HHS Has Undertaken an Unprecedented Expansion of the PREP Act Over the Past Year to Combat COVID-19, but Will Litigants, and the Courts, Get the Message?

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Executive Summary

The Public Readiness and Emergency Preparedness Act (PREP Act) is a dramatic and wide-ranging grant of liability and suit immunity to private entities that the government wishes to enlist in the battle against COVID-19. Its goal is clear: to shift the costs away from those wishing to engage in the fight and grant them certainty and protection against lawsuits for negligence. However, as of this writing, very few organizations have been successful in invoking its protections in the waves of litigation surrounding harm arising from the disease.

Meanwhile, the federal government's guidance regarding the PREP Act has evolved dramatically since the pandemic began rapidly spreading across the United States in March 2020. On March 10, 2020, the Secretary for the U.S. Department of Health and Human Services (HHS) issued a declaration applying the liability immunities of the Act to medical countermeasures against COVID-19.

Since then, HHS has issued seven amendments and six advisory opinions clarifying the declaration's scope and enlarging its application. Although the PREP Act became law in 2005, its invocation has been rare and never on a scale so potentially far-reaching. More recently the courts have split on whether the PREP Act is a complete preemption statute conferring federal jurisdiction, with the majority concluding it is not, contrary to guidance from HHS and the U.S. Department of Justice (DOJ).

This article endeavors to summarize these recent developments and raise important questions as to who is, and is not, taking advantage of this powerful statute.

I. Background of PREP Act and Overview of Key Provisions

1. Background

The PREP Act is invoked when the Secretary of HHS issues a declaration determining that a disease or other health condition constitutes a public health emergency.[1] If that determination is made, the Secretary "may make a declaration, through publication in the Federal Register, recommending . . . the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that [certain liability immunities are] in effect with respect to the activities so recommended."[2] Once the Secretary has issued a declaration, the PREP Act provides sweeping immunity for certain claims against certain covered individuals. On March 10, 2020, the Secretary invoked his authority under the PREP Act to provide

[1] 42 U.S.C. § 247d-6d(b).
[2] *Id.*

immunity for medical countermeasures against COVID-19 to certain health care professionals tasked with responding to the crisis.[3]

2. Scope of Immunity

The PREP Act affords broad federal immunity to a "covered person" with respect to claims relating to the authorized administration or use of a "covered countermeasure."[4] As a general matter, if all the elements of immunity are met, it makes a covered person immune from suit and liability under Federal and State law with respect to "all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure."[5]

The PREP Act further defines the scope of its coverage to apply to "***any claim for loss*** that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure."[6] Covered losses include claims for death, physical, mental or emotional injury, illness, disability or condition, fear of such harm or need for medical monitoring, and loss of or damage to property, including business interruption loss.[7]

Because it is a ***federal*** immunity, the PREP Act covers claims sounding in tort or contract, as well as claims for loss relating to compliance with local, state, or federal laws, regulations, or other legal requirements.[8] The PREP Act also preempts "any provision of law or legal requirement that . . . is different from, or is in conflict with, any requirement applicable under this section" and that is "relate[d] to" those countermeasures.[9]

In place of tort remedies, Congress created the Covered Countermeasure Process Fund to compensate eligible individuals for serious physical injuries or deaths from countermeasures identified in declarations issued by the Secretary.[10] The PREP Act also creates, as "the sole exception to the immunity from suit and liability," an "exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct" of that person.[11] It further establishes an exclusive venue for such excepted claims: "only" before a three-judge panel of the United States District Court for the District of Columbia.[12] Even such excepted claimants, though, must first apply for benefits through the federal Covered

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[3] *Id.* §§ 247d-6d, 247d-6e.
[4] *Id*. § 247d-6(d)(a)(1).
[5] *Id*. § 247d-6d(c)(3).
[6] *Id*. § 247d-6d(a)(2)(B).
[7] *Id*. § 247d-6d(a)(2)(A)(iv).
[8] *See id.* § 247d-6d(b)(8).
[9] *Id*. § 247d-6d(b)(8).
[10] *See id*. § 247d-6e.
[11] *Id*. § 247d-6d(d)(1); *see also id*. § 247d-6d(c), (e)(1).
[12] *Id*. § 247d-6d(e)(1), (e)(5).

Countermeasure Process Fund, which permits individuals to make no-fault benefits claims for certain injuries.[13]

3. Overview of PREP Act's Provisions

It is important to understand the elements that give rise to immunity for health care providers and others. Below is an analysis regarding key provisions of the PREP Act.

A. What constitutes a "covered person"?

"Covered persons" include, among others, manufacturers and distributors of covered countermeasures, along with "program planners," "qualified persons," and their officials, agents, and employees, as those terms are defined in the PREP Act.[14] Among these persons, a "program planner" includes state and local government organizations that are supervising or administering programs to administer or distribute approved countermeasures.[15] This may include private sector employers or community groups when carrying out one of these state or local government programs.[16] In addition, a "qualified person" includes licensed health professionals authorized under state law to administer countermeasures,[17] and any person authorized by an appropriate federal, state, or local governmental agency (e.g., an "Authority with Jurisdiction") to administer, deliver, distribute or dispense covered countermeasures.[18]

B. What constitutes a "covered countermeasure"?

"Covered countermeasures" include, among other things, a "qualified pandemic product," and includes any FDA-approved devices, as well as drugs, devices, and products authorized for emergency use or that are being researched under certain investigational provisions, and which to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or to limit the harm such pandemic or epidemic might otherwise cause.[19] HHS has issued a list of non-exhaustive medical devices and therapeutics that have been authorized for emergency use in combatting COVID-19.[20]

C. What constitutes authorized "administration" or "use" of a covered countermeasure?

With respect to what constitutes authorized "**administration**" or "**use**" of a covered countermeasure, liability immunity is afforded to Covered Persons ***only*** for "Recommended

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[13] *See id*. § 247d-6e(d)(1).
[14] *Id.* § 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B).
[15] *Id.* § 247d-6d(i)(6).
[16] *See* 85 Fed. Reg. 15,198, 15,202.
[17] 42 U.S.C. § 247d-6d(i)(8).
[18] 85 Fed. Reg. 15,198, 15,202.
[19] 42 U.S.C. § 247d-6d(i)(7); 21 C.F.R. pts 312 and 812.
[20] *See* https://www.fda.gov/media/136702/download; https://www.fda.gov/media/136832/download.

Activities" (which include the "distribution, administration, and use of the Covered Countermeasures") involving Covered Countermeasures that are related to:

- Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements;
- Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an Emergency;
- Any Covered Countermeasure that is FDA-approved to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID-19 and administered pursuant to an FDA Emergency Use Authorization.

Immunity applies ***only*** when a covered person engages in activities authorized by an "Authority Having Jurisdiction" to respond to a declared emergency.[21] HHS has interpreted this broadly to include (1) any arrangement with the federal government, or (2) any activity that is part of an authorized emergency response at the federal, regional, state, or local level.[22]

II. Evolution of the PREP Act Over the Past Year

Through further interpretation of the Act, and by providing key examples, the Declaration, its seven amendments, and six advisory opinions demonstrate the wide potential application of PREP Act immunity and preemption across various industries. Whether federal courts will follow HHS's recent guidance interpreting the Act remains a key question in how broadly the Act will apply to cases moving forward.

1. PREP Act Declaration and Its Seven Amendments

The PREP Act Declaration and its seven amendments have significantly expanded the scope of the PREP Act's application to the COVID-19 pandemic.

A. PREP Act Declaration

As mentioned above, on March 10, 2020, former Secretary of HHS Alex Azar issued a declaration, effective February 4, 2020, under the PREP Act declaring that certain "covered countermeasures" are necessary to beat back a public health emergency such as COVID-19.[23]

The Secretary's COVID-19 declaration specifically affords immunity for "the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures." The declaration also defines "Covered Countermeasures" as "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19 . . . or any device used in the administration of any such product, and all components and constituent materials of any such product," limited to activities concerning

[21] *See* 42 U.S.C. 247d–6d(a)(5) and (b)(2)(E).
[22] HHS Advisory Opinion 20-01, Apr. 14, 2020.
[23] *See* 85 Fed. Reg. 15,198 (Mar. 10, 2020).

federal agreements or to "activities authorized in accordance with the public health and medical response" of state or local public agencies."[24] The Secretary has declared the immunities of the PREP Act are in place to fight COVID-19 until October 1, 2024.[25]

B. First Amendment to Declaration

On April 10, 2020, the HHS Secretary issued the First Amendment[26] to the COVID-19 Declaration to extend liability immunity to covered countermeasures authorized under the newly passed Coronavirus Aid, Relief, and Economic Security (CARES) Act.[27] Enacted on March 27, 2020, the CARES Act created a new category of covered countermeasures eligible for liability immunity under the PREP Act, namely respiratory protective devices approved by the National Institute for Occupational Safety and Health (NIOSH) or any successor regulations that the Secretary determines to be a priority for use during a public health emergency.

C. Second Amendment to Declaration

On June 4, 2020, the Secretary issued a Second Amendment[28] to his March 10, 2020 Declaration applying the federal immunities of the PREP Act to the fight against COVID-19. This Amendment was brought about because the Secretary's March 10 Declaration had inadvertently omitted a key phrase in the statutory definition of covered countermeasure, which states that qualified pandemic and epidemic products may also include products that "limit the harm such a pandemic or epidemic might otherwise cause." To correct this omission, therefore, the Second Amendment clarified that HHS intended to include all qualified pandemic and epidemic products defined under the PREP Act as covered countermeasures.

D. Third Amendment to Declaration

On August 24, 2020, the Secretary for HHS issued a Third Amendment[29] to his COVID-19 Declaration, broadening the liability immunity protections afforded by the PREP Act. Specifically, the Third Amendment to the Declaration identifies an additional category of persons as "qualified persons" covered under the PREP Act: certain licensed pharmacists who order and administer, and pharmacy interns (who are acting under the supervision of a licensed pharmacist) who administer, any vaccine that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18.

E. Fourth Amendment to Declaration

On December 3, 2020, HHS issued the Fourth Amendment to the Declaration under the PREP Act. Among other things, the Fourth Amendment[30] expressly adopts and incorporates the HHS General Counsel's prior advisory opinions, lays the foundation for litigants to assert federal-

[24] *Id*. at 15,202.
[25] *Id.*
[26] *See* 85 Fed. Reg. 21,012 (Apr. 15, 2020).
[27] Public Law 116–136.
[28] *See* 85 Fed. Reg. 35,100 (June 8, 2020).
[29] *See* 85 Fed. Reg. 52,136 (Aug. 24, 2020).
[30] *See* 85 Fed. Reg. 79,190 (Dec. 9, 2020).

question jurisdiction, and unequivocally states that the PREP Act also applies in certain cases of ***non-use***, failure to use, and even refusal to use Covered Countermeasures.

Perhaps most important among its provisions, the Fourth Amendment makes explicit 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." This statement paves the way for defendants seeking federal jurisdiction to remove state-court cases that implicate PREP Act immunities.[31] It also attempts to resolve a longstanding dispute in the state and federal courts over whether the PREP Act can serve as the basis of federal-question jurisdiction, to the extent those courts now defer to this administrative agency's interpretation of the PREP Act.

The Fourth Amendment, moreover, clarifies the scope of PREP Act immunity by, for example, making explicit that even the failure to administer a Covered Countermeasure to a particular individual can nevertheless fit within the wide reach of the PREP Act's liability protections. This runs counter to a host of recent court cases interpreting the PREP Act's liability protections to only apply to circumstances involving affirmative misuse of Covered Countermeasures.

F. Fifth Amendment to Declaration

On January 28, 2021, HHS issued the Fifth Amendment to the PREP Act Declaration.[32] This Amendment expands the categories of qualified individuals authorized to administer FDA-approved COVID-19 vaccines such that doctors and nurses whose licenses expired within the past five years can now administer COVID-19 vaccines, subject to certain training and observation requirements.

Although this amendment represents the fifth time the PREP Act Declaration has been amended, it's the first such amendment issued by the Biden Administration. Given the further expansion of the PREP Act that the Fifth Amendment entails, it suggests the new administration is not inclined to scale back PREP Act coverage—at least not initially.

G. Sixth Amendment to Declaration

On February 10, 2021, HHS issued the Sixth Amendment to the PREP Act Declaration.[33] This amendment immunizes federal employees, contractors, and volunteers authorized by their Department or agency to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of their duties or responsibilities. The purpose of this amendment is to address what HHS identified as "an urgent need to expand the pool of available COVID-19 vaccinators in order to respond effectively to the pandemic."[34] The amendment further emphasizes that any state law that would otherwise prohibit a member of any of the classes of

[31] *See Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mf'g*., 545 U.S. 308 (2005) (holding that state-law claims which implicate significant federal issues allow for federal-court jurisdiction).
[32] *See* 86 Fed. Reg. 7,872 (Feb. 2, 2021).
[33] *See* 86 Fed. Reg. 10,588 (Feb. 22, 2021).
[34] https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID-Amendment-6.aspx.

"qualified persons" specified in the Declaration from administering a covered countermeasure is likewise preempted.

H. Seventh Amendment to Declaration

On March 12, 2021, HHS issued the Seventh Amendment to the PREP Act Declaration.[35] This amendment further expands the category of individuals authorized to administer COVID-19 vaccines to properly trained individuals even if prescribing, dispensing, and administering vaccines is not within the scope of their license or usual responsibilities. Specifically, the Amendment authorizes dentists, EMTs, midwives, optometrists, paramedics, physician assistants, podiatrists, respiratory therapists, and veterinarians, as well as medical students, nursing students, and other health care students in the professions listed under the PREP Act with proper training and professional supervision, to serve as vaccinators. As "covered persons" under the Act, the Amendment also affords these individuals sweeping PREP Act immunities from state and federal personal injury claims arising from the authorized administration of the vaccine.

2. Six Advisory Opinions Interpreting PREP Act and Declaration

As of the date of publication, the HHS Office of the General Counsel (OGC) has released six advisory opinions in response to various requests from stakeholders about whether certain activities in connection with COVID-19 qualify for PREP Act immunity.

Although the later advisory opinions which have not been incorporated by the declaration do not have the force of law and therefore do not bind HHS or the federal courts, they set forth the current views of the OGC and endeavor to provide needed clarity to the scope of PREP Act immunity during the COVID-19 pandemic. And like the various amendments to the Declaration, the advisory opinions emphasize the breadth of PREP Act immunity and provide guidance which demonstrates its expansive application to a broad range of entities that take reasonable steps to follow public-health guidelines and directives in using covered medical products.

A. Advisory Opinion 20-01

On April 14, 2020, the OGC issued Advisory Opinion 20-01[36] specifying that PREP Act immunity may extend beyond actual "qualified persons" and approved "countermeasures"—even though they are technically not covered by the PREP Act—if one could have reasonably believed the persons or countermeasures were covered. The advisory opinion concludes by encouraging all covered persons using or administering covered countermeasures to document the reasonable precautions they have taken to safely use the covered countermeasures.

[35] *See* 86 Fed. Reg. 14,462 (Mar. 16, 2021).
[36] https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf.

B. Advisory Opinion 20-02

On May 19, 2020, the HHS OGC published Advisory Opinion 20-02[37] concluding that the PREP Act preempts any state or local law which prohibits a pharmacist from ordering and administering authorized COVID-19 tests.

C. Advisory Opinion 20-03

On October 23, 2020, the OGC issued Advisory Opinion 20-03.[38] AO 20-03 reiterates that states or their sub-units may not impose any requirement that effectively prohibits a pharmacist from ordering and administering vaccines as authorized by the HHS Secretary.

D. Advisory Opinion 20-04

On the same day it issued AO 20-03, OGC also released Advisory Opinion 20-04.[39] In AO 20-04, the OGC addresses the scope and meaning of the terms "program planner" and "authority having jurisdiction" under the PREP Act and its implementing Declaration, and re-emphasizes the wide-ranging nature of PREP Act immunity. It also breaks with recent current court interpretations of the PREP Act and argues they are too narrow.

Under the PREP Act, the term "covered person" includes the United States or "manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees."[40] The PREP Act broadly defines a "program planner,"[41] and the Secretary's original Declaration explains that a program planner can be a "private sector employer or community group."[42] In short, ***any individual or organization can potentially be a program planner and receive PREP Act coverage***. According to AO 20-04, private businesses, public and private transportation providers, public and private schools, and religious organizations are all eligible for immunity under the PREP Act when they act in accordance with its requirements.

In addition, AO 20-04 expressly disagrees with the *Casabianca v. Mount Sinai Medical Center*[43] case in which a New York state court evaluated the PREP Act in the context of the H1N1 influenza pandemic and concluded that the PREP Act does not apply to inaction. The court observed that immunity under the PREP Act is limited to claims "resulting from the administration . . . or use" of a covered countermeasure, and that non-administration is not addressed, noting that "[n]othing is spoken of regarding a decision not to use the vaccine or of a failure to use it."[44] According to the OGC, the *Casabianca* "court was wrong" because it failed

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[37] https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf.
[38] https://www.hhs.gov/sites/default/files/advisory-opinion-20-03-hhs-ogc-public-readiness-emergency-preparedness-act.pdf.
[39] https://www.hhs.gov/sites/default/files/advisory-opinion-20-04-hhs-ogc-public-readiness-emergency-preparedness-act.pdf.
[40] 42 U.S.C. § 247d-6d(a)(4)(B).
[41] *Id*. § 247d-6d(i).
[42] *See* 85 Fed. Reg. at 15,199.
[43] 2014 WL 10413521 (N.Y. Sup. 2014).
[44] *Id.* *3-4.

to interpret the PREP Act consistent with its plain meaning by concluding that the PREP Act did not apply to the hospital's inaction.

E. Advisory Opinion 21-01

On January 8, 2021, HHS issued Advisory Opinion 21-01,[45] reinforcing the extent to which the PREP Act (1) provides complete preemptive federal jurisdiction and (2) applies to cases where the alleged harm results from failure to use (and even ***refusal to use***) a covered countermeasure when that failure arises out of the conscious allocation and prioritization of the countermeasures.

AO 21-01 also appears to evince HHS's frustration with private businesses' apparent failure to make full use of the PREP Act and the federal courts' apparent failure to properly interpret the PREP Act. Like AO 20-04, AO 21-01 criticizes recent courts' application of the Act as contrary to the plain language of the statute, while noting that courts appear "perplexed" by what circumstances may trigger federal PREP Act jurisdiction and immunity.

F. Advisory Opinion 21-02

On January 12, 2021, HHS issued Advisory Opinion 21-02[46] on the PREP Act and the Secretary's Declaration. This Advisory Opinion clarifies the meaning of the requirement, in the Third Amendment to the Declaration, that a COVID-19 vaccination "must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s)." Any person who orders or administers the COVID-19 vaccine to individuals within the ACIP-recommended age group satisfies the Third Amendment's requirement that the vaccination be "ordered and administered according to ACIP's COVID-19 vaccine recommendation(s). This is true regardless of whether the vaccine was ordered or administered to a person in a prioritized group.

III. The Courts, U.S. Attorneys' Office, and Office of Legal Counsel Tackle PREP Act Issues Involving Non-Use, Preemption, and Federal Jurisdiction

As we discuss below, many thorny questions regarding PREP Act immunity are making their way through the courts, such as (1) whether the PREP Act provides immunity in cases where a claim for loss arises from a defendant's failure to use, or even refusal to use, a covered countermeasure; (2) the extent to which the PREP Act and Declaration preempt conflicting state and local laws; and (3) whether the PREP Act provides complete federal preemption and, as a result, serves as a basis for federal jurisdiction.

1. Are claims arising from non-use of covered countermeasures subject to PREP Act immunity?

A growing number of suits are addressing whether PREP Act immunity arises in the use or non-use of covered countermeasures against COVID-19, including personal protective equipment ("PPE"). Many of these recent lawsuits involve nursing homes and other health care facilities,

[45] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf.
[46] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO-21-02-PREP-Act_1-12-2021_FINAL_SIGNED.pdf.

where patients or their estates allege that patients contracted COVID-19 because the facility, among other things, failed to provide its staff with PPE, failed to teach the staff how to properly use that equipment, or failed to ensure that its staff properly used the PPE that it had been given.

As mentioned above, the Fourth Amendment explicitly provides that the PREP Act's liability protections may apply to certain cases of ***non-use***, failure to use, and even refusal to administer a covered countermeasures to a particular individual. However, many courts have thus far reached the opposite conclusion, finding that the non-use of a covered countermeasure does ***not*** trigger the PREP Act.

For example, in *Lutz v. Big Blue Healthcare*, the district court concluded that "[t]here is simply no room to read [the PREP Act] as equally applicable to the non-administration or non-use of covered countermeasures."[47] Similarly, in *Casabianca v. Mount Sinai Medical Center*,[48] the district court held that PREP Act immunity is restricted to claims "resulting from the administration . . . or use" of a covered countermeasure, and that "[n]othing is spoken of regarding a decision not to use the vaccine or of a failure to use it."[49] As discussed above, AO 21-01 called out the court's holding in *Casabianca*, saying "the court was wrong." And in *Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC*,[50] which is currently on appeal, the court held that the PREP Act only provides immunity to facilities "when a claim is brought against them for the countermeasures the facility actually utilized," rather than failed to use.

HHS has been sharply critical of these courts, emphasizing that program planning inherently involves the allocation of resources and is expressly covered by the PREP Act. According to HHS, because the PREP Act extends immunity to anything "relating to" the administration of a covered countermeasure, decision-making that leads to the non-use of covered countermeasures by certain individuals is the core of program planning, and is expressly covered by PREP Act. However, a provider may not be covered, according to HHS, if the provider (1) purposefully fails to follow priorities contained in a Declaration and is therefore not a "covered person"[51]; or (2) fails to act purposefully or without making any decision at all.[52]

2. Do the PREP Act and Declaration preempt conflicting state and local laws?

The PREP Act's express preemption provision is 42 U.S.C. § 247d-6d(b)(8), which states in full:

> During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

[47] 480 F. Supp. 3d 1207, 1218 (D. Kan. 2020).
[48] 2014 WL 10413521 (N.Y. Sup. 2014).
[49] *Id.* *3-4.
[50] No. 20-cv-1198, 2020 WL 6140474 at *7 (W.D. Pa. Oct. 16, 2020).
[51] AO 20-04 at 3.
[52] AO 21-01 at 3.

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act.[53]

As such, the PREP Act clearly preempts conflicting state and local laws. Indeed, on January 19, 2021, the Office of Legal Counsel (OLC) for the DOJ issued a Memorandum Opinion regarding the preemption of state and local requirements under the Declaration.[54] In this Memo, the OLC affirmed that both the PREP Act and Declaration preempt state or local requirements, such as state licensing laws, that would prohibit or effectively prohibit qualifying state-licensed pharmacists from ordering and administering both FDA-approved COVID-19 tests and vaccines. The Memo formalizes the same conclusion reached in AO 20-02 discussed above regarding COVID-19 tests, and answers the related question of whether the same conclusion applies not just to COVID-19 tests but also to the administration of COVID-19 vaccines.

3. Does the PREP Act afford "complete preemption" such that its invocation results in federal jurisdiction?

Nursing home cases involving COVID-19 tend to be filed in state courts and assert a variety of state law-based torts. Thereafter, defendants often file removal petitions and plaintiffs respond with remand motions. To resolve the remand motions, courts first assess whether the doctrine of complete preemption applies.

At the time this article was submitted for publication, almost all of the cases applying the PREP Act in the context of COVID-19 have concluded the PREP Act does not offer complete preemption or give rise to federal jurisdiction. However, two out of the dozens of federal district courts to have reached the issue have found that the PREP Act provides complete preemption.[55]

A. Background on Federal Preemptive Jurisdiction

Ordinary preemption is a defense and does not support Article III subject matter jurisdiction,[56] which is a prerequisite for removal.[57] In contrast, complete preemption is "really a jurisdictional rather than a preemption doctrine, [as it] confers exclusive federal jurisdiction in certain instances where Congress intended the scope of a federal law to be so broad as to entirely replace any state-law claim."[58] Thus, complete preemption is fundamentally unlike the express

[53] 42 U.S.C. § 247d-6d(b)(8).
[54] https://www.justice.gov/olc/file/1356956/download.
[55] *See Rachal v. Natchitoches Nursing & Rehabilitation Center, LLC*, No. 1:21-cv-00334, *3 n.3 (W.D. La. Apr. 30, 2021); *Garcia v. Welltower OPCO Group LLC,* 2021 WL 492581, at *7 (C.D. Cal. Feb. 10, 2021).
[56] *See* 28 U.S.C. § 1331.
[57] *See Merrell Dow Pharmaceuticals v. Thompson*, 478 U.S. 804 (1986).
[58] *Marin General Hosp. v. Modesto & Empire Traction Co.*, 581 F.3d 941, 945 (9th Cir. 2009).

preemption provided by 42 U.S.C. § 247d-6d(b)(8) as well as other, substantive preemption doctrines (e.g., implied, field, conflict, impossibility, or obstacle preemption), which do not in and of themselves give rise to removability. And complete preemption sidesteps the general rule that a federal defense (like other, substantive types of preemption) does not provide grounds for removal to federal court.[59]

B. HHS Argues the PREP Act Is a Complete preemption statute

In AO 21-01, HHS has taken the position that the PREP Act is a complete preemption statute, opining that: "The *sine qua non* of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both."

C. Fourth Amendment to the Declaration Invokes the *Grable* Doctrine

In addition to complete preemption as the basis for Article III jurisdiction and removal, the Supreme Court in *Grable & Sons Metal Products, Inc. v. Darue Eng'g & Mf'g*.,[60] recognized a separate but related doctrine. Under *Grable*, even in the absence of a claim arising under federal law, "a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues."[61]

The Secretary, in the Fourth Amendment to his PREP Declaration, effectively concluded that a case implicating the PREP Act during the COVID-19 pandemic belongs in federal court, stating that

> [t]here are substantial federal legal and policy issues, and substantial federal legal and 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 unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities.[62]

As such, the Fourth Amendment provides the underlying basis for invoking the *Grable* doctrine with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.

In addition, 42 U.S.C. § 247d-6d(b)(7) provides that "[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection." Relying on that provision, the Secretary's Fourth Amendment states that "[t]hrough the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declarations." This statement therefore suggests that the Secretary's statement

[59] *See Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63, 66 (1987).
[60] 545 U.S. 308 (2005).
[61] *Id.* at 312.
[62] 85 Fed. Reg. at 79,197.

invoking *Grable* in the Fourth Amendment may be an unreviewable action pursuant to 42 U.S.C. § 247d-6d(b)(7).

D. Recent Developments on Federal Preemptive Jurisdiction

Federal district courts recently examining whether the PREP Act is a complete preemption statute have arrived at inconsistent conclusions. Although appellate courts have not yet opined on this exact issue, the overwhelming majority of the district courts that have considered it have held that the PREP Act dos not completely preempt state-law claims against nursing homes. However, two cases have reached the opposite conclusion.

i. Two Courts Have Recognized That the PREP Act Does Provide for Complete Preemption

To date, neither the Supreme Court nor any of the Court of Appeals has found complete preemption over claims implicating the PREP Act. A recent ruling from the Middle District of California in *Garcia v. Welltower OpCo Group, LLC*,[63] however, appears to be the first district court to have found that the plaintiffs' claims were completely preempted under the PREP Act.

In *Garcia*, the plaintiffs asserted various causes of action under California law including wrongful death. The defendants operate and manage a senior living facility. The decedent was a resident of the facility during the COVID-19 pandemic. Certain family members of the decedent filed suit in California state court alleging that the decedent died from COVID-19 while he was a resident of the facility, and the defendants removed the action to federal court in part based on federal question jurisdiction.

The plaintiffs filed a motion to remand, claiming that the PREP Act is inapplicable because it does not provide immunity to medical providers for negligence claims unrelated to vaccine administration and use. The defendants responded that federal question jurisdiction exists because the suit is completely preempted in light of the OGC's recent guidance in AO 21-01, which confirms Congress's intent that the PREP Act completely preempt state laws.

The court first considered whether the PREP Act provides for complete preemption. The court noted that other courts in the Central District of California have found that it did not.[64] Importantly, however, each of those cases preceded the issuance of AO 21-01. Without stating whether it was applying *Chevron* or *Skidmore* deference,[65] the court cited both Supreme Court decisions in agreeing with and ultimately adopting AO 21-01's interpretation that the Act is a

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[63] SACV2002250JVSKESX, 2021 WL 492581 (C.D. Cal. Feb. 10, 2021).

[64] *See, e.g.*, *Jackie Saldana v. Glenhaven Healthcare LLC*, No. CV205631FMOMAAX, 2020 WL 6713995, at *2 (C.D. Cal. Oct. 14, 2020) (finding that the PREP Act did not preempt plaintiffs' state law claims); *Martin v. Serrano Post Acute LLC*, 2020 WL 5422949, *1-2 (C.D. Cal. 2020) (same).

[65] *Chevron* deference requires a federal court to defer to an agency's interpretation of an ambiguous statute if the interpretation is deemed to be reasonable. *Chevron, Inc. v. NDRC, Inc*., 467 U.S. 837, 843 (1984). Unlike *Chevron* deference, *Skidmore* deference allows a federal court to determine the appropriate level of deference for each case based on the agency's ability to support its position. *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). While *Chevron* deference is binding for agency rules developed through administrative rulemaking (including notice and comment), *Skidmore* deference is applied to agency interpretations, such as advisory opinion letters, that are not required to be developed through the rulemaking process.

complete preemption statute. The court also pointed out that AO 21-01 disagreed with the other courts in the Central District of California and elsewhere that had come to the opposite conclusion, because they took too limited of a view concerning use or non-use of a covered countermeasure.

The court next considered whether the plaintiffs' allegations fall within the scope of the PREP Act. To fall within the ambit of the PREP Act, the plaintiffs' loss must have been caused by "a covered person" and "aris[e] out of, relat[e] to, or result[] from the administration to or the use by an individual of a covered countermeasure."[66] Here, the plaintiffs did not allege that the facility failed to provide any of its staff or patients with PPE but rather that the timing, quantity, and training with respect to the PPE provided by the facility was inadequate. The court relied on AO 20-02 and AO 20-04 in support of its conclusion that the defendants' actions in response to the pandemic easily fell within the scope of the Act. Therefore, the court held that an adequate basis for federal question jurisdiction exists.

Similarly, in its decision in *Rachal v. Natchitoches Nursing & Rehabilitation Center, LLC*,[67] issued two months after *Garcia*, the district court in Louisiana cited *Garcia* approvingly and held that the PREP Act is a complete preemption statute.

ii. The Overwhelming Majority of District Courts Conclude That the PREP Act Does Not Provide Complete Preemption

Garcia and *Rachal*, however, are in the minority, and subsequent courts that have addressed the issue have declined to follow them. Indeed, with the exception of these two cases, the unanimous consensus among the district courts across the country is that the PREP Act is not a complete preemption statute.[68]

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[66] *See* 42 U.S.C. § 247d-6d(a)(1).

[67] No. 1:21-cv-00334, *3 n.3 (W.D. La. Apr. 30, 2021).

[68] *See, e.g.*, *Robin Roebuck v. Mayo Clinic*, No. CV-21-00510-PHX-DLR, 2021 WL 1851414, at *5 (D. Ariz. May 10, 2021) ("[T]he Court joins the growing consensus finding that the PREP Act is not a complete preemption statute. The PREP Act does not satisfy the Ninth Circuit's complete preemption test because it does not completely replace state law claims related to COVID-19 and does not provide a substitute cause of action for [plaintiff's] medical negligence claim."); *Golbad v. GHC of Canoga Park*, No. 221CV01967ODWPDX, 2021 WL 1753624, at *2 (C.D. Cal. May 4, 2021) ("Simply put, the PREP Act does not satisfy the Ninth Circuit's two-part complete preemption test."); *Padilla v. Brookfield Healthcare Ctr.*, No. CV 21-2062-DMG (ASX), 2021 WL 1549689, at *4 (C.D. Cal. Apr. 19, 2021) ("Nearly every other federal court addressing the issue of complete preemption has found that the PREP Act is not a statute with complete preemptive effect."); *Bolton v. Gallatin Ctr. for Rehab. & Healing, LLC*, No. 3:20-CV-00683, 2021 WL 1561306, at *7 (M.D. Tenn. Apr. 21, 2021) ("[N]early every district court to consider whether the PREP Act completely preempts similar state-law claims against nursing homes has concluded the PREP Act is not a complete preemption statute, or at least does not have such an effect on claims like those presented here."); *Riggs v. Country Manor La Mesa Healthcare Center*, 21-CV-331-CAB-DEB, 2021 WL 2103017, at *2 (S.D. Cal. May 25, 2021) (holding that the plaintiffs' state-law claims against a nursing home were not completely preempted by the PREP Act); *Evans v. Melbourne Terrace Rcc, LLC*, No. 6:21-CV-381-JA-GJK, 2021 WL 1687173, at *2 (M.D. Fla. Apr. 29, 2021) ("[T]he PREP Act is not a complete preemption statute. . . . And even if it were, [plaintiff's] allegations accusing [defendant] of inaction—versus prioritization or purposeful allocation of countermeasures—are not within the scope of the PREP Act. Federal district courts across the country have nearly unanimously so held since the start of the pandemic."); *see also Shapnik v. Hebrew Home for the Aged At Riverdale*,

iii. The DOJ Weighs in

On January 19, 2021, the DOJ submitted a Statement of Interest in a civil matter before the U.S. District Court for the Middle District of Tennessee to address the preemptive effect of the PREP Act and assist the court in resolving a pending motion to remand.[69] In its Statement of Interest, the DOJ took the position that the PREP Act completely preempts claims relating to the administration or use of covered countermeasures with respect to a public health emergency, as declared by the Secretary. Thus, according to the DOJ, cases that include such claims necessarily include federal questions and are therefore removable. However, as a nonparty, the United States took no position as to whether the Act applies to any particular claim alleged in the plaintiff's complaint in the case.[70]

The Statement of Interest further argues that a recent and oft-cited case to the contrary, *Maglioli v. Andover Subacute Rehabilitation Center*,[71] appears to have interpreted the complete preemption doctrine and the PREP Act "imprecisely." The court's holding, "that the PREP Act does not so occupy the field as to squeeze out state court jurisdiction over what are state-law claims of negligence and require an exclusive federal forum,"[72] frames the inquiry incorrectly. Field preemption is a different doctrine than complete preemption and the PREP Act ***does*** include a completely preemptive provision, as evidenced by its creation of immunity for a certain class of claims and an exclusive federal forum for exceptions to that immunity.[73]

In its decision, the court, while "mindful of the United States' policy arguments that reasonably emphasize the urgent need for the federal judiciary to provide a consistent national interpretation of the PREP Act during a pandemic that has taken the lives of more than 500,000 citizens," ultimately rejected the DOJ's argument and remanded the matter to Tennessee state court.[74] The court also noted that *Garcia* is nonbinding, and joined the other district courts that have unanimously concluded that the HHS's Advisory Opinions should not receive unlimited deference.[75] The court disagreed that the Advisory Opinion is entitled *Chevron* deference because the Advisory Opinion itself expressly states that "[i]t is not a final agency action or a

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No. 20-CV-6774 (LJL), 2021 WL 1614818, at *16 (S.D.N.Y. Apr. 26, 2021) (collecting cases); *Dupervil*, 2021 WL 355137, at *12 (E.D.N.Y. Feb. 2, 2021) (collecting cases).

[69] *Bolton v. Gallatin Center for Rehabilitation & Healing, LLC*, Case No. 3:20-cv-00683.

[70] *See* Dkt 35-1, at 1, Case No. 3:20-cv-00683.

[71] No. 20-6605, 2020 WL 4671091 (D.N.J. 2020).

[72] *Id*. at *11.

[73] 42 U.S.C. § 247d-6d(a), (d)(1).

[74] *Bolton v. Gallatin Ctr. for Rehab. & Healing, LLC*, 3:20-CV-00683, 2021 WL 1561306, at *9 (M.D. Tenn. Apr. 21, 2021).

[75] *E.g.*, *Dupervil*, 2021 WL 355137; *Winfred Cowan*, 2021 WL 1225965; *Robertson v. Big Blue Healthcare, Inc.*, No. 2:20-cv-02561-HLT-TJJ, 2021 WL 764566 (D. Kan. Feb. 26, 2021); *Estate of McCalabb v. AG Lynwood, LLC*, No. 2:20-cv-09746-SB-PVC, 2021 WL 911951 (C.D. Cal. Mar. 1, 2021); *Lopez v. Life Care Ctr. of Am., Inc.*, No. CV 20-0958 JCH/LF, 2021 WL 1121034 (D.N.M. Mar. 24, 2021); *Schuster v. Percheron Healthcare, Inc.*, No. 4:21-cv-00156-P, 2021 WL 1222149 (N.D. Tex. Apr. 1, 2021); *see also Ivey v. Serrano Post Acute, LLC*, No. CV 20-11773 DSF, 2021 WL 1139741 (C.D. Cal. Mar. 25, 2021) (concluding that "HHS has not been delegated authority over the interpretation of judge-created federal jurisdiction doctrines such as complete preemption and is due no deference for its musings on such matters"); *Golbad*, 2021 WL 1753624, at *3 (noting that "[t]he court in *Garcia* deferred to the HHS Secretary's opinion of PREP Act complete preemption, but did not consider the Ninth Circuit's two-part complete preemption test).

final order" and "does not have the force or effect of law."[76] Moreover, "[e]ven if the [Advisory Opinion] did not include the clear disclaimer language, the authority Congress delegated to HHS to make rules carrying the force of law did not include authority to interpret the jurisdiction of the federal courts."[77] Finally, and most important to the court, the Advisory Opinion's interpretation lacks the "power to persuade," because it "cites no cases for its proposition that an exclusive federal administrative remedy is sufficient for complete preemption."[78]

IV. Where is the PREP Act headed? Anticipated future impact on vaccine distribution systems and changes in light of the new Biden Administration.

1. Vaccine Distribution Systems

With respect to the world of vaccine distribution systems, many employers are hesitant to mandate their employees get the COVID-19 vaccine out of fear being sued by their employees and/or the general public. The PREP Act clearly applies in this situation. In fact, the CDC COVID-19 vaccination program provider agreement[79] even expressly references the PREP Act, stating that "[c]overage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services."

2. Anticipated Changes From the Nascent Biden Administration

All but two of the amendments to the PREP Act Declaration and all of the advisory opinions were issued by HHS under the Trump Administration, which raises the question of whether the new Biden Administration might have different priorities in this regard and whether the new Secretary of HHS might amend the Declaration to expand or contract its application.

However, we can likely expect more of the same from the Biden Administration. The Fifth, Sixth, and Seventh Amendments to the Declaration was issued in the first few days of the Biden Administration. Given the further expansion of the PREP Act that these amendments afford, they suggest the new administration is not inclined to scale back PREP Act coverage.

Conclusion

As stated above, the PREP Act affords extraordinarily broad federal immunity from suit and liability to a covered person with respect to claims relating to the authorized administration or use of a covered countermeasure. Except for willful misconduct that proximately causes death or serious injury, it covers all claims for loss, including contract and tort claims as well as claims

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[76] *Bolton*, 2021 WL 1561306, at *9 (citing *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 642 (6th Cir. 2004) ("[O]nly those administrative interpretations that Congress and the agency intend to have the 'force of law,' as opposed to those merely characterized as 'authoritative,' qualify for *Chevron* deference.")).
[77] *Id.* (quoting *Estate of Jones v. St. Jude Operating Co., LLC*, No. 3:20-cv-01088-SB, 2021 WL 900672, *6 (D. Or. Feb. 16, 2021)).
[78] *Id.* (citing *Dupervil*, 2021 WL 355137, at *10).
[79] https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html.

for loss relating to compliance with local, state, or federal laws, regulations, or other legal requirements.

Immediately after COVID-19 reached the United States, HHS issued a series of declaration amendments and advisory opinions interpreting the contours of the PREP Act in an even more expansive way, e.g., opining that it provides complete preemptive federal jurisdiction and even may apply to cases where the alleged harm results from non-use of a covered countermeasure so long as the non-use was the result of conscious decision-making.

However, federal courts haven't all interpreted it in the broad manner suggested in guidance from HHS. Whatever the case may be, there is ample time to invoke its protections. Again, the Secretary has declared the immunities of the PREP Act are in place to fight COVID-19 until October 1, 2024, so the PREP Act immunities will have a long term impact on health care facilities as well as many other industries and settings and the risk for liability in the years to come.