP Act requires the secretary to specify a population of individuals to whom the administration or use of countermeasures will trigger immunity.[97] Under the Declaration, that population is defined to include "any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration."[98] Thus, the Declaration imposes no appreciable limitation with this requirement because if a countermeasure is used or administered in the first instance, immunity attaches. In any event, this would-be requirement is not applicable to manufacturers or distributors, and program planners and qualified persons are afforded a "reasonable belief" safeguard.[99] Moreover, there is no apparent requirement that the claimant be a member of this population for a suit to be barred; rather, it appears that so long as the recommended activity is taken for a COVID-19 related purpose, immunity will attach.

Finally, the PREP Act requires the Secretary to identify a "geographic area" within which the administration or use of covered countermeasures will trigger immunity.[100] However, under the Declaration, the Secretary provided immunity "without regard to geographic location," explaining that it was possible for suits arising outside of the United States to apply U.S. law to

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[95]85 Fed. Reg. 79190

[96] The Preamble to the Declaration explains that, with respect to government entities that are "program planners," this requirement was intended, in part, to deter seizure of privately held stockpiles of covered countermeasures. 85 Fed. Reg. 15200.

[97] *See* 42 U.S.C.A. §§ 247d-6d(a)(3)(C), 247d-6d(b)(2)(C)

[98] 85 Fed. Reg. 15198, at 15202.

[99] *Id.*

[100] 42 U.S.C.A. § 247d-6d(b)(2)(D)

resolve the dispute.[101] Moreover, even if there were an appreciable "geographic area" requirement, like the "population" requirement, it would not apply to manufacturers or distributors, and program planners and qualified persons are afforded a "reasonable belief" safeguard.[102]

6. Exceptions to Immunity:

PREP Act immunity is not absolute. It does not apply to civil enforcement proceedings, criminal proceedings, or claims for equitable relief, since those do not involve a "claim for loss" as that term is defined.[103]

However, when the PREP Act does apply, the only exception to immunity is a claim for "willful misconduct." The procedural and substantive requirements for a claim for "willful misconduct" are set forth in detail below.

III. PREP ACT LITIGATION

Any defendant named in a suit related to COVID-19 must be ready to use the PREP Act to defend the claim. As discussed below, the applicability of the PREP Act will impact many aspects of litigation, including jurisdiction, substantive defenses, motion practice, and discovery. For present purposes, we divide potential claims into two main categories: (1) claims for "willful misconduct," and (2) claims for negligence or gross negligence.

1. Defending a Claim for "Willful Misconduct"

A. "Willful Misconduct" Defined

Under the PREP Act, willful misconduct is defined as an act or omission that is taken (1) intentionally to achieve a wrongful purpose, (2) knowingly without legal or factual justification,

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[101] 85 Fed. Reg. 15198, at 15202.

[102] *Id.*

[103] *See* 42 U.S.C.A. §247d-6d(a)(2)(A); Advisory O
pinion.

and (3) 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.[104] Further, the PREP Act instructs courts to construe this definition as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.[105] It also requires proof by "clear and convincing evidence."[106] Thus, the PREP Act places a high burden on plaintiffs in COVID-19 related suits that seek to circumvent the statute's immunity.

The PREP Act also provides a substantive defense by exempting certain conduct from the definition of "willful misconduct." If the defendant is a "program planner" or a "qualified person," they cannot have engaged in "willful misconduct" as a matter of law if: (1) they acted "consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration of a covered countermeasure"; (2) they received information that the administration or use of a countermeasure resulted in "serious or injury or death"; and (3) within seven days of actual discovery of that information, they provided notice of the same to the Secretary or a State or local health authority.[107] Therefore, during the COVID-19 pandemic, a medical provider should provide prompt notice of any COVID-19 deaths to the applicable state or local health authority (and document the same), as well as and any other injuries for which the Defendant may be entitled to immunity under the PREP Act.

B. Pleading With Particularity

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[104] 42 U.S.C.A. § 247d-6d(c)(1)(A).

[105] 42 U.S.C.A. § 247d-6d(c)(1)(B). Interestingly, the PREP Act dictates that the "substantive law" to be applied in a claim for willful misconduct shall be "derived" from the law of the state in which the alleged willful misconduct occurred, unless it is inconsistent with or preempted by Federal law. 42 U.S.C.A. § 247d-6d(e)(2). Given the clear statutory definition for "willful misconduct," the standard of conduct would be set forth by the PREP Act itself, but the issues of whether there were "legal justification," and what constitutes "intentional" or "knowing" conduct would be derived by state law, with the court instructed to apply a higher standard than "recklessness."

[106] 42 U.S.C.A. § 247d-6d(c)(3).

[107] 42 U.S.C.A. § 247d-6d(c)(4). A substantive defense is also afforded to manufacturers and distributors if there has been no enforcement action initiated against them for the alleged misconduct or if an enforcement action was resolved in their favor. § 247d-6d(c)(5).

When a plaintiff alleges willful misconduct as an exception to PREP Act immunity, the PREP Act also requires a plaintiff to plead with particularity each element of the plaintiff's claim, including—(1) each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure administered to or used, (2) facts supporting the allegation that such alleged willful misconduct proximately cause the injury claims, and (3) facts supporting the allegation that the plaintiff suffered death or serious physical injury.[108] "Serious physical injury" is further defined as an injury that is (1) life threatening, (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body.[109]

C. Verification, Affidavit, and Medical Record Requirements

In addition to the above, a plaintiff must verify under oath that a filed complaint is true to the best of his or her knowledge.[110] A plaintiff must also file with the complaint an affidavit of a non-treating physician certifying and explaining the bases for such physician's belief, that such person suffered serious physical injury or death alleged in the complaint and that such injury or death was proximately caused by the administration or use of a covered countermeasure.[111] Lastly, a plaintiff must also file with the complaint a certified copy of the medical records documenting such injury or death to establish a proximate causal connection.[112] Since the clerk is instructed to reject any document not meeting these requirements,[113] a defendant served with a pleading that

[108] 42 U.S.C.A. § 247d-6d(e)(3).
[109] 42 U.S.C.A. § 247d-6d(i)(10).
[110] 42 U.S.C.A. § 247d-6d(e)(4)(B)(i).
[111] 42 U.S.C.A. § 247d-6d(e)(4)(C)(i).
[112] 42 U.S.C.A. § 247d-6d(e)(4)(C)(ii).
[113] 42 U.S.C.A. § 247d-6d(e)(4)(A).

has been filed and does not meet these criteria should consider a mandamus action to compel the rejection of the filing, or a motion to dismiss for failure to state a claim.

D. Exhaustion of Administrative Remedies

Before filing suit for "willful misconduct," a plaintiff must apply for compensation through the "Covered Countermeasure Process Fund" (the "Fund"), which is a no-fault scheme established to supply benefits to individuals who sustain "serious injury" from a covered countermeasure.[114] In fact, a plaintiff may proceed with a claim for willful misconduct only if: (1) no funds have been appropriated to the Fund, (2) the HHS Secretary fails to make a final determination on the individual's request for compensation within 240 days, or (3) the individual decides not to accept the compensation provided.[115] If an individual seeks and receives compensation through the Fund, they are then prohibited from bringing any action related to PREP.[116] Therefore, if a defendant receives such a suit, and the plaintiff did not apply for benefits, a motion to dismiss should be brought on the basis that the plaintiff failed to exhaust administrative remedies. If, however, the plaintiff did apply for and receive benefits, the claim should be dismissed for lack of standing.

E. Procedural Requirements:

A claim for "willful misconduct" can only be brought in the U.S. District Court for the District of Columbia.[117] Therefore, if a complaint is filed in state court and includes such a claim, the defendant should move as soon as possible to have the case dismissed, because the court would be without subject-matter jurisdiction and because the action would have been brought in the

[114] 42 U.S.C.A. § 247d-6e(d)(1).
[115] 42 U.S.C.A. § 247d-6d(e)(1), (4), (5).
[116] 42 U.S.C.A. § 247d-6e(d)(1).
[117] 42 U.S.C.A. § 247d-6d(e)(1).

wrong venue.[118] Alternatively, a defendant could file a Notice of Removal within 30 days of service of the pleading to remove the case to the local Federal District Court, and as immediately as possible move to dismiss or transfer to the District Court for the District of Columbia due to improper venue.[119] If, however, the action was originally brought in federal court but in the incorrect District, a defendant should move to dismiss for improper venue and request, in the alternative, that the action be transferred to the District of Columbia.[120]

Once filed in the proper court, the action is assigned to a special panel of three judges, who have jurisdiction for purposes of considering motions to dismiss, motions for summary judgment, and all matters related thereto.[121] Thereafter, if the case is not dismissed or if the time for motions expires, the case is referred to an individual judge at the discretion of the chief judge for that district.[122] Sanctions, including attorneys fees, are required for any violation of F.R.C.P. 11(b) (i.e., frivolous practice, suits brought for improper purposes, and factual contentions or denials made without evidentiary support).[123]

F. Statute of Limitations

Notably, the PREP Act does not specify a statute of limitations for a claim for "willful misconduct." However, it does provide that the limitations period shall be tolled during the pendency of any claim for benefits under the Fund,[124] and it also provides that a defective pleading

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[118] *See* 42 U.S.C.A. §§ 247d-6d(d)(1), (e)(1); 247d-6e(d). A defendant could also move for dismissal because of plaintiff's failure to exhaust administrative remedies that are a procedural requirement to suit. *See* 42 U.S.C. § 247d-6e(d)(1).

[119] *See* 28 U.S.C. § 1446(a), (b).

[120] If the complaint does not meet the heightened pleading requirements or is otherwise defective, any motion should raise all such objections to avoid any possibility of waiver.

[121] 42 U.S.C.A. § 247d-6d(e)(5).

[122] *Id.*

[123] 42 U.S.C.A. § 247d-6d(e)(9).

[124] 42 U.S.C. § 247d-6e(d)(2).

does not toll the limitations period.[125] Because there is no generally applicable statute of limitations for federal claims,[126] it would appear that the statute of limitations for the state in which the action arose should apply.[127] However, since a claim for "willful misconduct" is a creature of Federal law, it may not be readily apparent, in a given state, which statute of limitations should be applied.[128] A defendant in such actions should therefore argue that the statute of limitations for intentional torts applies, given the requirements for "intentional" and "knowing" conduct, and the fact that the claim is intended to impose a stricter standard than negligence or recklessness.[129] However, of course, if a shorter statute of limitations could apply (for example, under a claim for professional negligence), the defendant should first attempt to assert the shorter time period on a motion to dismiss the claim.

G. Limitations on Discovery:

Under a claim for "willful misconduct," discovery is only available to "with respect to matters directly related to [contested] material issues," and responses to discovery demands can be compelled only upon a finding that the likely benefits outweigh the burden of production.[130] Moreover, no discovery is permitted (1) before a covered person has a "reasonable opportunity" to file a motion to dismiss; (2) before the court rules on any such motion; or (3) before an

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[125] 42 U.S.C.A. § 247d-6d(e)(4)(A).

[126] Actions brought against the United States are subject to a 2-year statute of limitations. 28 U.S.C. § 2401.

[127] Under 42 U.S.C.A. § 247d-6d(e)(2), state "substantive" law will govern a claim for willful misconduct to the extent that it is not inconsistent with or preempted by Federal law. Under the *Erie* doctrine, state statutes of limitation are deemed "substantive" in diversity cases, even though state "choice of law" rules may deem a statute of limitations "procedural." *Compare Guar. Tr. Co. of N.Y. v. York*, 326 U.S. 99, 110 (1945) *with* Sun Oil Co. v. Wortman, 486 U.S. 717, 722–29 (1988).

[128] For example, in New York, negligence claims are subject to a 3-year statute of limitations, medical malpractice claims are subject to a 2.5-year statute of limitations, and intentional torts are subject to a 1-year statute of limitations. *See* NY C.P.L.R. §§ 214, 214-A, 215.

[129] *See* 42 U.S.C.A. § 247d-6d(c)(1).

[130] 42 U.S.C.A. § 247d-6d(e)(6)(B).

interlocutory appeal is decided after the denial of such motion.[131]

H. Limitations on Damages:

The PREP Act places two limits on the amount of recovery a plaintiff bringing a claim for "willful misconduct" would be entitled to. First, the amount of damages is reduced by the amount of collateral source benefits that the claimant received, and no collateral source provider may assert a lien or subrogation rights.[132] These include benefits obtained under state or federal law, insurance coverage, contract, employee benefits, or "any other publicly or privately funded program."[133] Second, there is no joint liability for non-economic damages (e.g., pain and suffering), and such damages may only be awarded in direct proportion to a defendant's equitable fault.[134]

2. Defending a Claim for Negligence or Gross Negligence

Given the high burden the PREP Act places on a plaintiff, many plaintiffs will first attempt to circumvent the Act by bringing a claim in state court for ordinary negligence, or professional negligence, and will likely also allege gross negligence. In such situations, a defendant has several litigation strategies available to assert PREP Act immunity and ultimately have a COVID-19 claim dismissed. Depending on the specific allegations in a complaint and where it is filed, a defendant has the option of removing a claim to federal court, filing a motion to dismiss, asserting affirmative defenses, and/or filing a motion for summary judgment. In some cases early motion practice may dismiss the claim entirely, or at least narrow the allegations, while in other cases it may be advisable to develop information and evidence through discovery before bringing any motion.

A. Removal to Federal Court

[131] 42 U.S.C.A. § 247d-6d(e)(6)(A).

[132] 42 U.S.C.A. § 247d-6d(e)(7)(A-B).

[133] 42 U.S.C.A. § 247d-6d(e)(7)(C).

[134] 42 U.S.C.A. § 247d-6d(e)(8). Traditionally, defendants are jointly and severally liable for the full amount of damages.

i. Whether to Remove or Defend in State Court

One of the first decisions to make in defending a claim that invokes the PREP Act is whether to remove the action to Federal court or to defend the action in state court. The benefits of removal include (1) having a federal judge who is, presumably, more qualified to apply federal law than a state court judge and more willing to afford deference to federal law; (2) forcing a plaintiff's attorney to litigate in an unfamiliar venue; (3) obtaining benefits under federal rules of procedure that are not available in some state jurisdictions;[135] and (4) obtaining federal appellate review of a trial court's decision regarding a motion to dismiss.[136] However, a state court could also consider the applicability of the PREP Act and dismiss the claim on the basis of preemption, even though the PREP Act is a creature of Federal statute. Also, the removal process itself will create additional defense costs upfront, and if unsuccessful, the case would return to its starting position in state court. Therefore, a defendant may opt to forego the benefits of a federal forum and litigate the issue of PREP Act applicability in state court.

Thus, at the outset, a cost-benefit analysis should be conducted to determine whether to remove in the first place, with due consideration for the likelihood of a successful PREP Act defense against the claims that are plead, benefits or disadvantages of local procedure as compared to federal procedure, judicial philosophies in state court versus federal court, the relative prowess of plaintiff's counsel, and the potential amount of financial exposure.

ii. Grounds for Removal

Unless there is a basis for diversity jurisdiction, a defendant will only be able to obtain federal removal jurisdiction if it is established that the complaint asserts a federal question.

[135] For example, some states, such as New York, do not require expert discovery.

[136] As opposed to following state appellate procedure that would not guarantee any federal court take up the issue unless the Supreme Court granted *certiorari* after state appeals are exhausted.

Unfortunately for a defendant seeking to invoke the PREP Act, if the complaint does not assert "willful misconduct," it will only appear on its face to assert state law claims.

The presence or absence of "federal-question" jurisdiction is governed by the "well-pleaded complaint rule," which provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff's properly pleaded complaint.[137] Under this rule, a case arises under federal law ". . . 'only when the plaintiff's statement of his own cause of action shows that it is based' on federal law."[138] Thus, as a general rule a case will not be removable if the complaint does not affirmatively allege a federal claim.[139] This is true even if a defendant asserts an affirmative defense that is rooted in federal law, even if that defense is based on federal preemption of state law, and even if the plaintiff anticipates the defense of preemption in the initial pleadings.[140]

However, the Supreme Court has recognized that this general rule is not applicable when a federal statute wholly displaces the state-law cause of action through "complete preemption."[141] The doctrine of "complete preemption" is considered a corollary to the "well-pleaded complaint rule."[142] It applies in circumstances where certain federal statutes are deemed to possess "extraordinary pre-emptive power," and is a decision in which the courts reach reluctantly.[143] Under the complete preemption doctrine, "once an area of state law has been completely pre-

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[137] *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987) (citation omitted).

[138] *Devon Energy Prod. Co., L.P. v. Mosaic Potash Carlsbad, Inc*., 693 F.3d 1195, 1202 (10th Cir. 2012) (citation omitted).

[139] *Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 6 (2003).

[140] *Id.*

[141] *See generally, Beneficial Nat. Bank v. Anderson*, 539 U.S. 1 (2003). The Court also recognized another exception, applicable when the federal statute in question expressly permits removal of state claims. *Id.* at , 6-7 (*discussing* Price–Anderson Act, 42 U.S.C. § 2014(hh)). However, there is no such language under the PREP Act.

[142] *Caterpillar Inc. v. Williams*, 482 U.S. 386, 393 (1987).

[143] *Gaming Corp. of America v. Dorsey & Whitney*, 88 F.3d 536, 543 (8th Cir.1996) (quoting *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 65 (1987)).

empted, any claim purportedly based on that pre-empted state law is considered, from its inception, a federal claim, and therefore arises under federal law."[144] Determining whether federal law preempts a state-law cause of action is a question of congressional intent.[145]

Until 2003, the Supreme Court had only applied "complete preemption" as a basis for federal question removal in two categories of cases: certain causes of action under the Labor Management Relations Act of 1947 (LMRA) and Employee Retirement Income Security Act (ERISA) of 1974.[146] In each instance, the relevant federal statutes provided an exclusive cause of action for the claim asserted and also set forth procedures and remedies governing that cause of action.[147] For example, the relevant portion of the Labor Management Relations Act of 1947, 29 U.S.C.A. § 185 states:

> [S]uits for violation of contracts between employer and a labor organization representing employees in an industry affecting commerce . . . may be brought in any district court of the United States have jurisdiction of the parties….[148]

The Supreme Court observed that this section's preemptive force was "so powerful as to displace entirely any state cause of action 'for violation of contracts between an employer and a labor organization.'"[149] It concluded that "[a]ny such suit is purely a creature of federal law, notwithstanding the fact that state law would provide a cause of action in the absence of § 301."[150]

Virtually identical language is at play under ERISA. Thus, in *Metro. Life Ins. Co. v. Taylor*[151], the Supreme Court held that claims that could be brought under § 502(a) of ERISA (29

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[144] *Caterpillar Inc. v. Williams*, 482 U.S. 386, 393 (1987).

[145] *Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 252 (1994).

[146] *Avco Corp. v. Aero Lodge No. 735, Intern. Ass'n of Machinists and Aerospace Workers*, 390 U.S. 557 (1968); *Franchise Tax Bd. of State of Cal. v. Construction Laborers Vacation Trust for Southern California*, 463 U.S. 1 (1983).

[147] *Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 8 (2003) citing 29 U.S.C.A. § 1132 (West 2020).

[148] 29 U.S.C.A. 185(a).

[149] *Franchise Tax Bd. of State of Cal.*, 463 U.S. 1, 23-24 (1983).

[150] *Franchise Tax Bd. of State of Cal.*, 463 U.S. 1, 23-24 (1983).

[151] 481 U.S. 58 (1987)

U.S.C.A. § 1132(a)) were subject to the "complete preemption" doctrine because of the language contained in § 502(f) of ERISA (29 U.S.C. § 1132(f)):

> The district courts of the United States shall have jurisdiction, without respect to the amount in controversy or the citizenship of the parties, to grant the relief provided for in subsection (a) of this section in any action.

However, the Court also drew upon the legislative history of ERISA, which included a Conference Report addressing the issue of federal question jurisdiction and drawing parallels to the LMRA.[152]

In 2003, the Supreme Court expanded the "complete preemption" doctrine to claims for usury asserted against a national bank in *Beneficial Nat. Bank v. Anderson*.[153] The Court observed:

> [A] state claim may be removed to federal court … when a federal statute wholly displaces the state-law cause of action through **complete pre-emption**. When the federal statute completely pre-empts the state-law cause of action, a claim which comes within the scope of that cause of action, even if pleaded in terms of state law, is in reality based on federal law. In the two categories of cases where this Court has found complete pre-emption … the federal statutes at issue **provided the exclusive cause of action** for the claim asserted and also **set forth procedures and remedies governing that cause of action**.

539 U.S. 1, 8 (2003) (emphasis added; internal citations and footnotes omitted). There, the applicable statutory language was the usury provisions of the National Bank Act (12 U.S.C. §§ 85 and 86).[154] The Court held that the usury provisions under §§ 85 and 86 collectively "supersede both the substantive and the remedial provisions of state usury laws and create a federal remedy for overcharges that is exclusive."[155]

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[152] *Id.* at 65-66, *citing* H.R.Conf.Rep. No. 93–1280, p. 327 (1974).

[153] 539 U.S. 1 (2003).

[154] National Bank Act (12 U.S.C. §§ 85 and 86). (Section 85 defines usury, and section 86 provides "a forfeiture of the entire interest" for usury engaged in knowingly, or "the person by whom it has been paid, or his legal representatives, may recover back, in an action in the nature of an action of debt, twice the amount of the interest thus paid from the association taking or receiving the same.").

[155] 539 U.S. 1, 11 (2003).

Circuit and district courts considering the issue have subsequently found "complete preemption" where a federal statute (1) expressly preempts state law and (2) creates an exclusive federal remedy for preempted state claims.[156] In fact, since 2003, the doctrine of "complete preemption" has been applied by the lower courts to at least ten other statutes.[157] Of these statutes, the Air Transportation Safety and System Stability Act ("ATSSSA") is particularly analogous to the PREP Act, with a similar framework. Enacted in the immediate aftermath of the September 11, 2001 terrorist attacks, it broadly preempts any state law claim "related to" the attacks and it creates exclusive federal remedies in the form of (1) a federal Victim Compensation Fund to provide benefits to certain categories of claimants, and (2) an exclusive federal cause of action for damages "arising out" the attacks vests exclusive jurisdiction for such actions in the Southern District of New York.[158] The United States Court of Appeals for the Second Circuit held that the broad preemptive language, coupled with the exclusive federal remedy for some claims, conferred federal removal jurisdiction over all claims for injuries "related to" the attacks, even if pled in state law.[159] Notably, the operative language from the various sections of the Act include the phrases

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[156] *See, e.g.*, In re WTC Disaster Site, 414 F.3d 352, 380 (2d Cir. 2005); Spear Marketing, Inc. v. Bancorp South Bank, 791 F.3d 586 (5th Cir. 2015); Nott v. Aetna U.S. Healthcare, Inc., 303 F.Supp.2d 565 (E.D.Pa. 2004); Devon Energy Prod. Co. v. Mosaic Potash Carlsbad, Inc., 693 F. 3d 1195, 1204, 1207 (10th Cir. 2012)) ("For complete preemption to apply, the federal remedy must provide some vindication for the same basic right or interest alleged by the plaintiff").

[157] These include the Transportation Safety and System Stabilization Act (*In re WTC Disaster Site*, 414 F.3d 352 (2d Cir. 2005)); the Bankruptcy Code (*In re Miles*, 430 F.3d 1083 (9th Cir. 2005)); the Carmack Amendment to the Interstate Commerce Act (*see, e.g., Smallwood v. Allied Van Lines, Inc.*, 660 F.3d 1115 (9th Cir. 2011)); the Interstate Commerce Commission Termination Act (*see, e.g., Elam v. Kansas City Southern Ry. Co.*, 635 F.3d 796 (5th Cir. 2011)); the Copyright Act (*see, e.g., Spear Marketing, Inc. v. BancorpSouth Bank*, 791 F.3d 586 (5th Cir. 2015)); the Federal Communications Act (*see, e.g., Bastien v. AT&T Wireless Services, Inc.*, 205 F.3d 983 (7th Cir. 2000)); the Federal Deposit Insurance Act (*Vaden v. Discover Bank*, 556 U.S. 49, 129 S. Ct. 1262, 173 L. Ed. 2d 206 (2009)); the Federal Railroad Safety Act (*see, e.g., Lundeen v. Canadian Pacific R. Co.*, 532 F.3d 682 (8th Cir. 2008)); the National Labor Relations Act (*see, e.g., Price v. Union Local 25*, 787 F. Supp. 2d 63 (D.D.C. 2011)); and the Securities Litigation Uniform Standards Act (SLUSA) (*see, e.g., Brockway v. Evergreen Intern. Trust*, 496 Fed. Appx. 357 (4th Cir. 2012))

[158] *See* 49 U.S.C.A. § 40101.

[159] *See In re WTC*, 414 F.3d at 375

"arising out of," "resulting from," and "relating to," all of which appear in the first clause of the PREP Act.[160]

The PREP Act satisfies the first prong of the "complete preemption" analysis because it broadly preempts any state law claim that falls within its ambit.[161] Indeed, the broad preemptive impact of the PREP Act was acknowledged by Supreme Court Justices Sotomayor and Ginsburg in dissent in *Bruesewitz v. Wyeth, LLC,* where they used it for juxtaposition against the language of the National Childhood Injury Vaccine Act (NCIVA).[162] The New York Appellate Division for the Third Department also recognized the broad preemptive effect of the PREP Act in *Parker v. St. Lawrence County Public Health Dept*.[163] There, the court held that the PREP Act preempted state law claims for negligence and battery asserted arising from the administration of a vaccine to a child without parental consent.[164]

Moreover, HHS and DHHS guidance, as well as the Fourth Amendment to the Declaration provide additional support for the PREP Act's preemption of state law claims. On October 8, 2020, the Office of the Assistant Secretary for Health issued a letter to the Nevada Department of Health and Human Services addressing preemption.[165] On October 2, 2020, the Nevada Department of Health and Human Service's Chief Medical Officer issued a directive requiring skilled nursing

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[160] *See id.;* 42 U.S.C.A. § 247d-6d(a)(1).

[161] Under § 247d-6d(a)(1), immunity is granted "from suit and liability under Federal and **State** law" (emphasis added); this could only be accomplished through preemption. Moreover, the express preemption clause applies to any form of state law that "is different from, or in conflict with, any requirement applicable under this section [§ 247d-6d] and relates to … the administration by qualified persons of the covered countermeasure." § 247d-6d(b)(8).

[162] 562 U.S. 223, 253 (2011) (observing that the PREP Act's "categorical (e.g., 'all') and/or declarative language (e.g., 'shall')" indicated a clear intent to preempt all claims within its ambit.). Notably, the NCIVA has a similar framework to the PREP Act and the ATSSSA. However, the *Bruesewitz* Court was not confronted with the issue of "complete preemption" because that case was brought under diversity jurisdiction.

[163] 102 A.D.3d 140, 144 (3d Dep't 2012) ("we conclude that Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified per-son *** The provision of these exclusive federal remedies further supports our finding of preemption.")

[164] *Id.*

[165] Letter from the Office of the Assistant Secretary, Secretary of the Department of Health and Human Services (Oct. 8, 2020).

facilities to immediately discontinue the use of all COVID-19 antigen tests until the accuracy of the tests could be better evaluated.[166] In response, the Office of the Assistant Secretary issued the October 8, 2020 letter stating that "[u]nder federal law, Nevada may not prohibit or effectively prohibit such testing at congregate facilities . . . [because this] action is ***inconsistent with and preempted by federal law.***"[167] HHS explained that the Nevada directive ignored the August 31, 2020 issuance from the Office of the Assistant Secretary extending coverage under the PREP Act to healthcare providers prescribing or administering FDA-authorized COVID-19 tests.[168] The October 8, 2020 letter supports that individuals and facilities who administer covered countermeasures, such as a COVID-19 tests receive coverage under the PREP Act, which preempts state law claims.

Likewise, the Fourth Amendment to the Declaration reiterates that PREP Act liability protections invoke federal jurisdiction under the *Grable* test.[169] Secretary Azar states that "[t]hrough the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance," and that "there are substantial federal legal and policy issues, and substantial federal and legal policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mf'g*, 545 U.S. 308 (2005), in having a uniform interpretation of the PREP Act.[170]

Additionally, on January 8, 2021, General Counsel for the Department of Health and Human Services issued Advisory Opinion 21-01 to address the scope of the PREP Act's preemption provision in light of the Fourth Amendment to the Act and the growing number of

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[166] Letter from the Nevada Department of Health and Human Services Division of Public and Behavioral Health, (Oct. 2, 2020).

[167] Letter from the Office of the Assistant Secretary, Secretary of the Department of Health and Human Services (Oct. 8, 2020).

[168] *Id.*

[169] 85 Fed. Reg. 79190; *See Grable & Sons Metal Prods. v. Darue Eng'g & Mfg.*, 545 U.S. 308 (2005) (providing for embedded federal question jurisdiction).

[170] 85 Fed. Reg. 79190, at 79194.

COVID-19 related lawsuits.[171] The HHS General Counsel's position supports complete preemption, stating that the PREP Act both establishes a federal cause of action as the only viable claim and vests exclusive jurisdiction in a federal court.[172] First, Advisory Opinion 21-01 explains that, as clarified by the Fourth Amendment to the PREP Act, acts of prioritization or purposeful allocation of a Covered Countermeasure, though potentially resulting in non-use by some individuals, nonetheless "relate to" the administration of a covered countermeasure, bringing such lawsuits under the PREP Act and its immunity.[173] Contrastingly, the Advisory Opinion notes that non-use of covered countermeasures that is the result of a failure to make any decisions whatsoever or of nonfeasance fall within the category of wanton and willful actions that are exempted from immunity, but which cases should be transferred to the District Court for the District of Columbia.[174] Second, in addition to recognizing complete preemption of the PREP Act, Advisory Opinion 21-01 notes a basis of removal to federal court under the *Grable* doctrine.[175] Thus, in addition to finding complete preemption, the DHHS General Counsel notes that a substantial federal question is implicated because "ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means that the case belongs in federal court."[176]

The PREP Act also satisfies the second prong of the "complete preemption analysis." As set forth in detail above, it provides for an exclusive set of federal remedies, and even establishes

[171] Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act and The Secretary's Declaration Under the Act, DHHS, (Feb. 8, 2021) (herein referred to as "Advisory Opinion 21-01").

[172] *Id*. at 2.

[173] *Id*. at 3.

[174] *Id*. at 3-4.

[175] *Id*. at 4-5 (citing *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308 (2005).

[176] *Id*. at 5.

the procedures applicable to those remedies.[177] The exclusivity of these remedies was also acknowledged by the *Parker* court:

> Congress created an alternative administrative remedy—the Countermeasures Injury Compensation Program—for covered injuries stemming from countermeasures taken in response to the declaration of a public health emergency (see 42 USC § 247d-6e [a]; 74 Fed Reg at 51154), as well as a separate federal cause of action for wrongful death or serious physical injury caused by the willful misconduct of covered individuals or entities (see 42 USC §247d-6d [d]). The provision of these exclusive federal remedies further supports our finding of preemption.[178]

Finally, the PREP Act contains a conspicuously worded provision that implies that removal jurisdiction would be appropriate. In listing various "procedures for suit," the PREP Act provides ten subparagraphs.[179] The first nine of these paragraphs all contain the qualifying phrase "in an action under subsection (d)," which refers to a claim for "willful misconduct."[180] However, the tenth provision, which omits this qualifying phrase, provides that the Court of Appeals for the District of Columbia Circuit "shall have jurisdiction of an interlocutory appeal by a covered person taken within 30 days of an order denying a motion to dismiss or a motion for summary judgment based on an assertion of the immunity from suit conferred by subsection (a) …."[181] Given that this provision does not appear to be limited to claims for willful misconduct, it would arguably apply to claims of ordinary negligence. This suggests an intent to permit removal, since it is not clear how any such appeal could be taken to the D.C. Circuit otherwise.

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[177] *See* 42 U.S.C.A. §§ 247d-6d(a)(1), (d)(1) (claim for "willful misconduct" is the sole exception to immunity), (e)(1) (claim for "willful misconduct" shall be maintained exclusively in the U.S. District Court for the District of Columbia), (e)(2-10) (establishing detailed procedural requirements and pleading requirements for a claim for "willful misconduct"); 247d-6e (establishing a no-fault compensation fund for certain categories of claimants, and requiring anyone bringing a claim for "willful misconduct" to exhaust the administrative claims process before commencing suit).

[178] 102 A.D.3d 140, 144 (3d Dep't 2012)

[179] 42 U.S.C.A. § 247d-6d(e).

[180] 42 U.S.C.A. § 247d-6d(e)(1-9). These requirements are discussed *supra,* Part III, 1A.

[181] 42 U.S.C.A. § 247d-6d(e)(10).

Before the COVID-19 pandemic, the only reported decision to squarely address removal jurisdiction under PREP is *Kehler v. Hood*.[182] There, a vaccine manufacturer was impleaded by the original defendants, a physician and a local hospital, on the theory of products liability. The manufacturer removed the case to federal court based on federal officer jurisdiction, claiming that the manufacturing process was pursuant to a government contract and subject to government specifications.[183] Once removed, the manufacturer moved to dismiss on the basis of, *inter alia*, immunity under the PREP Act. The district court granted dismissal as to the manufacturer, but declined to dismiss the original action against the physician and the hospital, instead remanding the action back to state court. It reasoned that, without the manufacturer, it could not exert federal question jurisdiction over the original complaint because the issue of PREP immunity was advanced as a defense.[184] In a footnote, the court summarily concluded that the doctrine of "complete preemption" did not apply.[185] However, neither the physician nor the hospital raised the issue of "complete preemption" in opposition to plaintiff's motion for remand, so the issue was never briefed.[186] Moreover, the H1N1 Declaration at issue in *Kehler* was much more narrowly worded than the current COVID-19 Declaration.[187]

Therefore, although it is a novel question of law, the existing authorities provide a colorable argument for a defendant seeking to remove an action to Federal court on the basis that the PREP

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[182] *Kehler v. Hood*, 4:11CV1416 FRB, 2012 WL 1945952, at *4 (E.D.Mo. May 30, 2012).

[183] We do not recommend arguing federal officer jurisdiction unless a defendant was acting under the direct oversight and direction of a federal officer. Compliance with regulations, and CMS guidelines, would not be sufficient. *See Watson v. Philip Morris Companies, Inc.*, 551 US 142, 153 (2007) ("A private firm's compliance (or noncompliance) with federal laws, rules, and regulations does not by itself fall within the scope of the statutory phrase 'acting under' a federal 'official.' And that is so even if the regulation is highly detailed and even if the private firm's activities are highly supervised and monitored.")

[184] *Id.*

[185] *Id.* at N5.

[186] Court filings available upon request.

[187] *Compare* 74 Fed. Reg. 30294 (Jun. 25, 2009) *with* 85 Fed. Reg. 15198 (Mar. 17, 2020).

Act applies to the claim. Recent opinions considering this issue in response to the COVID-19 pandemic are addressed in Part "3", below.

Most recently, the U.S. Department of Justice ("DOJ") filed a Statement of Interest on January 19, 2021, urging that the PREP Act "completely preempts claims relating to the administration or use of covered countermeasures with respect to a public health emergency."[188] Noting the importance of the courts giving credence to the Congressional bargain this country has made with private actors, such as hospitals, skilled nursing facilities, long-term care facilities, and other healthcare providers and facilities, to participate in an urgent national strategy without fear of disparate treatment in the various state courts, the DOJ recognized eight main points:

1. That the PREP Act is crucial to the "whole-of-nation response" to public health emergencies, such as the COVID-19 pandemic.[189]
2. That this response depends on the cooperation among private-sector partners and state and local officials across the nation.[190]
3. That "sweeping" immunity was granted to encourage such cooperation.[191]
4. That federal jurisdiction is proper since the PREP Act's exclusive federal cause of action creates federal question jurisdiction.[192]
5. That the nature of the complaint determines complete preemption, not the stated claims.[193]
6. That the PREP Act establishes as the sole exception to a grant of immunity for all Federal and state law claims, as well as over the excepted claims process, making the PREP Act a complete preemption statute.[194]
7. That *Maglioli* and its progeny's interpretations of the PREP Act's complete preemptive effect are incorrect and that their holdings should be limited to their facts.[195]
8. That HHS's Advisory Opinions are entitled to considerable weight.[196]

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[188] "Statement of Interest of the United States," *Debbie Ann Bolton v. Gallatin Center for Rehabilitation & Healing, LLC*, No. 3:30-cv-00683 (MD Tenn. Jan. 19, 2021) (hereinafter "DOJ Statement of Interest").

[189] *Id*. at 1-2.

[190] *Id*. at 2.

[191] *Id*.

[192] *Id*. at 5.

[193] *Id*. at 6.

[194] *Id*. at 7-8.

[195] *Id*. at 10-12.

[196] *Id*. at 13.

Notably, the DOJ's Statement of Interest should be considered the official position of the United States' interest in enforcement of the PREP Act, in ensuring the protections afforded by Congress under it, and in establishing consistency in its interpretation and application.

B. Motion to Dismiss

A defendant may also several grounds to file a motion to dismiss, both procedural and substantive. If the action is removed to Federal court, the three basis for dismissal are pursuant to the Federal Rules of Civil Procedure ("F.R.C.P.") are: (1) § 12(b)(1) for lack of subject-matter jurisdiction; (2) § 12(b)(6) for failure to state a claim upon which relief can be granted; and (3) § 12(b)(3) for improper venue.[197] Alternatively, if the pleadings in an action are closed, a defendant may move pursuant to F.R.C.P. § 12(c) for judgment on the pleadings. There are analogous procedures in state court for obtaining a dismissal.

When first reviewing a complaint, a defendant should assess whether they can move to dismiss on grounds that it asserts claims that are barred by the PREP Act. When the complaint alleges that the defendant affirmatively misused a product that would qualify as a countermeasure, a motion to dismiss that allegation should be brought, and the defendant should request judicial notice that the product was a countermeasure. However, the decision is less clear when the complaint does not reference the use of any products, or only raises generalized allegations of negligence with respect to infection control. In such instances, a defendant should determine whether the complaint will put into issue the defendant's countermeasure activities, and if so, attempt a motion to dismiss.[198] At the very least, such a motion will likely have the effect of

[197] In most instances it behooves a defendant to assert all of these grounds for dismissal simultaneously, since, given the lack of case law on the issue, it is not clear whether the applicability of the PREP Act will be considered an issue of subject-matter jurisdiction, failure to state a claim, or improper venue.

[198] If the complaint is overly vague, a motion to compel a more precise statement can be brought. F.R.C.P. § 12(e).

narrowing the allegations of negligence, since a plaintiff may retract certain allegations in response to the motion in an attempt to avoid dismissal.

Because the only viable claim in a situation where the PREP Act applies is a claim for "willful misconduct," a defendant arguing for dismissal on the basis that the PREP Act applies should assert, as alternative bases for dismissal, that the procedural and pleading requirements for a claim for "willful misconduct" are not met.[199] This is true even when the complaint does not allege "willful misconduct," since otherwise a plaintiff may attempt to recast their complaint or seek leave to amend.[200] As noted above, these requirements include pleading with specificity, attaching certain documents to the pleadings, bringing the claim in the proper venue, and exhausting all administrative remedies.

C. Affirmative Defenses

Regardless of whether the case is removed to Federal court, a defendant must be sure to assert PREP Act specific affirmative defenses in an Answer to the complaint. If there is any possibility that the PREP Act might apply to the complaint, the statute itself should be raised as an affirmative defense, on the collective bases of preemption, immunity, lack of subject-matter jurisdiction, and failure to state a claim.[201] This affirmative defense should be sufficiently specific to comply with the applicable pleading requirements of the jurisdiction, and if necessary set forth

[199] Again, these should be asserted under FRCP § 12(b)(1), (3), and (6), since it is not clear which of these are appropriate in this context and there is a plausible argument for each.

[200] Even though the standard for "willful misconduct" is greater than negligence or recklessness, a plaintiff may try to argue that boilerplate allegations of gross negligence and wrongful conduct are actually claims for "willful misconduct."

[201] Arguably, the statute deprives courts of subject matter jurisdiction to entertain preempted claims, which cannot be waived, so a defendant who fails to raise the statute may still be able to move for dismissal. However, because the courts have not squarely addressed whether the PREP Act is an affirmative defense, it behooves a defendant to err on the side of caution and assert it in any responsive pleading.

a brief statement of facts indicating that the defendant was a "covered person" and was engaging in a "recommended activities" with respect to "covered countermeasures."

If the complaint includes any language suggesting that gross negligence or willful conduct is claimed, even if boilerplate, a defendant should also assert all defenses that would be available against a claim for willful misconduct, including that the plaintiff failed to properly plead willful misconduct and serious physical injury, failed to exhaust administrative remedies, brought the case in the wrong venue, failed to attach the necessary documents, and did not meet the applicable statute of limitations. A defendant who is a program planner or qualified person should also include, if applicable, the defense that it promptly notified state, local, or federal authority about an injury arising from the administration of a countermeasure.

In addition, if the plaintiff contracted COVID-19, a defendant should argue the traditional common law negligence defenses such as (1) comparative negligence; (2) assumption of risk; (3) superseding and intervening cause; (4) public/private emergency doctrine; and (5) act of God or force of nature beyond the defendant's control.

Lastly, a defendant should assert state and local liability protections that may stem from executive orders, good Samaritan laws, emergency medicine statutes, or recent legislative enactments. Otherwise, a defendant may be deemed to have waived these defenses.

D. Counterclaim

A defendant may also have grounds to file a counterclaim for declaratory judgment[202] concerning the applicability of the PREP Act. Jurisdiction would likely exist over such a

[202] Federal Rules of Civil Procedure 13 and 57 govern counterclaims and declaratory judgments respectively.

counterclaim pursuant to 28 U.S. Code § 1331, in that a justiciable controversy exists regarding the immunities and other requirements of the PREP Act.[203] Based on the allegations of the plaintiff's complaint, an actual and justiciable controversy between a plaintiff and a defendant have arisen and likely exist– whether Defendants are afforded immunity from Plaintiff's lawsuit pursuant to the PREP Act.

In the context of the PREP Act, the declaratory judgment should seek a judicial declaration that:

a. Defendants were engaged in the administration and/or use of covered countermeasures, including, without limitation, the administration and/or use of an infection control program, PPE, symptom screening, COVID-19 testing, and social distancing;
b. Defendants are immune from Plaintiff's lawsuit and claims pursuant to the PREP Act;
c. Plaintiff has failed to exhaust administrative remedies set forth in the PREP Act; and
d. Plaintiff's Complaint for Damages must be dismissed with prejudice.

Filing a counterclaim for declaratory judgment at the outset of the case creates speedy resolution of the controversy and potentially saves the parties and the Court tremendous expense, and will preserve resources.

[203] "Federal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn v. Minton*, 568 U.S. 251, 258, 133 S.Ct. 1059, 185 L.Ed.2d 72 (2013).

E. Discovery Needed

If a claim proceeds to discovery, a defendant should propound specific written requests in an effort to obtain evidence for establishing PREP Act immunity, in addition to the standard written discovery requests. These requests should focus on a timeframe beginning in January 2020 given that is when COVID-19 began spreading. Interrogatories should solicit details regarding any COVID-19 testing and treatment a plaintiff received, including the timing, location, type, and results, as well as information related to a plaintiff's recent travels, any shelter-in-place orders of their locale, and any individuals they may have encountered who were diagnosed with COVID-19. A defendant should also propound specific interrogatories requiring a plaintiff to disclose all facts showing willful misconduct, exhaustion of administrative remedies, and all facts evidencing a serious physical injury.

In the same vein, Requests for Production of Documents should revolve around medical records related to a plaintiff's diagnosis of COVID-19 and related injuries, hospitalizations, treatment, and healthcare providers. Defendants should also request communications or warnings received from the defendants, governmental entities, hospitals, or healthcare providers related to COVID-19. Additionally, requests should aim to uncover any collateral sources a plaintiff may have received in order to reduce a plaintiff's available remedy.

Finally, a defendant should send Requests for Admissions that establish: (1) the care provided to a plaintiff was within timeframe for immunity established by the Declaration (February 4, 2020 to October 1, 2024); (2) that the defendant was using and administering countermeasures as part of its infection control protocols; (3) that a public health emergency had been declared; (4) that the defendant was a covered person; and (5) that the care provided included efforts to diagnose or treat COVID-19, or prevent its spread. By obtaining the above information, documents, and

admissions, a defendant can develop evidence for a Motion for Summary Judgment arguing that PREP Act immunity applies.

F. Motion for Summary Judgment

If an initial motion to dismiss is not successful, a defendant can use the evidence obtained from PREP Act specific written discovery requests, as well as deposition testimony and affidavits from individuals with firsthand knowledge of the infection control practices being implemented, to file a Motion for Summary Judgment as soon as they are able. Unlike a Motion to Dismiss, a Motion for Summary Judgment provides the defendant with the ability to offer evidence to demonstrate, affirmatively, that they were a "covered person" engaging in a "recommended activity" with a "covered countermeasure," thus shifting the burden onto plaintiff to disprove those claims. The Motion for Summary Judgment should first outline a plaintiff's claims in a manner that makes it clear that there is a "causal nexus" between the allegations of negligence and the defendant's "recommended activities," and then outline all of the facts that demonstrate the defendant was in fact using or administering covered countermeasures.[204] The Motion should also address any deficiencies in plaintiff's expert testimony, such as (1) a failure to establish to a reasonable degree of professional certainty when, where, and how the claimant was exposed to COVID-19; and (2) a failure to establish that a standard of care existed at the time of the alleged conduct.

3. Recent PREP Act Litigation

Since the COVID-19 pandemic, U.S. district courts have addressed whether a state law claim can be removed to federal court under the PREP Act. All but one of those opinions have

[204] For example, by highlighting all broad allegations of negligence with respect to infection control, and broad allegations that all of the defendant's conduct proximately caused the injury alleged, before offering factual evidence to demonstrate that the defendant's infection control practices involved the use of covered countermeasures.

held that removal was improper, albeit for different reasons. Some of the notable cases are addressed below in chronological order. Because appellate rights are limited in situations where a court remands a case for lack of federal subject-matter jurisdiction, their precedential impact is limited and other district courts are not obligated to follow them. Notably, no cases appear to have been filed for "willful misconduct" in the District of Columbia.

Note, in the case that denied plaintiffs' request for remand, the Court also granted dismissal based upon the PREP Act.

A. *Maglioli v. Andover Subacute Rehab. Ctr.*

The first opinion to consider the applicability of the PREP Act in the context of the COVID-19 pandemic was *Maglioli v. Andover Subacute Rehab. Ctr*.[205] In a decision from Judge Kevin McNulty of the District Court for the District of New Jersey, issued August 12, 2020, the court remanded a case back to state court after concluding that it lacked federal question jurisdiction.[206] The case involved a COVID-19 outbreak at a nursing home, of which the four decedents were residents. It was alleged that the management "failed to take the proper steps to protect the residents and/or patients at their facilities from the Covid-19 virus" and that masks were only provided to certain staff members, and not others. It was also alleged that the defendants failed to observe a variety of precautions, including restrictions on visitors and monitoring of employees.[207] The defendants removed the case, asserting "complete preemption" under the PREP Act.[208] In rejecting that argument, the court narrowly construed the preemptive impact of the PREP Act and

[205] Nos. 20-6605, 20-6985, 2020 WL 4671091 (D.N.J. Aug. 12, 2020).

[206] The court was not entirely clear about whether it determined that "complete preemption" did not apply to the PREP Act, or whether it determined that the applicability of the PREP Act was not sufficiently clear on the face of the pleadings.

[207] *Id.* at *2.

[208] The defendants also attempted to assert "federal officer" jurisdiction because of the amount of federal guidance that had been issued in response to COVID-19, but the court rejected that argument as well. *Id.* at **11-13. *See supra*.

concluded that it does not "occupy the field" of malpractice law but only "limits the range of what the plaintiff can sue for."[209] It also reasoned that that the PREP Act would not apply to an allegation of a "failure" to provide a countermeasure and implied, without deciding, that the plaintiff might have such a claim.[210] It also observed that the plaintiffs were not claiming to have been injured from a countermeasure itself.[211]

A defendant seeking to remove a suit should be prepared to address this opinion, as it will likely be raised by the plaintiff on a motion to remand. In this regard, it should be argued that the *Maglioli* court committed five key errors in reasoning: (1) it conflated the doctrine of "field preemption" with "conflict preemption," and never considered the two-prong test for complete preemption under *Beneficial Nat'l Bank*[212]; (2) it narrowly construed the preemptive impact of the PREP Act, in stark contrast to the plain wording of the Act[213]; (3) it adopted a dichotomy between "action" and "inaction," and failed to account for the possibility that the plaintiff was challenging systemic conduct, which would include a combination of action and inaction[214]; (4) it did not appreciate the broad definition of "administration," which extends well beyond the physical provision of countermeasures to recipients[215]; and (5) it mistakenly believed that the plaintiffs would have to be claiming injury from the countermeasure itself, despite the examples in the Declaration of a slip-and-fall injury and a vehicular accident, both of which could trigger immunity.[216] Moreover, because appellate rights are limited on an order remanding for lack of

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[209] *Id.* at *9.

[210] *Id.* at *10.

[211] *Id.* at *10.

[212] 539 U.S. 1, 6 (2003); *Devon Energy Prod. Co., L.P. v. Mosaic Potash Carlsbad, Inc.*, 693 F.3d 1195, 1204 (10th Cir. 2012). *See supra*, Part III, 2, A, ii.

[213] *See* 42 U.S.C.A. §247d-6d(a)(1), (b)(8).

[214] *See supra*, Part II, 2.

[215] *See* the Declaration; *supra*, Part II, 2.

[216] *See id.*

subject-matter jurisdiction, courts of coordinate jurisdiction are not bound to follow the *Maglioli* opinion.

B. *Baskin v. Big Blue Healthcare, Inc.*

The next case to address the issue was the District Court for the District of Kansas, in an opinion dated August 19, 2020, in a *Baskin v. Big Blue Healthcare, Inc*.[217] That opinion was one of 12 substantively identical opinions filed in related cases with identical allegations of negligence, all of which arose out of a COVID-19 outbreak at a post-acute rehabilitation facility in Kansas City, Kansas.[218] Unlike the *Maglioli* court, the *Baskin* court did not arrive at the issue of "complete preemption," instead it remanded all 12 cases back to state court after concluding that the pleadings did not "clearly" fall under the scope of the PREP Act.[219] The court disregarded the "broadly worded" allegations of negligence, and concluded that the plaintiffs had primarily alleged that the defendants "failed" to provided countermeasures, as opposed to providing them negligently.[220] In this regard, the court relied heavily on pre-COVID-19 cases that involved the H1N1 declarations, all of which pertained to vaccine administration.[221] The court also reasoned that the PREP Act would not provide immunity to an entire facility simply because a single individual within that facility was using or administering countermeasures, since a claim against

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[217] No. 2:20-cv-2267, 2020 WL 4815074 (D.Kan., Aug, 19, 2020).

[218] Collectively, the 12 case numbers are as follows: No. 2:20-cv-2267-HLT-JPO, 2020 WL 4815074; No. 2:20-cv-2262-HLT-JPO, 2020 WL 4815076; No. 2:20-cv-2261-HLT-JPO, 2020 WL 4815078; No. 2:20-cv-2263-HLT-JPO, 2020 WL 4815079; No. 2:20-cv-2265-HLT-JPO, 2020 WL 4815082; No. 2:20-cv-2291-HLT-JPO, 2020 WL 4815085; No. 2:20-cv-2318-HLT-JPO, 2020 WL 4815097; No. 2:20-cv-2266-HLT-JPO, 2020 WL 4815098; No. 2:20-cv-2259-HLT-JPO, 2020 WL 4815099; No. 2:20-cv-2316-HLT-JPO, 2020 WL 4815100; No. 2:20-cv-2319-HLT-JPO, 2020 WL 4815102; and No. 2:20-cv-2264-HLT-JPO (not available on westlaw). All pinpoint citations that follow will be in reference to the first of these opinions.

[219] *Baskin*, No. 2:20-cv-2267, 2020 WL 4815074, **6-8 (D.Kan., Aug, 19, 2020).

[220] *Id.* at *6.

[221] *Id.* at *6. *Compare* 74 FR 30294 (Jun. 25, 2009), 74 Fed. Reg. 50968 (Oct. 2, 2009), and 74 Fed. Reg 51153 (Oct. 5, 2009) *with* the Declaration.

the facility would not necessarily be causally related to that individual's conduct.[222] Notably, however, the court limited its holding on the wording of the pleadings, and acknowledged that "[t]o the extent Plaintiffs' claims evolve, the applicability of the PREP Act could certainly be revisited."[223]

Like the *Maglioli* opinion, a defendant seeking to remove a case to Federal court under the PREP Act should be prepared to address the *Baskin* opinion. In this regard, it should be emphasized that the *Baskin* court made three main errors in reasoning: (1) it did not appreciate that the allegations of the complaint pertained to systemic misconduct, as opposed to the individual misconduct that was at issue in the H1N1 cases; (2) in relying on the H1N1 cases, it did not acknowledge that the COVID-19 Declaration provides for a much broader swath of covered countermeasures, many of which are intended to maintain a clean environment through which many individuals will pass, as opposed to vaccines which are administered to a single individual at a time; and (3) it narrowly construed the pleadings to allege only inaction, without explanation for why it was abandoning the traditional rule that pleadings are to be liberally construed. Even so, the *Baskin* opinion can be helpful in that it did acknowledge the broad preemptive impact of the PREP Act where it does apply, and it left the door open for the defendants to show, through affirmative evidence, that they were in fact engaging in countermeasure activities that would bring plaintiff's broadly worded allegations under the scope of the PREP Act.

C. *Hopman v. Sunrise Villa Culver City*

On August 25, 2020, Judge R. Gary Klausner of the Central District of California issued an order *sua sponte* remanding the case back to state court in *Hopman v. Sunrise Villa Culver*

[222] *Id.* at *7.

[223] *Id.* at Note 15. *See also, id.* at Note 12.

City.[224] The case involved an assisted living resident who contracted COVID-19 and passed away. His estate brought claims for elder abuse, negligence, breach of contract, willful, misconduct, and wrongful death. Defendants removed the case to federal court, citing "complete preemption" as a basis for removal. Shortly after removal, they moved to dismiss. Although the plaintiff did not move to remand, the court issued an "in chambers" order remanding the case back to state court, without providing an opportunity for the defendants to brief or argue the issue.[225] In its brief opinion, the court reasoned that the Complaint did not facially assert a claim under the PREP Act, and that the defendants could not rely on the affirmative defense of the PREP Act. Notably, the court never addressed the defendant's argument that the doctrine of "complete preemption applied." The motion to dismiss was not considered.

A defendant seeking to address this outcome should stress that the court never provided an opportunity for any party to brief the issue of removal jurisdiction, and never considered the issue of complete preemption. Moreover, it did not engage in any analysis of the PREP Act, except to note that the defendants sought immunity under it.

D. *Haro v. Kaiser Foundation Hospitals*

On September 3, 2020, Judge George H. Wu of the Central District of California issued an opinion in *Haro v. Kaiser Foundation Hospitals* remanding the matter to state court.[226] There, the employees of the defendant brought claims for back pay for the approximately 15 minutes that they were required to spend before the start of their shifts for COVID-19 screening.[227] The defendants removed the case to federal court, arguing that the PREP Act completely preempted

[224] No. 2:20-cv-07141-RGK-JEM (C.D.Cal., Aug. 25, 2020) (not available on Westlaw).

[225] Opinion available upon request.

[226] No. CV 20-6006-GW-JCx, 2020 WL 5291014 (C.D. Cal. Sep. 3, 2020).

[227] *Id.* at *1.

the claims because their screening process involved the use of countermeasures.[228] The court did not address the merits of the complete preemption argument, instead finding that the PREP Act did not apply to the claims.[229] The court reasoned that the claims were not causally related to the countermeasures, but to the fact that the employees were required to appear 15 minutes before their shift and were not being compensated for that time.[230] It explained that the screening procedures could easily have occurred during the employees' shifts, instead of beforehand, so the administration of those countermeasures had no causal relationship to the claims for back pay.[231]

The factual context of these claims make this opinion readily distinguishable from any case arguing that the plaintiff contracted COVID-19 as a result of negligent infection control. Unlike a claim for back pay, the use of countermeasures is causally related to the spread of COVID-19 within a given environment, so claims that the environment is unsafe are causally related to the use and administration of countermeasures. The *Haro* scenario is more akin to the example of a staff member who assaults a patient while wearing a surgical mask—the countermeasure is merely incidental to the underlying claim. Moreover, although it did not reach this issue, there is an argument that a claim for back pay is not a type of "loss" that congress intended to provide immunity for under the PREP Act.[232]

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[228] *Id.*

[229] *Id.* at *3.

[230] *Id.*

[231] *Id.*

[232] *See* 42 U.S.C. 247d-6d(a)(2)(A). Although the term "loss" is defined as "any type of loss," none of the examples provided include wage and hour claims. Moreover, if congress had intended to provide immunity against such claims, then manufacturers and front-line providers could forego paying their employees, who are manufacturing, using, and administering covered countermeasures, with impunity. This would be an absurd result and would run contrary to the congressional intent of encouraging action during a public health immunity.

E. *Martin v. Serrano Post Acute LLC*

On September 10, 2020, Judge Dale S. Fischer of the Central District of California issued an order remanding the matter back to state court in *Martin v. Serrano Post Acute LLC*.[233] That case involved a nursing home resident who contracted COVID-19. After he passed away, his family brought suit against the facility, alleging failure to properly staff, failed to prevent the spread of COVID-19, and failed to react properly to cases of infection.[234] The defendants removed the case to federal court, arguing in part that complete preemption applied.[235] The Court rejected that argument, reasoning that the plaintiff did not bring a claim under the PREP Act for willful misconduct, and that congress had not "completely occupied the field of actions or inactions related to COVID-19 spread and treatment …."[236] The court also noted that the defense did not provide any justification for why complete preemption applied, aside from stating the standard for complete preemption.[237]The court instructed the defendants to invoke the PREP Act defense by filing a demurrer in state court.[238]

This outcome, and reasoning, is similar to that adopted by the *Maglioli* court. It suffers from some of the same deficiencies in that it (1) never addressed the two-part inquiry for "complete

[233] No. 2:20-cv-05937-DSF-SK, 2020 WL 5422949 (C.D.Cal., Sep. 10, 2020).

[234] *Id.* at * 1.

[235] The defendants also argued "federal officer" jurisdiction (*see supra*) and "embedded federal question" jurisdiction (*see, e.g., Gunn v. Minton*, 568 U.S. 251 (2013)). The court rejected the first argument because mere compliance with federal regulations does not create federal officer jurisdiction. *Martin*, 2020 WL 5422949, *1. The court rejected the second argument because the federal question was presented by way of defense, and because the case raised no substantial questions important to the federal system as a whole. *Id.* at **2-3.

[236] *Id.* at * 2.

[237] *Id.*

[238] *Id.*

preemption" under the Supreme Court precedent of *Beneficial Nat'l Bank*[239]; and (2) it conflated "field preemption" with "complete preemption."[240]

Most recently, this case has been Re-Removed back to federal court following the State Court's directive based upon the Fourth Amendment to the PREP Act and the recent guidance issued in January 2021.

F. *Saldana v. Glenhaven Healthcare LLC*

On October 14, 2020, Judge Fernando M. Olguin of the U.S. District Court for the Central District of California issued an order of remand in the matter of *Saldana v. Glenhaven Healthcare LLC*.[241] The claim involved a nursing home that allegedly prevented employees from wearing face coverings and did not distribute a box of face masks provided by the local fire department. It was also alleged that the nursing home misrepresented its efforts to combat COVID-19 and downplayed the virus.[242] The plaintiffs brought claims for negligence, elder abuse, willful misconduct, and wrongful death. The defendants removed the matter to Federal Court based on "complete preemption" under the PREP Act and "federal officer jurisdiction" because of CDC and CMS directives.[243]

The court did not permit oral argument on the motion to remand, and issued an in-chambers order that was not intended for publication. With respect to the "complete preemption" argument, the court did not apply the two-prong standard set forth by the Supreme Court case of *Beneficial Nat'l Bank*. Instead, the court held that immunity under the PREP Act would amount to an

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[239] 539 U.S. 1, 6 (2003); *See supra,* Part III, 2, A, ii.

[240] *See Devon*, 693 F.3d at 1204 (10th Cir. 2012).

[241] No. CV 20-5631-FMO, 2020 WL 6713995 (C.D.Cal., Oct. 14, 2020).

[242] *Id.* at *1.

[243] *Id.*

affirmative defense (preemption) that would not provide a basis for removal. It did not reach the merits of whether the PREP Act applied.

Like *Maglioli* and *Martin*, the *Saldana* remand order never addressed the two-part inquiry for "complete preemption" under the Supreme Court precedent of *Beneficial Nat'l Bank*[244] The only discussion of complete preemption within the opinion is the court's observation that the PREP Act was "not one of the three statutes that the Supreme Court has determined has extraordinary preemptive force."[245] However, the court did not acknowledge that the lower courts have applied the doctrine to at least 10 other statutes than the three that the Supreme Court has addressed, nor did it acknowledge that the framework of the PREP Act is similar to many of those other statutes.

G. *Sherod v. Comp. Health Mgt.*

On October 16, 2020 Judge Arthur Schwab issued an order remanding a case to state court after concluding that the PREP Act did not apply to the face of the complaint in *Sherod v. Comp. Healthcare Mgt*.[246] The complaint focused largely on a series of regulatory violations assessed against the defendant skilled-nursing facility, including the failure to implement proper sanitization protocols and to maintain and abide by an infection control policy.[247] The plaintiff also vaguely alleged failures in the use of PPE, that PPE was not provided or was refused, and that federal guidance was not followed.[248] The plaintiff also pled misrepresentation.[249] The defendants removed on the theory that the PREP Act applied, triggering "complete preemption," and that they were acting under the direction of federal officers, triggering "federal officer jurisdiction." [250]

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[244] 539 U.S. 1, 6 (2003); *See supra*, Part III, 2, A, ii.

[245] *Saldana*, 2020 WL 6713995 at *2.

[246] No. 20-CV-1198, 2020 WL 6140474 (W.D. Pa. Oct. 16, 2020).

[247] *Id.* at *2.

[248] *Id.* at *2-3.

[249] *Id.* at *4.

[250] *Id.* at *4-5.

The court relied heavily on the prior *Maglioli* and *Baskin* opinions. It concluded that the complaint alleged failure to use or provide countermeasures, and that the PREP Act did not apply to allegations of inaction.[251] The court did not decide whether claims falling under the PREP Act would trigger "complete preemption" because it concluded the PREP Act did not apply to the face of the complaint. The court also rejected the defendants' federal officer arguments in a subsequent opinion.

Embracing the flawed reasoning of *Maglioli* and *Baskin*, the *Sherod* remand order did not address the concept of systemic misconduct as opposed to individual inaction, adopting the action vs inaction dichotomy found in other opinions. It also did not address the argument that any allegation triggering the PREP Act would provide supplemental jurisdiction over the entirety of the complaint, even if other allegations are outside of the scope of the PREP Act.

H. *Fields v. Arbor Terrace*

On October 28, 2020 Judge Batten of the Northern District of Georgia issued an order of remand in *Fields v. Arbor Terrance*[252] finding the PREP Act inapplicable to the plaintiff's complaint. In the complaint, the plaintiff alleged the defendant facility failed to take appropriate precautions designed to prevent the spread of COVID-19 to residents and staff leading to the decedent's contraction of COVID-19 and eventual death. The complaint included allegations that the defendant's staff failed to wear personal protective equipment, the facility allowed asymptomatic staff who had been exposed to COVID-19 to continue providing patient care, and

[251] *Id.* at *7-8.

[252] No. 1:20-CV-2346-TCB (N.D. Ga. Oct. 28, 2020) (not available on Westlaw).

the facility failed to restrict visitation by individuals from outside the facility.[253] The defendant filed a notice of removal on the basis of the PREP Act, and the plaintiff file a motion to remand.

Judge Batten granted the motion to remand finding the defendants did not show they were involved in a "recommended activity" relative to a "covered countermeasure."[254] The court found that the definition of "administration" is limited to the physical provision of a countermeasure to a recipient and does not include management and operation of facilities that distribute and dispense countermeasures.[255] Embracing the rationale of *Baskin*, *Maglioli*, *Martin*, and *Haro*, the court held that the failure to take preventive measures to stop the spread of COVID-19 within a facility is not covered by the PREP Act.[256] As a result, because the court found the PREP Act does not apply, it does not preempt the plaintiff's state law claims.

The *Fields* remand order echoes and embraces the flawed reasoning established by *Baskin*, *Maglioli*, *Martin*, and *Haro*. The *Fields* remand order was also issued without consideration of HHS Advisory Opinion 20-04, which expressly extends PREP Act immunity beyond the physical provision of countermeasures.

I. *Gunter v. CCRC OPCP-Freedom Square, LLC*

On October 29, 2020, Judge Charlene Edwards Honeywell issued an order of remand in *Gunter v. CCRC OPCP-Freedom Square, LLC*. The plaintiff brought a negligence action in state court against the defendant healthcare facility based on an alleged failure to appropriately implement COVID-19 infection control procedures, including *inter alia* the failure to supply proper masks and gowns, follow CDC guidelines, and avail themselves of available PPE. The

[253] *Id.* at *6.
[254] *Id.*
[255] *Id.* at *7.
[256] *Id.* at *8-10.

defendants removed the case to federal court arguing that the PREP Act preempts the plaintiff's complaint and in turn supplies federal subject matter jurisdiction.

Relying on *Maglioli* and *Baskin*, the court issued an order of remand finding that the plaintiff pled a failure to act, which has nothing to do with the administration of qualified pandemic or epidemic product, drug, biological product, or device for which the PREP Act provides immunity. The *Gunter* court also distinguished Advisory Opinion 20-04 (which explained that the PREP Act can extend to claims to non-use) by confining the Opinion to the context of operating a vaccination program, which were not in issue in the plaintiff's complaint.

J. *Hendrix v. Arbor Terrace*

On October 23, 2020, Judge Mark Cohen of the Northern District of Georgia issued a remand order in *Hendrix v. Arbor Terrace*[257] finding it lacked subject matter jurisdiction. The plaintiffs filed suit against the defendant assistant living facility alleging claims of "failure to act" to prevent and stop the spread of COVID-19 causing the decedent's death. Similar to *Fields*, the *Hendrix* plaintiffs alleged the facility failed by (1) allowing asymptomatic staff who had been exposed to COVID-19 to continue working, (2) failing to enforce visitation restrictions, and (3) failing to confirm all staff members wore personal protective equipment.[258]

First, utilizing the reasoning established by *Gunter*, *Sherod*, *Martin*, *Baskin* and *Maglioli*, the *Hendrix* court held that the failure to take adequate countermeasures to prevent the spread of COVID-19 within a facility is not preempted by the PREP Act.[259] Second, the court rejected the defendant's argument that federal question jurisdiction still exists because there is a "substantial

[257] No. 1:20-CV-2326-MHC (N.D. Ga. Nov. 23, 2020) (not available on Westlaw).

[258] *Id.* at *3-4.

[259] *Id.* at 11-12.

imbedded question of federal law."[260] The court reasoned that no imbedded federal question exists because the raised federal issue is the defendant's defense, rather than related to the actual claims made by the plaintiffs. Third, the remand order distinguished Advisory Opinion 20-04, which explained that *Casabianca v. Mount Sinai Med. Ctr.*, 2014 WL 10413521 (N.Y. Sup. Ct. Dec. 12, 2014) was wrongly decided. Judge Cohen explained that Advisory Opinion 20-04 does not undermine prior COVID-19 remand opinions relying on *Casabianca* because the decision in *Casabianca* to prioritize the H1N1 vaccine when the same was not generally available is not akin to the failure to undertake ***any*** covered countermeasures as alleged by the plaintiffs in the *Hendrix* complaint. [261]

K. *Johnson v. Arbor Terrace*[262]

Judge William Ray of the Northern District of Georgia issued a remand order in the above referenced case on December 1, 2020. The Court held the plaintiff's complaint did not implicate the PREP Act because it only alleged a "failure to use" covered countermeasures, which is outside of PREP Act immunity. In support, the *Johnson* Court adopted the reasoning utilized in *Fields* and *Maglioli*, which held that claims of inaction concerning the use of covered countermeasures are not preempted by the PREP Act.

L. *Deleon v. Trinity Health Center*

On December 22, 2020, Judge Robert Pitman of the United States District Court for the Western District of Texas-Austin Division issued a remand order in the above referenced case,[263] which involved a skilled-nursing facility resident who died of COVID-19. The Court ordered

[260] *Id*. at *13.

[261] *Id*. at *15-16.

[262] No. 1:20-cv-02328-WMR (N.D. Ga. Dec. 1, 2020) (not available on Westlaw).

[263] No, 1:20-cv-00945-RP (W.D. Tex. Dec. 22, 2020) (not available on Westlaw).

remand finding that: (1) the PREP Act did not apply to the allegations because they amounted to claims of "failure" to implement infection control measures; and (2) federal officer jurisdiction did not apply where the defendant asserted only compliance with CMS regulations and CDC guidelines. The court denied sanctions for improper removal, noting that this is "not a well settled area of law." As seen in other remand orders, the *Deleon* Court failed to take into account the true nature of the claims before it, and essentially relied on *Maglioli,* without adding much else to the equation.

M. *Parker v. St. Jude Operating Company, LLC d/b/a Healthcare at Forest Creek*[264]

The District court remanded the *Parker* case, which involved a skilled nursing resident who died of COVID-19. The Court found that the PREP Act did not trigger the doctrine of "complete preemption" because (1) is did not "wholly displace" all state tort-law claims involving healthcare facilities and COVID-19, and (2) the narrow remedy of a "willful misconduct" claim did not provide a total "substitute" cause of action for claims subject to PREP Act immunity. Notably, the Court assumed *arguendo* that the defendant was using "covered countermeasures" at the time, and noted that at least some of plaintiff's claims amounted to allegations of "misuse," despite their argument that they were claiming a complete "failure" to use countermeasures. Also, the Court stated that: "[w]hat PPE was in use … and the extent of the allegations related to misuse

[264] No. 3:20-cv-01235-HZ (D. Ore. Dec. 28, 2020) (not available on Westlaw).

will be determined during discovery and at trial," leaving the door open for the state court to decide the issue.

N. Garcia v. Welltower OpCo Group, LLC, et al.[265]

The District Court denied Plaintiffs' Motion to Remand and granted Defendants' Motion to Dismiss. Plaintiff was a resident at Defendants' facility from 2017 through the COVID-19 pandemic, passing away on July 3, 2020. The crux of Plaintiff's claim was that Defendants "failed to implement appropriate infection control measures or follow local or public health guidelines in preparing for and preventing COVID-19 spread" and as a result plaintiff was caused to contract COVID-19 and pass away from the same. The primary basis of his conclusion has been what Defendants across the country have been arguing: that the PREP Act applies to nursing facilities by virtue of their classification as "program planners" administering and using covered countermeasures, such as PPE and that the PREP Act is a complete preemption statute. In support of his conclusions, he relies upon the Fourth Amendment to the PREP Act Declaration for COVID-19 Countermeasures and Advisory Opinion 20-01 from January 8, 2021. Of note, in the context of senior living and long term care specifically, Judge Selna states that, "[t]aken as true, all Plaintiffs' FAC discloses are possible unsuccessful attempts at compliance with federal or state guidelines – something which the PREP Act, the Declaration, and the January 8, 2021 Advisory Opinion cover.

O. Key Takeaways

There are 94 federal district courts, with 677 different judges, and it is common for courts to disagree on how a novel issue of law should be resolved. These early opinions reinforce the importance of thoroughly briefing the issue of "complete preemption" and the applicability of the PREP Act in any case that is removed. Some courts did not address the appropriate two-prong

[265] No. 8:20-cv-02250-JVS-KES (Central District of California February 10, 2021) (not available on Westlaw).

standard for "complete preemption"; some courts mistakenly required that the doctrine required the statute to displace an entire "field" of law, such as medical malpractice claims involving COVID-19; and no court has acknowledged the parallels between the ATSSSA and the PREP Act.[266] Also, the courts that considered the applicability of the PREP Act to the face of the pleadings fail to acknowledge the broad definition of the phrase "administration" or the examples of a slip-and-fall and a vehicular accident. Likewise, some courts have adopted an extremely narrow interpretation of Advisory Opinion 20-04, and similarly, other courts have construed the pleadings far more narrowly than they would be construed in any other setting.[267] Most importantly, most of these opinions was issued ***prior to*** the Fourth Amendment of the Declaration, which clarifies the substantial federal legal and policy interests related to COVID-19 and PREP Act claims. Notably, although the *Deleon* and *Parker* remands were issued after adoption of the Fourth Amendment, neither opinion addresses the Fourth Amendment to the Declaration or Advisory Opinion 20-04 that rejected *Casabianca*.

Critically, these opinions are not binding on any future court. They are also limited to the pleadings of each case, which will vary between cases. Other courts faced with the same issues may arrive at a different outcome, especially considering the novelty of the issues and the lack of guiding appellate court precedent. Therefore, any defendant seeking to obtain the benefits of a federal forum for their PREP Act defense should not be dissuaded by these early opinions.

IV. CONCLUSION

Given the number of confirmed cases and deaths due to COVID-19, hospitals, long term care facilities, and healthcare providers should anticipate an increase in lawsuits criticizing their

[266] *See supra*, Part III, 2, A, ii.

[267] *See supra*, Part II, 2.

care and response. The PREP Act has great potential to provide a strong defense against such claims, and it should be utilized in preparing motions, defenses, and discovery. Each case will require a fact-specific PREP Act analysis, but if there is any possibility that it applies, a defendant should make every effort to enjoy the procedural and substantive benefits it affords. The PREP Act was intended to reward action in the face of a national public health emergency, and the COVID-19 pandemic is the greatest such emergency in modern history. Front-line healthcare and senior care workers should be rewarded, not punished, for their actions during the pandemic.