ORAL ARGUMENT NOT YET SCHEDULED

No. 21-7067

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ANNE JEAN CANNON, Deceased; ESTATE OF ANNE JEAN CANNON, By and Through JOHN CANNON and FRANCIS CANNON, Executors of the Estate of Anne Jean Cannon,

Plaintiffs-Appellees,

v.

WATERMARK RETIREMENT COMMUNITIES, INC.; WATERMARK OPERATOR, LLC, doing business as BLUE BELL PLACE; WATERMARK RETIREMENT COMMUNITIES, LLC,

Defendants-Appellants.

On Appeal from the United States District Court
for the Eastern District of Pennsylvania

BRIEF FOR APPELLEES

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

Anne Jean Cannon, Deceased, and the Estate of Anne Jean Cannon, by and through John Cannon and Francis Cannon, Executors of the Estate of Anne Jean Cannon, (collectively, the Estate) are the plaintiffs in the district court and are the appellees in this Court.

Watermark Retirement Communities, Inc.; Watermark Operator, LLC, doing business as Blue Bell Place; and Watermark Retirement Communities, LLC (collectively, Watermark) are the defendants in the district court and are the appellants in this Court.

There are no intervenors or amici in the district court and no amici have given notice of intent to participate in this Court.

B. Ruling Under Review

The ruling under review is the May 28, 2021 interlocutory order issued by Judge Nitza I. Quiñones Alejandro of the United States District Court for the Eastern District of Pennsylvania, as supplemented by a July 19, 2021 memorandum opinion, which denied Defendant-Appellants' motion to dismiss Plaintiff-Appellees' Pennsylvania state law claims based on the abuse, neglect, and eventual death of Anne Jean

Cannon, while she resided at the Blue Bell Place senior living community.

C. Related Cases

This case was not previously before this Court or any other appellate court. Counsel is not aware of any related cases currently pending in this Court or in any other court, as provided in Cir. R. 28(a)(1)(C).

The Court previously ordered the parties in this appeal to brief the question of whether 42 U.S.C. § 247d-6d(e)(10) provided this Court with jurisdiction over this appeal, and to file letters of supplemental authority following the Court's resolution of *Hatcher v. HCP Prairie Village KS OpCo*, No. 21-7017, which raised the same jurisdictional issue. Sept. 15, 2021 Order. The Appellant in *Hatcher* later voluntarily dismissed its appeal. *See Hatcher*, Sept. 28, 2021 Order of Dismissal. Counsel is aware of one additional pending appeal that implicates the same jurisdictional question, however, *Beaty v. Delaware County*, No. 21-7096.

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GLOSSARY

CARES Act	Coronavirus Aid, Relief, and Economic Security Act
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
HHS	United States Department of Health and Human Services
PREP Act	Public Readiness and Emergency Preparedness Act, commonly referred to and referred to by the District Court as the PREP Act

STATEMENT OF JURISDICTION

The Estate agrees with Watermark that the United States District Court for the Eastern District of Pennsylvania has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1), because the parties are citizens of different states and the Estate seeks damages in excess of $75,000, exclusive of interest and costs. The Estate disagrees with Watermark's suggestions that the district court also has federal-question jurisdiction pursuant to 28 U.S.C. § 1331 on the ground that this action is completely preempted by the PREP Act or poses a "substantial, embedded question of federal law," or that the district court has jurisdiction pursuant to 28 U.S.C. § 1442 on the ground Watermark has been acting under the direction of a federal officer since the onset of the COVID-19 pandemic. Appellants' Br. 1. Indeed, the Third Circuit has explicitly rejected these arguments in an opinion that binds the district court in this case. *See Estate of Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393 (3d Cir. 2021).

This Court lacks jurisdiction over this interlocutory appeal from the Pennsylvania district court's decision, as explained in detail below. *See* Argument, pp. 20–35. Watermark's suggestion that subsection (e)(10) of

the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. § 247d-6d(e)(10), provides this Court with jurisdiction to hear interlocutory appeals from district courts outside the District of Columbia relies on an untenable statutory interpretation that could yield chaos in the district courts.

STATEMENT OF THE ISSUES

(1) Whether the PREP Act provides this Court with jurisdiction to hear an interlocutory appeal from a decision by any of the nation's 94 district courts rejecting an assertion of immunity under that statute, but not from any decision finding such immunity exists.

(2) Whether the PREP Act provides a basis to dismiss claims or parts of claims unrelated to the administration or use of a "covered countermeasure" where a defendant contends that *other* claims in the same pleading relate to the administration or use of a covered countermeasure.

(3) Whether claims relating to the administration of a drug fall within the liability protections of the PREP Act where such administration did not comply with the conditions specified in a PREP Act declaration.

STATUTES AND REGULATIONS

Relevant provisions of the PREP Act, 42 U.S.C. §§ 247d-6d–247d-6e, and the Secretary's PREP Act Declaration, appear in the Addendum to this brief.

STATEMENT OF THE CASE[1]

I. The Neglect, Abuse, and Unauthorized Experimental Treatment Leading to the Death of Anne Jean Cannon

In January 2020, Anne Jean Cannon was admitted into Blue Bell Place (Blue Bell), an assisted living facility operated by Watermark, in Blue Bell, Pennsylvania. JA245. Approximately three weeks after Mrs. Cannon was admitted, her family noticed signs of abuse and neglect. First, the family observed that Mrs. Cannon was not being provided assistance with bathing, clothing, and other important daily personal care and hygiene tasks. JA246. These failures continued throughout the four months that Mrs. Cannon lived at the facility. JA246–28. Second, the family was given reason to believe that Mrs. Cannon had been

[1] All facts are taken from the Estate's amended complaint, JA242–77. As the district court correctly noted, in ruling on Watermark's motion to dismiss pursuant to Rule 12(b)(6), it was required to accept as true all the factual allegations in that complaint. JA567 (citing *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210–11 (3d Cir. 2009)); *see also, e.g.*, *Bowman v. Iddon*, 848 F.3d 1034, 1039 (D.C. Cir. 2017).

physically abused by Blue Bell staff—including via a telephone call from Blue Bell's executive director regarding "suspicious" bruises on Mrs. Cannon's body, and a report that Mrs. Cannon had been "roughed up" by a staff member. JA248–49. Third, Mrs. Cannon experienced multiple falls, resulting in bruises to her head and face. JA249. Blue Bell did not implement a fall protocol to protect Mrs. Cannon from these injuries. *Id.*

On or around April 11, 2020, Blue Bell staff informed Mrs. Cannon's family that two facility residents had tested positive for COVID-19 and that the facility would be on "lockdown," with all residents restricted to their rooms. JA249. On or around April 22, 2020, Mrs. Cannon tested positive for COVID-19, though she was asymptomatic. JA250. Nonetheless, that evening, a Blue Bell nurse assistant contacted Mrs. Cannon's son, Robert Cannon, who held her medical power of attorney, and stated that she wanted to provide Mrs. Cannon with the experimental treatment of hydroxychloroquine and doxycycline. *Id.* Robert did not provide consent for this treatment to be used on his mother. *Id.* To the contrary, Robert stated that his family had concerns about the treatment given its experimental status and Mrs. Cannon's

preexisting heart conditions and wished to conduct further research. JA251.

Despite the lack of consent, and the fact that the prescribing physician never saw or spoke with Mrs. Cannon, Blue Bell administered the experimental hydroxychloroquine and doxycycline treatment to Mrs. Cannon for five days beginning on April 22, 2020. JA251, JA257. Within three days, Mrs. Cannon began complaining of nausea, stomach pain, headaches, vomiting, and diarrhea. *Id.* In the coming days, she reported severe pain, and was weak, barely able to move, and disoriented. *Id.* On the morning of May 4, 2020, she was found lying on the floor, moaning in pain, after having fallen out of her bed. JA252. She died that same day. The causes of death given were a cardiac event and COVID-19. JA252.

II. The PREP Act and Its Implementation

A. The PREP Act

Initially enacted in 2005 "[t]o encourage the expeditious development and deployment of medical countermeasures during a public health emergency, the [PREP Act] authorizes the Secretary of [HHS] to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines." Cong. Res. Serv., *The PREP Act and COVID-19: Limiting Liability for*

Medical Countermeasures 1 (updated Sept. 23, 2021), https://crsreports.congress.gov/product/pdf/LSB/LSB10443. Broadly, the statute functions by (1) providing immunity against state and federal claims related to the administration or use of certain "covered countermeasures," 42 U.S.C. § 247d-6d(a); (2) creating an exception to that immunity for claims based on "willful misconduct," which are to be brought under an exclusive federal cause of action, subject to detailed procedural requirements and subject to the exclusive jurisdiction of a three-judge court of the District Court for the District of Columbia, *id.* § 247d-6d(d)–(e); and (3) creating an administrative compensation scheme that may serve as a substitute for claims that are either precluded or channeled to the D.C. district court, *id.* § 247d-6e.

None of these provisions is self-executing. Rather, the Act's provisions are triggered only when the HHS Secretary issues a formal declaration determining that a public health emergency exists, and "recommending" the "manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures." 42 U.S.C. § 247d-6d(b)(1); *see also Maglioli*, 16 F.4th at 400–01 (summarizing statute). In such a declaration, the Secretary may limit the

statute's liability protections to certain time periods, populations, geographic areas, and covered countermeasures that were obtained or used pursuant to specific means of distribution. 42 U.S.C. §§ 247d-6d(b)(1)–(3).

In the scenarios covered by a Secretarial declaration, subsection (a) of the PREP Act limits liability by providing "covered persons" with immunity for liability under state or federal law for "any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure." *Id.* §§ 247d-6d(a)(1), (a)(2)(B). That immunity only applies where the countermeasure was administered or used during the effective period of a Secretarial declaration, § 247d-6d(a)(3)(A); for the purposes specified in a Secretarial declaration, § 247d-6d(a)(3)(B), and to or by an individual in the population and geographic area specified in the Secretarial declaration, § 247d-6d(a)(3)(C). With respect to this last set of conditions only, the statute includes a "safe harbor" provision, providing immunity to certain covered persons so long as they "reasonably could have believed that the countermeasure was administered or used in accordance with the conditions." *Id.* § 247d-6d(a)(4)(B).

Subsection (d) of the statute creates a carveout from the subsection (a) immunity for suits brought against covered persons "for death or serious physical injury proximately caused by willful misconduct." *Id.* § 247d-6d(d)(1). For claims within the carveout, the statute creates an "exclusive Federal cause of action," *id.*, with a federal "standard for liability," *id.* § 247d-6d(c)(1)(B), and provides special procedures for adjudication, vesting exclusive jurisdiction in a three-judge court of the District Court for the District of Columbia, *id.* § 247d-6d(e).

Finally, the statute creates an administrative scheme, administered by the Department of Health and Human Services (HHS), to provide "compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure" subject to a PREP Act declaration. 42 U.S.C. § 247d-6e(a).

B. The COVID-19 PREP Act Declaration

On March 10, 2020, the HHS Secretary invoked the PREP Act by issuing a Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19. *See* 85 Fed. Reg. 15,198, 15,198 (published Mar. 17, 2020). In that

Declaration, he recommended the "manufacture, testing, development, distribution, administration, and use" of certain countermeasures to combat COVID-19: "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product." *Id.* at 15,202. Consistent with the statute, though, the Secretary expressly noted that his recommendation was limited to "qualified pandemic or epidemic products," "security countermeasures," or "drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the [Food, Drug and Cosmetic] Act, and the Public Health Service Act." *Id.*

The Secretary also included a provision entitled "Limitations on Distribution," under which he explicitly limited liability immunity to "Recommended Activities involving Covered Countermeasures that are related to" (a) federal contracts and agreements, or (b) "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." *Id.* at 15,202. He defined "Authority Having Jurisdiction" as "the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, state, or federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority." *Id.*

The Secretary has amended the initial Declaration several times. Notably, in the Fourth Amendment to the Declaration, seven months after Mrs. Cannon died, the Secretary "amend[ed] the Declaration to extend PREP Act coverage to additional private-distribution channels," including by providing that the liability protections of the statute apply to covered countermeasures that are "licensed, approved, cleared, or authorized by the FDA" to treat or limit the spread of COVID-19. HHS, Notice of Amendment & Republished Declaration, 85 Fed. Reg. 79,190, 79,196 (Dec. 9, 2020).[2] To qualify for immunity under this additional channel, the Covered Countermeasures must have been used "pursuant

[2] All other amendments to the Declaration are available at https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.

to the FDA licensure, approval, clearance, or authorization." *Id.* at 79,197. This provision was explicitly not made retroactive. *Id.* at 79,198.

III. Hydroxychloroquine and COVID-19

On March 28, 2020, the FDA issued an Emergency Use Authorization letter, authorizing the use of hydroxychloroquine sulfate (hereafter, "hydroxychloroquine") "for the treatment of 2019 coronavirus disease (COVID-19) when administered by a [healthcare provider] pursuant to a valid prescription of a licensed practitioner as described in the Scope of Authorization (section II) of this letter." Letter from RADM Denise M. Hinton re: Request for Emergency Use Authorization For Use of Chloroquine Phosphate or Hydroxychloroquine Sulfate Supplied From the Strategic National Stockpile for Treatment of 2019 Coronavirus Disease (Mar. 28, 2020), JA338, 342. Relevant to this action, the scope of authorization was limited to the use of hydroxychloroquine "to treat adult and adolescent patients who weigh 50 kg or more hospitalized with COVID-19, for whom a clinical trial is not available, or participation is not feasible." JA341.[3] The Emergency Use Authorization was

[3] Watermark's brief includes a lengthy discussion about the use of hydroxychloroquine to treat COVID-19, relying on factual assertions outside the Complaint. Appellants' Br. 33–34. The Court may disregard

subsequently revoked by the FDA on June 15, 2020. *See* JA338; FDA, Notice, Authorizations and Revocation of Emergency Use of Drugs During the COVID-19 Pandemic; Availability, 85 Fed. Reg. 56,231, 56,232 (Sept. 11, 2020).

IV. Procedural History

A. The Estate's Claims

On February 3, 2021, the Estate commenced this action in the Montgomery County (PA) Court of Common Pleas, based on the abuse and neglect throughout Mrs. Cannon's residence at Blue Bell, including inadequate care both before and after her diagnosis with COVID-19, and the nonconsensual administration of hydroxychloroquine. JA44. Watermark removed the action to the United States District Court for the Eastern District of Pennsylvania on March 26, 2021. JA8. The operative complaint, filed on April 15, 2021, contains four Pennsylvania state law causes of action. JA242.

First, the Estate alleged that Watermark was negligent, grossly negligent, careless, and reckless in fourteen specific ways, including by "[f]ailing to appropriately monitor and assist Mrs. Cannon with her daily

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these assertions, which are not properly considered in resolving a Rule 12(b)(6) motion to dismiss and not relevant to the issue on appeal.

living and hygiene needs," failing to protect Mrs. Cannon from physical injury by Blue Bell Place staff, failing to take adequate precautions to prevent Mrs. Cannon from falling, failing to provide Mrs. Cannon with adequate nutrition, failing to provide adequate medical treatment to Mrs. Cannon after her diagnosis with COVID-19, failing to keep Mrs. Cannon's family apprised of her condition, injuries, and illness in a timely manner, and administering hydroxychloroquine to Mrs. Cannon without consent. JA253–54.

Second, the Estate averred that Watermark's conduct throughout Mrs. Cannon's residence at Blue Bell constituted negligence per se under Pennsylvania law, 18 Pa. C.S.A. § 2713, which creates criminal penalties for neglect of care-dependent persons. JA255–56.

Third, the Estate claimed that the administration of hydroxychloroquine to Mrs. Cannon without informed consent, and contrary to her proxy's wishes, constituted reckless and outrageous conduct. JA256–57.

Fourth, the Estate averred that Watermark's acts and neglect caused Mrs. Cannon's wrongful death, and gave rise to a claim under the

Pennsylvania Wrongful Death Act Statute, 42 Pa. C.S.A. § 8301. JA257–58.

Finally, the Estate brought a claim pursuant to the Pennsylvania Survival Act, 42 Pa. C.S.A. § 8302, based on Watermark's actions and inactions. JA259.

B. Watermark's Motion to Dismiss

On April 28, 2021, Watermark moved to dismiss the amended complaint in its entirety, pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). JA278–79. In its supporting memorandum, it made three arguments.

First, Watermark argued that all of the Estate's claims were subject to immunity under the PREP Act since the claims related to "the use and administration of the covered countermeasure Hydroxychloroquine," JA302, citing to the PREP Act definition of "covered countermeasure" as including "any drug, biological product or device authorized for emergency use by the Federal Food, Drug, and Cosmetic Act (FDCA)," and the Secretary's Declaration. JA303. It also argued that PREP Act immunity applied under the statute's "safe harbor" provision. JA304–05.

Second, Watermark asserted the complaint should be dismissed in its entirety due to a failure to exhaust administrative remedies under the PREP Act. JA310–12.

Finally, Watermark asserted that "to the extent that Plaintiffs have attempted to bring forth any claims for willful misconduct" pursuant to subsection (d) of the PREP Act, those claims should be dismissed for failure to state a claim as not pleaded with sufficiency, or dismissed for lack of subject matter jurisdiction or transferred to the District Court for the District of Columbia. JA312–13.

In opposition, the Estate pointed out that the claims in the Complaint were not limited to ones arising out of the administration of hydroxychloroquine, but arose from a broader "pattern and practice of grossly negligent behavior." JA495. But Watermark had presented no basis for dismissing claims unrelated to hydroxychloroquine. JA502. The Estate also argued that, because Mrs. Cannon was not within the scope of the population for which the FDA's authorized emergency use of hydroxychloroquine and there was no evidence that the Declaration's means of distribution limitation was satisfied, the administration of hydroxychloroquine to her was not within the scope of the Secretary's

Declaration, and thus did not qualify for immunity under the PREP Act. JA496, 500–01. Finally, it argued that Watermark's arguments related to subsection (d)'s willful misconduct exception were irrelevant because none of the provisions of the statute applied at all. JA496.

The district court denied Watermark's motion in its entirety on May 28, 2021, without an opinion. JA534. On June 18, 2021, Watermark filed a notice of appeal to this Court. JA561. On July 19, 2021, the district court issued a memorandum opinion to supplement its order in light of this appeal. JA566 n.1. In that opinion, the court explained that even "[a]ssuming for the purposes of this Opinion only" that Watermark was a "covered person" under the PREP Act, "the administration of the [hydroxychloroquine] treatment *as Defendants used it* cannot be considered a covered countermeasure because it was not 'authorized for investigational or emergency use, as those terms are defined in the [FDCA],' as required by the PREP Act." JA571 (quoting 85 Fed. Reg. at 15,202). Further, construing the facts alleged in the complaint in favor of the Estate, the court found that the statutory safe harbor provision did not apply, because there was nothing to suggest that it would have been reasonable for the facility to believe that Mrs. Cannon was in the

population specified by the Emergency Use Authorization, those "hospitalized with COVID-19" who had been determined to be ineligible for any clinical trial. JA573.

SUMMARY OF ARGUMENT

I. This Court lacks jurisdiction over this interlocutory appeal from the denial of a motion to dismiss by the United States District Court for the Eastern District of Pennsylvania. While subsection (e)(10) of the PREP Act creates a right to interlocutory appeal to this Court of decisions denying certain motions to dismiss, that provision, like the other provisions of subsection (e), applies only to cases brought in the District Court for the District of Columbia asserting claims under the exclusive federal cause of action created by subsection (d) of the PREP Act. Watermark's contrary reading could place district courts in the impossible position of being subject to conflicting precedents of two circuits at once and committing reversible error however they ruled.

II. On the merits, the district court was correct to deny Watermark's motion to dismiss. First, the PREP Act provides for dismissal of "claims" relating to the administration or use of covered countermeasures. Here, though Watermark contends that the entire

complaint should have been dismissed, the only purported administration or use of a covered countermeasure addressed in its brief is the administration of hydroxychloroquine to Mrs. Cannon. Thus, Watermark offers no basis to disturb the district court's denial of the motion to dismiss as to the claims and parts of claims brought by the Estate based on abuse and neglect, and unrelated to hydroxychloroquine.

Second, the district court properly declined to dismiss the claims and parts of claims related to the administration of hydroxychloroquine. Based on the facts alleged, Watermark's administration of the drug to Mrs. Cannon was plainly outside the scope of immunity conferred by the Secretary's Declaration. Pursuant to the PREP Act's limitations-on-distribution provision, the Secretary explicitly limited immunity to claims tied to the use or administration of covered countermeasures related to federal contracts or agreements, or "[a]ctivities authorized in accordance with" the public health response of a government agency. 85 Fed. Reg. at 15,202. Nothing in the complaint and documents referenced therein establishes that Watermark's use of hydroxychloroquine fell within either of these categories. To the contrary, the complaint alleges that the administration of hydroxychloroquine to Mrs. Cannon was *not*

an activity authorized in accordance with the FDA's response to the pandemic, since that use was not within the scope of the Emergency Use Authorization. *Id.*

Additionally, based on the statute's population provision, the Secretary limited immunity to situations where the covered countermeasure was used or administered "in accordance with" his declaration. *Id.* Hydroxychloroquine was only a covered countermeasure under the Declaration to the extent that it was authorized by the FDA for emergency use on hospitalized patients. Any use of hydroxychloroquine outside the scope of that authorization, as alleged here, cannot be said to have been "in accordance with" the declaration based on the face of the complaint.

Finally, the safe harbor provision only applies where one of the two conditions listed in subsection (a)(3)(C) of the statute was not met, but a covered person could have reasonably believed that they did. It thus has no bearing on Watermark's failure to meet the limitations-on-distribution requirement. As to Watermark's failure to show its actions were in accordance with the Declaration, as the district court correctly concluded, the complaint does not establish that Watermark reasonably

could have believed that the administration of hydroxychloroquine to Mrs. Cannon was within the scope of the Emergency Use Authorization.

ARGUMENT

I. This Court lacks jurisdiction to review the Pennsylvania district court's denial of Appellants' motion to dismiss.

This appeal is unusual for two reasons. First, it is an interlocutory appeal of an order denying a motion to dismiss. Such orders are not generally appealable as of right. *See* 28 U.S.C. § 1291. Second, it is an appeal from an order of the U.S. District Court for the Eastern District of Pennsylvania. Subject to three exceptions, none of which applies here, "appeals from reviewable decisions" of district courts "shall be taken to the court of appeals for the circuit embracing the district," 28 U.S.C. § 1294(1)—here, the Third Circuit.

Watermark argues that subsection (e)(10) of the PREP Act, 42 U.S.C. § 247d-6d(e)(10), provides exceptions to both the rule against interlocutory appeals and the rule that district courts' decisions are appealed to their respective regional court of appeals. Appellants' Br. 1–2. Watermark is correct that subsection (e)(10), *where it applies*, provides a right to an interlocutory appeal. Subsection (e)(10) is ambiguous, however, as to whether it applies in cases like this one, where district

courts outside this Circuit have declined to dismiss state-law causes of action, or whether it applies only in cases brought in the District Court for the District of Columbia pursuant to the federal cause of action created by subsection (d) of the PREP Act, the procedures for which are specified in subsection (e). 42 U.S.C. §§ 247d-6d(d), (e). Because the former interpretation would lead to an untenable situation for district courts around the country, while the latter interpretation would avoid this difficulty and remain consistent with the statutory scheme, this Court should read the provision narrowly.

A. Subsection (e)(10) does not unambiguously apply to orders by district courts outside this Circuit addressing state-law claims.

The "first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997). In determining whether a statute is plain and unambiguous, courts refer "to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Id.*; *see also Cares Cmty. Health v. HHS*, 944 F.3d 950, 957 (D.C.

Cir. 2019). In the PREP Act, the language of subsection (e)(10) is ambiguous.

As explained above, *supra* p. 8, subsection (d) creates an exception to immunity otherwise conferred by subsection (a) of the PREP Act for claims relating to "willful misconduct," and creates an "exclusive Federal cause of action" for such claims. 42 U.S.C. § 247d-6d(d)(1). Subsection (e), entitled "Procedures for Suit," contains ten numbered paragraphs. Paragraphs numbered 1 through 9 expressly apply to "action[s] under subsection (d)." *Id.* § 247d-6d(e)(1)–(9). Those paragraphs set forth pleading requirements and limitations on discovery, and the specification that "[a]ny action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia." *Id.* § 247d-6d(e)(1). Paragraph 5 provides that, in such an action, a three-judge panel of that court shall consider motions to dismiss and motions for summary judgment, and paragraph 6 provides for a stay of discovery during the pendency of such a motion or an interlocutory appeal from the denial of such a motion. Paragraph 10, entitled "Interlocutory appeal," states:

> The United States 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) or based on an assertion of the exclusion under subsection (c)(5).

The appeal in this case does, literally, concern "an order denying a motion to dismiss" based on an assertion of subsection (a) immunity. But subsection (e)(10) is silent about *which courts'* orders and *what kinds* of actions it governs. On its face, the provision, which does not refer to motions under the Federal Rules of Civil Procedure or cite any provision of Title 28 of the U.S. Code, could be read to provide this Court with jurisdiction to hear interlocutory appeals from denials of motions to dismiss by Pennsylvania *state* courts. Such jurisdiction would be highly unusual, to say the least.

Moreover, the right to an interlocutory appeal provided for in subsection (e)(10) "does not stand alone." *Guam v. United States*, 141 S. Ct. 1608, 1613 (2021). The individual provisions of subsection (e) are "properly read in 'sequence' as 'integral parts of a whole.'" *Id.* (quoting *New Prime Inc. v. Oliveira*, 139 S. Ct. 532, 538 (2019)). The provision for "interlocutory appeals" is the tenth in a list of provisions, 42 U.S.C. § 247d-6d(e), all of which dictate "procedures for suit" that expressly

apply *only* to subsection (d) cases, which are subject to the exclusive jurisdiction of the District Court for the District of Columbia, *id.* § 247d-6d(e)(1). Other provisions include the creation of a three-judge panel to hear motions to dismiss and motions for summary judgment in "any action under subsection (d)," *id.* § 247d-6d(e)(5), and an automatic stay of discovery in "an action under subsection (d)" when an interlocutory appeal from the denial of a motion to dismiss is pending, *id.* § 247d-6d(e)(6)(A)(iii). In this context, the "interlocutory appeal" right in subsection (e)(10) is best read to apply to the same set of motions to dismiss and summary judgment discussed in the preceding provisions of subsection (e). Although the phrase "any action under subsection (d)" is not repeated in paragraph (e)(10), such an "effort to tear [subsection (e)(10)] away from its companions based on a negative implication falters in light of the other strong textual links among them." *Guam*, 141 S. Ct. at 1615.

Reading subsection (e)(10) as creating a right to interlocutory appeals of motions to dismiss and for summary judgment only in cases otherwise governed by subsection (e) would also give each paragraph of subsection (e) a coherent meaning. Where a plaintiff files an action under

subsection (e)(1) in the District Court for the District of Columbia asserting the exclusive federal cause of action under subsection (d), a defendant may move a three-judge panel to dismiss or for summary judgment on any number of grounds, pursuant to subsection (e)(5). In such a motion, the defendant could argue generally that the plaintiff's claims are *not* grounded on willful misconduct, and thus that "the immunity from suit conferred by subsection (a)" applies—one of the two bases of a motion for which interlocutory appeal is permitted. *See* 42 U.S.C. § 247d-6d(e)(10). Or the defendant could argue that "the exclusion under subsection (c)(5)" applies—the other basis for which interlocutory appeal is permitted. *Id.*; *see* 42 U.S.C. § 247d-6d(c)(5) (providing that the administration or use of certain regulated products cannot constitute "willful misconduct" for purposes of subsection (d)). If accepted, the latter argument, which *only* applies to subsection (d) claims, would require dismissal of the subsection (d) cause of action. Subsection (e)(10) provides a right to an interlocutory appeal to this Court if the U.S. District Court for the District of Columbia denies motions to dismiss or for summary judgment on either of these grounds—exactly what the statutory heading suggests. *See Guam*, 141 S. Ct. at 1613 (noting that the title of the

subsection was a "clue" to limited scope); *Fla. Dep't of Revenue v. Piccadilly Cafeterias, Inc.*, 554 U.S. 33, 47 (2008) (noting that "statutory titles and section headings 'are tools available for the resolution of a doubt about the meaning of a statute'" (quoting *Porter v. Nussle,* 534 U.S. 516, 528 (2002)). And if the appeal is from the denial of a motion to dismiss in "an action under subsection (d)," paragraph 6 provides for a stay of discovery pending resolution of that "interlocutory appeal." 42 U.S.C. § 247d-6d(e)(6)(A)(iii).

Additionally, in enacting subsection (e)(10), Congress did not amend 28 U.S.C. § 1294, which specifies that *any* appealable decision of the District Court for the Eastern District of Pennsylvania is reviewed by the Third Circuit, unless it falls under one of the specifically referenced exceptions providing for review by the Federal Circuit. To find jurisdiction over appeals like this one, this Court would have to infer that Congress intended to amend section 1294 *sub silentio*—contrary to the rule of statutory construction that "amendments by implication, like repeals by implication, are not favored, and will not be found unless an intent to repeal or amend is clear and manifest." *Agri Processor Co., Inc. v. NLRB*, 514 F.3d 1, 4 (D.C. Cir. 2008) (cleaned up). Congress's previous

amendments of section 1294 with respect to patent, international trade, and other subjects within the Federal Circuit's jurisdiction show that Congress knows how to route district court appeals to courts other than regional courts of appeals. That it did not do so in the PREP Act counsels strongly for construing subsection (e)(10) to apply only to actions under subsection (d), not to actions filed in district courts outside the District of Columbia. *See Al-Bihani v. Obama*, 619 F.3d 1, 32 (D.C. Cir. 2010) ("[C]ourts construe ambiguous statutes to conform to preexisting statutes."); *cf.* 42 U.S.C. § 247d-6d(d)(1) (explicitly addressing PREP Act's interaction with Federal Tort Claims Act, 28 U.S.C. § 2679(b)(2)(B)).

Finally, under Watermark's interpretation of the statute, paragraph 10 provides this Court with jurisdiction over *interlocutory* appeals of all court decisions *denying* motions to dismiss or for summary judgment based on PREP Act defenses, but not over appeals from *final* decisions of any district court (outside the District of Columbia) *granting* motions to dismiss or summary judgment, on the basis of subsection (a) immunity or on any other grounds, or, for that matter, trial judgments finding PREP Act immunity does not apply. Those appeals would be

heard in the regional circuits pursuant to 28 U.S.C. § 1294(1). Indeed, there is at least one such appeal pending in the Ninth Circuit. *See Garcia v. Welltower OpCo Grp. LLC*, 9th Cir. Appeal No. 21-55224.

Appellant cites no statute in which two different courts of appeals would have jurisdiction to review an order resolving the same issues presented in a single motion based on whether that motion was granted or denied.[4] That is because where Congress directs appeals to a single Circuit, the purpose is to develop a uniform body of law on the relevant subject matter. *See, e.g.*, *United States v. Hohri*, 482 U.S. 64, 71 (1987) (noting the "evident congressional desire for uniform adjudication of Little Tucker Act claims" in channeling cases to Federal Circuit); *Nat'l*

[4] Watermark states that "more than 100 other statutes" identify this Court as "the exclusive or alternative forum" for appeal. Appellants' Br. 28 (citing Eric M. Fraser, et al., *The Jurisdiction of the D.C. Court*, 23 Cornell J.L. & Pub. Pol'y 131, 154 (2013)). But the cited list simply contains "more than 150 statutory provisions that specifically refer to the D.C. Circuit, with over 130 of these specifically relating to jurisdiction." 23 Cornell J.L. & Pub. Pol'y at 143. The provisions "specifically relating to jurisdiction" do not provide *appellate* jurisdiction from district court orders. Rather, they provide jurisdiction for direct review from agency orders and rules. *See, e.g.*, 8 U.S.C. § 1189 (establishing venue for judicial review of designation of foreign terrorist organization by the Secretary of State; 21 U.S.C. § 333(f)(6) (specifying venue for review of FDA no-tobacco-sale orders). None provides for appeals to this Court from district courts other than the District Court for the District of Columbia.

Env't Dev. Ass'n's Clean Air Project v. Envtl. Prot. Agency, 891 F.3d 1041, 1053 (D.C. Cir. 2018) (noting that the Clean Air Act sends "national issues to our circuit for uniform resolution"). To achieve this objective, Congress directs to the specified court *all* decisions arising under the particular statute—not only decisions denying certain motions and not only interlocutory decisions. *See, e.g.*, 28 U.S.C. § 1295(a)(1) (providing exclusive jurisdiction in the Federal Circuit over any "appeal from a final decision of a district court" involving claims "relating to patents or plant variety protection"); *id.* § 1292(c)(1) (providing exclusive jurisdiction in the Federal Circuit over interlocutory appeals in any cases in which it would have jurisdiction over appeals of final orders); *see also Hohri*, 482 U.S. at 73 (noting the "conspicuous feature" of "creation of exclusive Federal Circuit jurisdiction over *every appeal* from a Tucker Act or nontax Little Tucker Act claim"). A scheme that directs orders *denying* motions to dismiss to one court of appeals and orders *granting* those motions to another court of appeals, and that directs interlocutory appeals of rulings on certain motions to one court but final appeals of rulings resolving the same issues to another, would not serve that (or any other) purpose.

The notion that this Court has jurisdiction over all cases involving interpretation of the PREP Act is also contradicted by the undisputed proposition that this Court lacks jurisdiction over another category of cases requiring interpretation of the PREP Act: appeals from remand orders where a state-court defendant has invoked the PREP Act as a federal defense for purposes of the federal-officer removal statute or as a purported basis for federal question removal jurisdiction. Appeals by defendants of such remand orders are pending in at least six courts of appeals. *See, e.g.*, *Rivera-Zayas v. Our Lady of Consolation Geriatric Care Ctr.*, No. 21-2164 (2d Cir.); *Perez v. Southeast SNF*, No. 21-50399 (5th Cir.) (argued Dec. 6, 2021); *Hudak v. Elmcroft of Sagamore Hills*, No. 21-3836 (6th Cir.); *Martin v. Petersen Health Ops., LLC*, No. 21-2959 (7th Cir.); *Saldana v. Glenhaven Healthcare LLC*, No. 20-56194 (9th Cir.) (argued October 20, 2021); *Schleider v. GVDB Operations, LLC*, No. 21-11765 (11th Cir.). The parties in each case dispute the scope of the PREP Act, and the regional courts of appeals' interpretations of the PREP Act's scope will be binding on district courts within their circuits both when ruling on remand motions and when adjudicating the merits of immunity defenses where jurisdiction exists.

B. Appellants' interpretation would create an unworkable situation in the district courts.

"[W]hen deciding which of two plausible statutory constructions to adopt, a court must consider the necessary consequences of its choice." *Clark v. Martinez*, 543 U.S. 371, 380 (2005). Here, interpreting the PREP Act to allow Watermark to appeal to this Court the district court's interlocutory order denying its motion to dismiss, even though the Estate's appeal of an adverse decision on the very same motion would go to the Third Circuit, would create an unworkable situation for the nation's district courts. Each of those courts (except the District Court for the District of Columbia) would be bound by precedent from two courts of appeals, neither of which has an obligation to follow the other.

The federal judicial system contemplates that courts of appeals may interpret the same statute differently, but district courts are only bound by the decisions of a single court of appeals. *See, e.g.*, *In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171, 1176 (D.C. Cir. 1987), *aff'd sub nom. Chan v. Korean Air Lines, Ltd.,* 490 U.S. 122 (1989) ("Binding precedent for all is set only by the Supreme Court, and for the district courts within a circuit, only by the court of appeals for that circuit."); *cf. Rates Tech. Inc. v. Speakeasy, Inc.*, 685 F.3d 163, 174 n.9 (2d Cir. 2012)

(noting that district courts are "bound to follow the holdings of the Federal Circuit" on issues of patent law).[5] Under Watermark's interpretation of subsection (e)(10), however, district courts could be bound by the precedents of two different courts of appeals on a single issue. For example, should this Court come to a different conclusion than the Ninth Circuit in the pending *Garcia* or *Saldana* appeals as to the scope of the immunity provisions of the PREP Act, district courts within the Ninth Circuit would be in an untenable situation in future cases: If Ninth Circuit precedent required denying a motion to dismiss, but this Court's precedent required granting that same motion, the decision

[5] Watermark states that it is "not [] unprecedented for a single district court to be bound by the decision of more than one court of appeals," pointing to the statutory provision for review of decisions of the United States Tax Court, 26 U.S.C. § 7482(b)(1). Appellants' Br. 28 n.36. The Tax Court, however, is not a district court, but rather an Article I tribunal. *See Freytag v. Comm'r of Internal Revenue*, 501 U.S. 868 (1991). That review of its decisions is based on the location of the parties before it is similar to the review process of actions of many other administrative boards and commissions. *See, e.g.*, 29 U.S.C. §§ 160(e)–(f) (National Labor Relations Act). Moreover, the problem of multiple masters posed by Watermark's interpretation does not exist with Tax Court appeals: whether the government/respondent or taxpayer/petitioner is seeking review of an order in a given case, the same court of appeals will have jurisdiction.

would be reversed on appeal no matter which precedent the district court faithfully applied.

It is not plausible that Congress intended to put courts and litigants in such an untenable situation. *Cf. E. Band of Cherokee Indians v. U.S. Dep't of the Interior*, 534 F. Supp. 3d 86, 100 (D.D.C. 2021) (rejecting proffered reading where "it is not plausible that Congress intended to create such a bizarre law-school hypothetical"). For this reason, even if the statute were not ambiguous, the Estate's proposed narrower interpretation would be the best reading of the statute under the canon against absurdity, because it would be "so bizarre" and "illogical" that "Congress could not plausibly have intended" that a district court's ruling as to a single issue raised in a motion to dismiss would be reviewed by two different courts of appeals, depending on how the district court ruled. *See Stovic v. R.R. Ret. Bd.*, 826 F.3d 500, 505 (D.C. Cir. 2016) (citations omitted).

The importance of avoiding such conflicts is reflected in case law of the Federal Circuit, exercising its appellate jurisdiction over cases from district courts around the country pursuant to the three exceptions noted in section 1294, including patent cases. "[T]o avoid the risk that district

courts and litigants will be forced to select from two competing lines of authority based on which circuit may have jurisdiction over an appeal that may ultimately be taken," that Court has adopted a rule where it "appl[ies] regional circuit law to nonpatent issues" and the law of the Federal Circuit to patent-specific questions. *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999) (en banc) *abrogated on other grounds*; *see also Atari, Inc. v. JS & A Grp., Inc.*, 747 F.2d 1422, 1439 (Fed. Cir. 1984), *overruled on other grounds by Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998) (noting it would be unfair to hold that a district court "should have 'served two masters', or that it should have looked, Janus-like, in two directions in its conduct of that judicial process").

Here, no such solution to the two-master problem would be possible. Section 1295(a)(1) vests exclusive jurisdiction in the Federal Circuit jurisdiction for *all* appeals in civil actions involving patents, thus ensuring that district courts never face the risk of looking to two masters on issues of patent law. In contrast, under Watermark's reading of paragraph 10(e), this Court conducts interlocutory review of PREP Act

issues, while regional circuits conduct review of final orders posing *the same issues* in the same cases.

In sum, "[w]hen possible, statutes should be interpreted to avoid untenable distinctions, unreasonable results, or unjust or absurd consequences." *Kaseman v. District of Columbia*, 444 F.3d 637, 642 (D.C. Cir. 2006) (cleaned up). Such an interpretation is readily available here by reading paragraph 10 to apply only to cases brought pursuant to subsection (d)'s cause of action, a cause of action that can be brought only in the District Court for the District of Columbia.

II. The Pennsylvania district court correctly denied Watermark's motion to dismiss.

A. Standard of Review

Should this Court conclude that it has jurisdiction over this interlocutory appeal from the decision of the Pennsylvania District Court, it must then determine what law to apply in reviewing decisions of district courts outside the D.C. Circuit. Appellee respectfully suggests that this Court adopt an approach similar to that adopted by the Federal Circuit by applying its "own law with respect to [PREP Act] issues, but with respect to [non-PREP Act] issues … generally apply[ing] the law of the circuit in which the district court sits." *Midwest Indus.*, 175. F.3d at

1359 (in patent context); *see also Russell v. United States*, 661 F.3d 1371, 1376 (Fed. Cir. 2011) (noting law of the regional circuit applies to any "question that is not unique to cases arising under the Little Tucker Act"). Here, the law of the Third Circuit would thus govern to the extent that the appeal raises questions not unique to cases where a party has invoked the PREP Act, including the standards of decision for Rule 12 motions. *See, e.g.*, *Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253, 1257 (Fed. Cir. 2017) ("We apply regional circuit law when reviewing motions to dismiss for failure to state a claim."); *Bayer Schering Pharma AG v. Lupin, Ltd.,* 676 F.3d 1316, 1327 (Fed. Cir. 2012) ("Pleading standards are a matter of regional circuit law."); *Madey v. Duke Univ.*, 307 F.3d 1351, 1358 (Fed. Cir. 2002) (holding law of the regional circuit applies to review of dismissal for lack of subject matter jurisdiction).

Where the Third Circuit has jurisdiction over the interlocutory appeal of a denial of a motion to dismiss, its review is *de novo*, "accept[ing] as true all well-pled factual allegations in the complaint and all reasonable inferences that can be drawn from them." *Taksir v. Vanguard Grp.*, 903 F.3d 95, 96–97 (3d Cir. 2018) (quoting *Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 242 (3d Cir. 2008)); *see also Vila v. Inter-*

American Inv. Corp., 570 F.3d 274, 278 (D.C. Cir. 2009) (applying same standard). Because Watermark sought dismissal based on an affirmative defense, it bears the burden of establishing "that the defense is apparent on the face of the complaint and documents relied on in the complaint." *Lupian v. Joseph Cory Holdings LLC*, 905 F.3d 127, 130 (3d Cir. 2018) (cleaned up); *see also Klayman v. Zuckerberg*, 753 F.3d 1354, 1357 (D.C. Cir. 2013) (holding that statutory immunity defense can only "support a motion to dismiss if the statute's barrier to suit is evident from the face of the complaint").

B. The Estate's claims do not fall within subsection (a)(1) of the PREP Act.

Watermark's principal merits argument is that the district court should have dismissed the operative complaint in its *entirety* because Watermark is immune from suit under subsection (a)(1) of the PREP Act. Appellants' Br. 29–50. That argument is incorrect for several reasons. First, immunity under subsection (a)(1) applies only "with respect to [] *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" within the scope of a PREP Act declaration. 42 U.S.C. § 247d-6d(a)(1) (emphasis added). Watermark does not argue that the

complaint contains any such claims other than those relating to hydroxychloroquine, and thus there is no basis to dismiss any of the Estate's claims to the extent they do not relate to hydroxychloroquine. Second, Watermark is not entitled to immunity for claims relating to its administration of hydroxychloroquine to Mrs. Cannon, as its use outside the scope of the FDA's Emergency Use Authorization was not covered by the Secretary's Declaration. Third, to the extent the safe harbor provision is relevant at all, the facts as alleged do not establish that Watermark is entitled to invoke that provision.

1. The claims and parts of claims unrelated to the use of hydroxychloroquine are not impacted by subsection (a)(1).

The immunity from liability and provisions relating to the willful misconduct carveout from that immunity apply only to "claim[s] for loss that ha[ve] a causal relationship with the administration to or use by an individual of a covered countermeasure" that is within the scope of a Secretarial declaration. 42 U.S.C. §§ 247d-6d(a)(2)(B); 247d-6d(a)(1). Watermark asserts that this immunity requires dismissal of the entire complaint because certain claims, or parts of claims, relate to the administration of a covered countermeasure, hydroxychloroquine, to

Mrs. Cannon. Even if Watermark were correct about the claims as to hydroxychloroquine, subsection (a)(1) would support dismissal only of the claims insofar as they are based on the administration of hydroxychloroquine. The Estate's complaint, however, alleges that Watermark violated Pennsylvania law in a number of ways completely apart from its nonconsensual administration of hydroxychloroquine to Mrs. Cannon. Of the five causes of action in the operative complaint, only the one for recklessness and outrageous conduct is based solely on the administration of hydroxychloroquine to Mrs. Cannon. JA256–57. As to the other four causes of action, the fact that the Estate has grouped within one cause of action several actions and inactions that give rise to each state-law claim does not mean that the entire claim falls if the PREP Act bars relief based on one of those actions/inactions. For example, the Estate's negligence claim is based on fourteen specific negligent actions and inactions by Watermark, and the administration of hydroxychloroquine is only implicated by one of the fourteen. *See* JA253–54. Watermark's failures to ensure Mrs. Cannon was adequately bathed and clothed, that she was not physically assaulted by Blue Bell staff, and that there were adequate safeguards to prevent her from falling, *id.*, do

not "relate to" the administration of hydroxychloroquine in even the broadest sense of the term, and Watermark's argument about the PREP Act provides no basis to dismiss the Estate's claims to the extent they are based on these actions and inactions.

That PREP Act immunity applies only to claims or parts of claims relating to the administration or use of a covered countermeasure, not an entire complaint, is consistent with the maxim that, "[a]s a general matter, if a complaint contains both good and bad claims, the court proceeds with the good and leaves the bad." *Jones v. Bock*, 549 U.S. 199, 221 (2007); *see also In re Lord Abbett Mutual Funds Fee Litig.*, 553 F.3d 248, 257 (3d Cir. 2009) ("[a]llowing those claims that do not fall within [Securities Litigation Uniform Standards Act of 1998's] preemptive scope to proceed, while dismissing those that do"). In determining what aspects of a complaint should be dismissed, courts look beyond how claims have been grouped or labeled in a complaint and focus on their substance. *See, e.g., Close v. Sotheby's, Inc.*, 894 F.3d 1061, 1074 (9th Cir. 2018) (dismissing claims as preempted to the extent that they were based on sales post-dating the effective date of the Copyright Act, but declining to dismiss to the extent that they were based on earlier sales); *Milanese v.*

Rust-Oleum Corp., 244 F.3d 104, 109 (2d Cir. 2001) (holding that tort claims should be dismissed as preempted by the Federal Hazardous Substances Act only to the extent that they sought to impose additional labeling requirements); *Wood v. Am. Fed. of Gov't Employees*, 255 F. Supp. 3d 190, 199 (D.D.C. 2017) (dismissing defamation claim to the extent that it challenged unfair labor practices, but declining to dismiss claim as to other allegations).

In this regard, there is nothing unique about the PREP Act and the immunity it provides for "claims," as reflected in the few cases addressing this issue. In *Ruiz v. ConAgra Foods Packaged Foods, LLC*, No. 21-CV-387-SCD, 2021 WL 3056275, at *3 (E.D. Wisc. July 20, 2021), for example, the court explained that even if it agreed with the defendant's arguments about covered countermeasures, "most of the amended complaint's allegations," which were about unsafe working conditions generally and "ha[d] nothing to do with covered countermeasures," "would remain untouched by the Act's immunity provision." And in *Mills v. Hartford Health Care Corp.*, No. HHDCV206134761S, 2021 WL 4895676, at *4 (Conn. Super. Ct. Sept. 27, 2021), a state court found that malpractice claims related to a hospital's use of a COVID-19 diagnostic

test were subject to PREP Act immunity. The court ordered the plaintiff's negligence claims dismissed only to the extent they related to that testing, however, and allowed them to proceed to the extent they were not related to such testing, i.e., not related to the use of a covered countermeasure. *Id.*

So too here, even if Watermark were to prevail on every issue raised in its appeal (which it should not), the Estate's claims should be allowed to proceed to the extent that they are unrelated to administration of the sole covered countermeasure identified by Watermark, hydroxychloroquine.

2. Claims and parts of claims relating to the administration of hydroxychloroquine to Mrs. Cannon are not subject to subsection (a) of the PREP Act.

As to the Estate's claims relating to the administration of hydroxychloroquine to Mrs. Cannon, the district court correctly denied Watermark's motion to dismiss. To establish that subsection (a) of the PREP Act applies, Watermark bears the burden to establish both that hydroxychloroquine was a covered countermeasure *and* that its administration of that covered countermeasure to Mrs. Cannon was within the scope of the Secretary's March 2020 Declaration. As to the

former, the declaration included two requirements—both of which the use of hydroxychloroquine meets in some circumstances. First, hydroxychloroquine is a "drug … used to treat …, diagnose, cure, prevent, or mitigate COVID-19." 85 Fed. Reg. at 15,202. Second, it is a "drug[] … authorized for investigational or emergency use, as those terms are defined in the PREP Act, the [FDCA], and the Public Health Service Act." *Id.*[6] But as the district court concluded, Watermark has not met its burden to establish that *its administration* of hydroxychloroquine to Mrs. Cannon as alleged in the complaint was within the scope of the immunity

[6] Watermark argues on appeal that its treatment of Mrs. Cannon with hydroxychloroquine constitutes the administration of a covered countermeasure on the alternative ground that it is a "qualified pandemic or epidemic product," as defined in 42 U.S.C. § 247d-6d(i)(7). Appellants' Br. 32–34, 36–37. But it did not make this argument in either its principal or reply briefs in the district court. *See* JA302 (argument based solely on the notion that hydroxychloroquine was a drug "authorized for emergency use," per § 247d-6d(i)(1)(C)). Accordingly, the argument has been forfeited. *See Keepseagle v. Perdue*, 856 F.3d 1039 (D.C. Cir. 2017) ("It is well settled that issues and legal theories not asserted at the District Court level ordinarily will not be heard on appeal.") (quoting *District of Columbia v. Air Fla., Inc.*, 750 F.2d 1077, 1084 (D.C. Cir. 1984)). Regardless, even if hydroxychloroquine were a qualified pandemic or epidemic product, PREP Act immunity would only apply if the "Limitations on Distribution" and "Population" conditions of the Secretary's Declaration were met. As explained below, they were not.

conferred by the Declaration for at least two reasons. First, the Complaint does not establish that Watermark's use of hydroxychloroquine met the Declaration's "Limitations on Distribution" requirement. Second, that use did not fall within the "Population" condition of the Declaration.

a. Watermark has not met the "Limitations on Distribution" requirement.

As noted above, at the relevant time period, the Declaration specified that "liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to" either federal contracts or agreements, or "[a]ctivities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency." 85 Fed. Reg. at 15,202. Watermark has not established that it met either of these requirements, and thus it is not entitled to immunity. *See Avicolli v. BJ's Wholesale Club, Inc.*, Civ. No. 21-1119, 2021 WL 1293397 (E.D. Pa. Apr. 7, 2021) (denying motion to dismiss where complaint did not provide a basis to infer that distribution requirement was met); *see also Mier v. CVS Pharmacy, Inc.*, No. SA CV

20-01979-DOC, 2021 WL 4134678, at *7 (C.D. Cal. Aug. 23, 2021) (striking PREP Act affirmative defense where distribution requirement not met).

In its brief on appeal, Watermark does not make any argument about this requirement. Below, Watermark asserted, without citation to the complaint or anything else, that it met this requirement because it was "acting at the direction of the state and federal government to prevent, treat and contain COVID-19 at the facility and in its care and treatment of Mrs. Cannon." JA309. On a Rule 12(b)(6) motion, this assertion is not entitled to any deference. *Cf. Maglioli*, 16 F.4th at 405–06 (rejecting argument that nursing homes were acting under federal government direction in responding to the pandemic). Moreover, this assertion does not establish that the relevant "Recommended Activit[y] involving Covered Countermeasures," 85 Fed. Reg. at 15,202, i.e., the administration of hydroxychloroquine to Mrs. Cannon, was related to an agreement or contract with the federal government, or any activity authorized in accordance with any agency's pandemic response.

Beyond the plain text of the Declaration, non-binding agency guidance addressing how a covered person can qualify for immunity

under the "authority having jurisdiction" means of distribution confirms this conclusion. In an October 2020 non-binding advisory opinion, HHS explained that:

> Public-health guidance from an applicable Authority Having Jurisdiction that recommends or requires using covered countermeasures in certain circumstances may qualify as authorizations under the PREP Act and the Declaration. But to obtain such authorization, a covered person must follow that public-health guidance.

Advisory Opinion 20-04 at 4 (as modified Oct. 23, 2020).[7] Under this view, Watermark's failure to identify any public-health guidance that it was following when it administered hydroxychloroquine to Mrs. Cannon is fatal to its immunity request. Indeed, the only conceivable guidance regarding hydroxychloroquine administration in the record is the FDA Emergency Use Authorization. And the complaint and documents referenced therein show that the administration of hydroxychloroquine to Mrs. Cannon did *not* follow the Emergency Use Authorization. There is no dispute that the FDA authorized the administration of hydroxychloroquine to treat COVID-19 *only* in hospitalized patients who

[7] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf.

were ineligible for clinical trials. *See* JA341. The complaint alleges, and Watermark does not dispute, that Mrs. Cannon was not such a patient.

Additionally, the fact that the Secretary only later declared that immunity could apply where the covered countermeasure was a drug distributed through private distribution channels (and used consistent with FDA authorization), *see* Fourth Amendment, 85 Fed. Reg. at 79,194, confirms that any use of hydroxychloroquine obtained through such channels was *not* subject to immunity under the Declaration in effect at the time of Mrs. Cannon's death.

Because the face of the complaint does not show that Watermark met the Declaration's limitations on distribution, Watermark was not entitled to dismissal on the basis of PREP Act immunity.

b. Mrs. Cannon was not within the scope of the population specified in the Declaration.

Watermark is also not entitled to immunity because Mrs. Cannon was not in the population specified in the Declaration—"any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration." 85 Fed. Reg. at 15,202. Watermark did not administer hydroxychloroquine to Mrs. Cannon "in accordance with" the Declaration.

In the Declaration, the Secretary "recommended" the use of "covered countermeasures" to combat COVID-19. As noted above, the Declaration only made hydroxychloroquine a covered countermeasure to the extent it was a "drug[]…authorized for investigational or emergency use" by the FDA. 85 Fed. Reg. at 15,202. Accordingly, any use of hydroxychloroquine outside the scope of its emergency use authorization—such as its use here to treat a patient who was not hospitalized—was not use "in accordance with" the Declaration.

This reading follows from the context of the Declaration and the statute as a whole. The PREP Act, and the Secretary's Declaration, aim to provide immunity for entities doing what the government told them to do. The statute does not allow covered persons to decide on their own what products to use or administer to respond to a pandemic. Rather, it limits immunity to products approved, cleared, or authorized by the FDA or the National Institute of Occupational Safety and Health. 42 U.S.C. § 247d-6d(i)(1), (7). And, as noted above, *supra* pp. 9–10, the Secretary's Declaration is expressly limited to actions consistent with agency guidance.

Watermark's suggestion that if a drug, product, or device becomes a covered countermeasure for any purpose, it is used "in accordance with" the Declaration any time it is used for any COVID-19 purpose would lead to absurd results. Under this reading, for example, an approved COVID-19 test would be used "in accordance with" the Declaration if a doctor directed a COVID-19 patient to swallow the testing solution to cure his symptoms. There is no indication that Congress, or the Secretary, intended to immunize such conduct. Even if there were any ambiguity on this point, the Court should adopt a narrow construction of the preemptive scope of the Declaration. *See, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (noting that the presumption against preemption applies to questions concerning the scope of a preemption provision consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety); *see also Commissions Import Export S.A. v. Republic of the Congo*, 757 F.3d 321, 332 (D.C. Cir. 2014).

c. The facts alleged do not establish that Watermark is entitled to invoke the population requirement's safe harbor provision.

Watermark argues that, even if it failed to satisfy the Declaration's conditions for immunity, the district court should have dismissed the complaint based on the safe harbor provision, 42 U.S.C. § 247d-6d(a)(4)(B). Properly applying the Rule 12(b)(6) standard, however, the district court construed the facts alleged in the complaint in the light most favorable to the Estate. As the court concluded, those facts, as a matter of law, do not establish that Watermark "reasonably could have believed" that its administration of hydroxychloroquine to Mrs. Cannon was "in accordance with the conditions described in paragraph (3)(C)," namely, that Mrs. Cannon was "in a population specified by the declaration." 42 U.S.C. § 247d-6d(a)(3)(C)(i).

As a threshold matter, the safe harbor provision does not apply to the limitations on distribution requirement. That condition is not one "described in paragraph (3)(C)," but rather one addressed in paragraph (5). Thus, if the Court agrees with the Estate as to the limitations on distribution requirement, it need not address the safe harbor provision at all. Watermark points to language in two Advisory Opinions for the

proposition that *anytime* a person "reasonably could have believed" a product that they used was a covered countermeasure, they will retain that immunity even if the product was not a covered countermeasure--for any reason. *See* Appellants Br at 7–8 (citing JA479 and Advisory Opinion 20-04 at 2). But the only statutory provision referenced in those advisory opinions is section (a)(4)(B), which unambiguously only creates a safe harbor for noncompliance "with the conditions described in paragraph (3)(C)." Nothing in the statute suggests that "the reasonably could have believed" standard applies elsewhere. To the extent that the Advisory Opinions suggest otherwise, the opinions lack the power to persuade. *See, e.g., Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) ("If uncertainty does not exist, there is no plausible reason for deference."); *see also D.C. Hosp. Ass'n. v. D.C.*, 224 F.3d 776, 780 (D.C. Cir. 2000) ("Because the provision at issue here is unambiguous, we owe no deference to a contrary construction even if formally adopted by the Secretary of Health and Human Services.").

As to the population condition of paragraph (3)(C)(i), nothing in the complaint or any document referenced in it suggests that Watermark could have reasonably believed that its administration of

hydroxychloroquine to Mrs. Cannon fell within the scope of the Emergency Use Authorization. As the district court noted, "[t]he very document that authorized hydroxychloroquine sulfate for emergency use *explicitly* specified the required populations to which use of the treatment was limited; *to wit*: the drug needed to be 'administered by a healthcare provider pursuant to a valid prescription' and administered to 'adult and adolescent patients who weigh 50 kg or more hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible.'" JA572 (quoting Emergency Use Authorization). And nothing in the complaint suggests that Watermark had reason to believe Mrs. Cannon actually *was* hospitalized with COVID-19 or speaks to her eligibility for a clinical trial. Because the facts that would be necessary to establish that the safe harbor provision applies do not appear on the face of the complaint, that provision is not a basis for granting a motion to dismiss under Rule 12(b)(6) motion to dismiss. *See, e.g.*, *Lupian*, 905 F.3d at 130; *Klayman*, 753 F.3d at 1357.

Furthermore, none of Watermark's arguments about the safe harbor provision has any real bearing on whether that provision applies—at the 12(b)(6) stage or otherwise. Rather, they conflate

Watermark's arguments (unsupported by the pleadings) on the ultimate merits question whether Watermark acted reasonably in giving Mrs. Cannon hydroxychloroquine, which is not before the Court, with the question whether Watermark had reason to believe that Mrs. Cannon was within the scope of the Emergency Use Authorization. First, Watermark claims that it was obligated under Pennsylvania law to administer hydroxychloroquine to Mrs. Cannon because it was prescribed to her by a physician. Appellants' Br. 45–46. Putting aside that nothing before the Court indicates that the prescriber was not an agent of Watermark, any such duty does not suggest, let alone conclusively establish, that Watermark had reason to believe that Mrs. Cannon was within the specified population—the only relevant question for purposes of the safe harbor provision.

Second, Watermark asserts that it engaged in unauthorized use of hydroxychloroquine at an "uncertain time," when "[t]here were numerous instances of the drug being administered to residents of assisted living facilities" and President Trump "was encouraging doctors to prescribe the medication." Appellants' Br. 46–48. These factual assertions, not contained anywhere in the complaint or documents referenced therein,

are not appropriately considered on a Rule 12(b)(6) motion. But even if they were, Watermark does not attempt to explain how these assertions, even if true, would establish as a matter of law that it had reason to believe administering hydroxychloroquine to Mrs. Cannon was within the scope of the Emergency Use Authorization.

C. Watermark's "willful misconduct" argument misunderstands the statutory scheme.

Watermark argues that "[a]fter the District Court erroneously concluded that Appellants were not entitled to PREP Act immunity at this stage of the litigation, it should have reviewed the allegations of willful misconduct under Rule 12(b)(1), and dismissed or transferred those claims to the D.D.C. for lack of subject matter jurisdiction." Appellants' Br. 20; *see* Appellants' Br. 50–52. This argument gets the statute, and the district court's decision, exactly backwards.

Once the district court concluded that the Estate's claims did not relate to the administration or use of a covered countermeasure within the scope of the Secretary's Declaration, there was no need to do anything else. *Cf. Avicolli*, 2021 WL 1293397 at *5 ("We need not address [defendant]'s remaining arguments regarding willful misconduct and transfer of venue as the Act does not apply based solely on the

allegations."). The subsection (d) cause of action, and any conceivable administrative exhaustion or exclusive venue requirement for that cause of action, is an "exception to the immunity from suit and liability of covered persons set forth in subsection (a)." 42 U.S.C. §247d-6d(d)(1). Thus, only if the district court had *agreed* with Watermark that some or all of the Estate's claims were subject to subsection (a) immunity would the court have needed to address the question whether those claims should be dismissed with prejudice or, because they were subject to the subsection (d) carveout, dismissed without prejudice for lack of jurisdiction.

Accordingly, if the Court agrees with the district court, and the Estate, that the claims do not relate to the administration or use of a covered countermeasure covered by the Secretary's Declaration, it need not address Watermark's additional arguments about subsection (d). On the other hand, if the Court determines that some of the Estate's claims or parts of claims *do* relate to such administration or use of a covered countermeasure, the Estate requests that the Court remand the matter to the district court to determine in the first instance which claims are subject to subsection (d) and to dismiss those claims without prejudice.

See Lewis v. Pension Benefit Guaranty Corp., 912 F.3d 605, 613 n. 2 (D.C. Cir. 2018) (noting this Court's "normal rule [] to avoid passing on an issue that the district court has not fully addressed" and to remand instead). Given Watermark's failure to specify which of the Estate's claims it believes constitute claims for willful misconduct, *see* Appellants' Br. 50–52, such a course would be particularly appropriate.

CONCLUSION

For the foregoing reasons, the appeal should be dismissed, or, in the alternative, the district court's decision affirmed.

Respectfully submitted,

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January 10, 2022

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and the Rules of this Court, it contains 11,119 words.

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word for Microsoft 365 MSO in 14-point Century Schoolbook.

January 10, 2022

/s/ Adam R. Pulver
Adam R. Pulver

ADDENDUM

ADDENDUM CONTENTS

42 U.S.C. § 247d-6d Targeted liability protections for pandemic and epidemic products and security countermeasures

(a) Liability protections

(1) In general

Subject to the other provisions of this section, a covered person shall be 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 if a declaration under subsection (b) has been issued with respect to such countermeasure.

(2) Scope of claims for loss

...

(B) Scope

The immunity under paragraph (1) applies 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.

(3) Certain conditions

Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if--

(A) the countermeasure was administered or used during the effective period of the declaration that was issued under subsection (b) with respect to the countermeasure;

(B) the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration; and

(C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the administration or use of the countermeasure, the countermeasure was administered to or used by an individual who--

(i) was in a population specified by the declaration; and

(ii) was at the time of administration physically present in a geographic area specified by the declaration or had a connection to such area specified in the declaration.

(4) Applicability of certain conditions

With respect to immunity under paragraph (1) and subject to the other provisions of this section:

(A) In the case of a covered person who is a manufacturer or distributor of the covered countermeasure involved, the immunity applies without regard to whether such countermeasure was administered to or used by an individual in accordance with the conditions described in paragraph (3)(C).

(B) In the case of a covered person who is a program planner or qualified person with respect to the administration or use of the covered countermeasure, the scope of immunity includes circumstances in which the countermeasure was administered to or used by an individual in circumstances in which the covered person reasonably could have believed that the countermeasure was administered or used in accordance with the conditions described in paragraph (3)(C).

(5) Effect of distribution method

The provisions of this section apply to a covered countermeasure regardless of whether such countermeasure is obtained by donation, commercial sale, or any other means of distribution, except to the extent that, under paragraph (2)(E) of subsection (b), the declaration under such subsection provides that subsection (a) applies only to covered countermeasures obtained through a particular means of distribution.

...

(b) Declaration by Secretary

(1) Authority to issue declaration

Subject to paragraph (2), if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

(2) Contents

In issuing a declaration under paragraph (1), the Secretary shall identify, for each covered countermeasure specified in the declaration--

(A) the category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure;

(B) the period or periods during which, including as modified by paragraph (3), subsection (a) is in effect, which period or

periods may be designated by dates, or by milestones or other description of events, including factors specified in paragraph (6);

(C) the population or populations of individuals for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation to all individuals);

(D) the geographic area or areas for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation), including, with respect to individuals in the populations identified under subparagraph (C), a specification, as determined appropriate by the Secretary, of whether the declaration applies only to individuals physically present in such areas or whether in addition the declaration applies to individuals who have a connection to such areas, which connection is described in the declaration; and

(E) whether subsection (a) is effective only to a particular means of distribution as provided in subsection (a)(5) for obtaining the countermeasure, and if so, the particular means to which such subsection is effective.

…

(c) Definition of willful misconduct

(1) Definition

(A) In general

Except as the meaning of such term is further restricted pursuant to paragraph (2), the term "willful misconduct" shall, for purposes of subsection (d), denote an act or omission that is taken--

(i) intentionally to achieve a wrongful purpose;

(ii) knowingly without legal or factual justification; and

(iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

(B) Rule of construction

The criterion stated in subparagraph (A) shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.

…

(d) Exception to immunity of covered persons

(1) In general

Subject to subsection (f), the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person. For purposes of section 2679(b)(2)(B) of Title 28, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized.

(2) Persons who can sue

An action under this subsection may be brought for wrongful death or serious physical injury by any person who suffers such injury or by any representative of such a person.

(e) Procedures for suit

(1) Exclusive Federal jurisdiction

Any action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia.

(2) Governing law

The substantive law for decision in an action under subsection (d) shall be derived from the law, including choice of law principles, of the State in which the alleged willful misconduct occurred, unless such law is inconsistent with or preempted by Federal law, including provisions of this section.

(3) Pleading with particularity

In an action under subsection (d), the complaint shall plead with particularity each element of the plaintiff's claim, including--

(A) 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 by the person on whose behalf the complaint was filed;

(B) facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed; and

(C) facts supporting the allegation that the person on whose behalf the complaint was filed suffered death or serious physical injury.

(4) Verification, certification, and medical records

(A) In general

In an action under subsection (d), the plaintiff shall verify the complaint in the manner stated in subparagraph (B) and shall file with the complaint the materials described in subparagraph (C). A complaint that does not substantially

comply with subparagraphs (B) and (C) shall not be accepted for filing and shall not stop the running of the statute of limitations.

(B) Verification requirement

(i) In general

The complaint shall include a verification, made by affidavit of the plaintiff under oath, stating that the pleading is true to the knowledge of the deponent, except as to matters specifically identified as being alleged on information and belief, and that as to those matters the plaintiff believes it to be true.

(ii) Identification of matters alleged upon information and belief

Any matter that is not specifically identified as being alleged upon the information and belief of the plaintiff, shall be regarded for all purposes, including a criminal prosecution, as having been made upon the knowledge of the plaintiff.

(C) Materials required

In an action under subsection (d), the plaintiff shall file with the complaint--

(i) an affidavit, by a physician who did not treat the person on whose behalf the complaint was filed, certifying, and explaining the basis for such physician's belief, that such person suffered the 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; and

(ii) certified medical records documenting such injury or death and such proximate causal connection.

(5) Three-judge court

Any action under subsection (d) shall be assigned initially to a panel of three judges. Such panel shall have jurisdiction over such action for purposes of considering motions to dismiss, motions for summary judgment, and matters related thereto. If such panel has denied such motions, or if the time for filing such motions has expired, such panel shall refer the action to the chief judge for assignment for further proceedings, including any trial. Section 1253 of Title 28 and paragraph (3) of subsection (b) of section 2284 of Title 28 shall not apply to actions under subsection (d).

(6) Civil discovery

(A) Timing

In an action under subsection (d), no discovery shall be allowed--

(i) before each covered person sued has had a reasonable opportunity to file a motion to dismiss;

(ii) in the event such a motion is filed, before the court has ruled on such motion; and

(iii) in the event a covered person files an interlocutory appeal from the denial of such a motion, before the court of appeals has ruled on such appeal.

(B) Standard

Notwithstanding any other provision of law, the court in an action under subsection (d) shall permit discovery only with respect to matters directly related to material issues contested in such action, and the court shall compel a response to a discovery request (including a request for admission, an interrogatory, a request for production of documents, or any other form of discovery request) under Rule 37, Federal Rules of Civil Procedure, only if the court finds that the requesting party needs the information sought

to prove or defend as to a material issue contested in such action and that the likely benefits of a response to such request equal or exceed the burden or cost for the responding party of providing such response.

(7) Reduction in award of damages for collateral source benefits

(A) In general

In an action under subsection (d), the amount of an award of damages that would otherwise be made to a plaintiff shall be reduced by the amount of collateral source benefits to such plaintiff.

(B) Provider of collateral source benefits not to have lien or subrogation

No provider of collateral source benefits shall recover any amount against the plaintiff or receive any lien or credit against the plaintiff's recovery or be equitably or legally subrogated to the right of the plaintiff in an action under subsection (d).

(C) Collateral source benefit defined

For purposes of this paragraph, the term "collateral source benefit" means any amount paid or to be paid in the future to or on behalf of the plaintiff, or any service, product, or other benefit provided or to be provided in the future to or on behalf of the plaintiff, as a result of the injury or wrongful death, pursuant to--

(i) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(ii) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(iii) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; or

(iv) any other publicly or privately funded program.

(8) Noneconomic damages

In an action under subsection (d), any noneconomic damages may be awarded only in an amount directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff. For purposes of this paragraph, the term "noneconomic damages" means damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses.

(9) Rule 11 sanctions

Whenever a district court of the United States determines that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure in an action under subsection (d), the court shall impose upon the attorney, law firm, or parties that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which may include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorney's fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

(10) Interlocutory appeal

The United States 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) or based on an assertion of the exclusion under subsection (c)(5).

…

(i) Definitions

In this section:

(1) Covered countermeasure

The term "covered countermeasure" means--

(A) a qualified pandemic or epidemic product (as defined in paragraph (7));

(B) a security countermeasure (as defined in section 247d-6b(c)(1)(B) of this title);

(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)),2 biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act; or

(D) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or any successor regulations), and that the Secretary determines to be a priority for use during a public health emergency declared under section 247d of this title.

…

42 U.S.C. § 247d-6e. Covered countermeasure process

(a) Establishment of Fund

Upon the issuance by the Secretary of a declaration under section 247d-6d(b) of this title, there is hereby established in the Treasury an emergency fund designated as the "Covered Countermeasure Process Fund" for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration, which Fund shall consist of such amounts designated as emergency appropriations under section 402 of H. Con. Res. 95 of the 109th Congress, this emergency designation shall remain in effect through October 1, 2006.

…

(d) Exhaustion; exclusivity; election

(1) Exhaustion

Subject to paragraph (5), a covered individual may not bring a civil action under section 247d-6d(d) of this title against a covered person (as such term is defined in section 247d-6d(i)(2) of this title) unless such individual has exhausted such remedies as are available under subsection (a), except that if amounts have not by law been provided for the Fund under subsection (a), or if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of this section within 240 days after such request was filed, the individual may seek any remedy that may be available under section 247d-6d(d) of this title.

Ohio, Court of Federal Claims No: 20–0225V
71. Shannon Pyers, Dresher, Pennsylvania, Court of Federal Claims No: 20–0231V
72. Lisa Macon, Englewood, New Jersey, Court of Federal Claims No: 20–0232V

[FR Doc. 2020–05525 Filed 3–16–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of declaration.

SUMMARY: The Secretary is issuing this Declaration pursuant to section 319F–3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID–19.

DATES: The Declaration was effective as of February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. This Declaration is subject to amendment as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F–3, which addresses liability immunity, and Section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d-6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in Section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

COVID–19 is an acute respiratory disease caused by the SARS-CoV-2 betacoronavirus or a virus mutating therefrom. This virus is similar to other betacoronaviruses, such as Middle Eastern Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). Although the complete clinical picture regarding SARS-CoV-2 or a virus mutating therefrom is not fully understood, the virus has been known to cause severe respiratory illness and death in a subset of those people infected with such virus(es).

In December 2019, the novel coronavirus was detected in Wuhan City, Hubei Province, China. Today, over 101 countries, including the United States have reported multiple cases. Acknowledging that cases had been reported in five WHO regions in one month, on January 30, 2020, WHO declared the COVID–19 outbreak to be a Public Health Emergency of International Concern (PHEIC) following a second meeting of the Emergency Committee convened under the International Health Regulations (IHR).

To date, United States traveler-associated cases have been identified in a number of States and community-based transmission is suspected. On January 31, 2020, Secretary Azar declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, for the entire United States to aid in the nation's health care community response to the COVID–19 outbreak.[1] The outbreak remains a significant public health challenge that requires a sustained, coordinated proactive response by the Government in order to contain and mitigate the spread of COVID–19.[2]

Description of This Declaration by Section

Section I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a Declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may constitute such an emergency. This determination is separate and apart from the Declaration issued by the Secretary on January 31, 2020 under Section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other Declarations or determinations made under other authorities of the Secretary. Accordingly in Section I of the Declaration, the Secretary determines that the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease, COVID–19, constitutes a public health emergency for purposes of this Declaration under the PREP Act.

Section II. Factors Considered by the Secretary

In deciding whether and under what circumstances to issue a Declaration with respect to a Covered Countermeasure, the Secretary must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure. In Section II of the Declaration, the Secretary states that he has considered these factors.

Section III. Activities Covered by This Declaration Under the PREP Act's Liability Immunity

The Secretary must delineate the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures

[1] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[2] CDC COVID–19 Summary; *https://www.cdc.gov/coronavirus/2019-ncov/summary.html,* accessed 27Feb2020,

(Recommended Activities). In Section III of the Declaration, the Secretary sets out the activities for which the immunity is in effect.

Section IV. Limited Immunity

The Secretary must also state that liability protections available under the PREP Act are in effect with respect to the Recommended Activities. These liability protections provide that, ''[s]ubject to other provisions of [the PREP Act], a covered person shall be 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 use by an individual of a covered countermeasure if a Declaration has been issued with respect to such countermeasure.'' In Section IV of the Declaration, the Secretary states that liability protections are in effect with respect to the Recommended Activities.

Section V. Covered Persons

Section V of the Declaration describes Covered Persons, including Qualified Persons. The PREP Act defines Covered Persons to include, among others, the United States, and those that manufacturer, distribute, administer, prescribe or use Covered Countermeasures. This Declaration includes all persons and entities defined as Covered Persons under the PREP Act (PHS Act 317F–3(i)(2)) as well as others set out in paragraphs (3), (4), (6), (8)(A) and (8)(B).

The PREP Act's liability immunity applies to ''Covered Persons'' with respect to administration or use of a Covered Countermeasure. The term ''Covered Persons'' has a specific meaning and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States. The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.

A manufacturer includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

A distributor means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to: Manufacturers; re-packers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

A program planner means a state or local government, including an Indian tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a Covered Countermeasure in accordance with the Secretary's Declaration. Under this definition, a private sector employer or community group or other ''person'' can be a program planner when it carries out the described activities.

A qualified person means a licensed health professional or other individual authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the Covered Countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's Declaration. Under this definition, the Secretary can describe in the Declaration other qualified persons, such as volunteers, who are Covered Persons. Section V describes other qualified persons covered by this Declaration.

The PREP Act also defines the word ''person'' as used in the Act: A person includes an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state, or local government agency or department.

Section VI. Covered Countermeasures

As noted above, Section III of the Declaration describes the activities (referred to as ''Recommended Activities'') for which liability immunity is in effect. Section VI of the Declaration identifies the Covered Countermeasures for which the Secretary has recommended such activities. The PREP Act states that a ''Covered Countermeasure'' must be a ''qualified pandemic or epidemic product,'' or a ''security countermeasure,'' as described immediately below; or a drug, biological product or device authorized for emergency use in accordance with Sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product means a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that is (i) manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device.

A security countermeasure is a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that (i)(a) The Secretary determines to be a priority to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined by the Secretary of Health and Human Services to be a necessary countermeasure to protect public health.

To be a Covered Countermeasure, qualified pandemic or epidemic products or security countermeasures also must be approved or cleared under the FD&C Act; licensed under the PHS Act; or authorized for emergency use under Sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product also may be a Covered Countermeasure when it is subject to an exemption (that is, it is permitted to be used under an Investigational Drug Application or an Investigational Device Exemption) under the FD&C Act and is the object of research for possible use for diagnosis, mitigation, prevention, treatment, or cure, or to limit harm of a pandemic or epidemic or serious or life-threatening condition caused by such a drug or device.

A security countermeasure also may be a Covered Countermeasure if it may reasonably be determined to qualify for approval or licensing within 10 years after the Department's determination that procurement of the countermeasure is appropriate.

Section VI lists medical countermeasures against COVID–19 that

are Covered Countermeasures under this declaration.

Section VI also refers to the statutory definitions of Covered Countermeasures to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, the Declaration notes that Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

Section VII. Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to Covered Countermeasures obtained through a particular means of distribution. The Declaration states that liability immunity is afforded to Covered Persons for Recommended Activities related to (a) present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements; or (b) 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.

Section VII defines the terms ''Authority Having Jurisdiction'' and ''Declaration of an emergency.'' We have specified in the definition that Authorities having jurisdiction include federal, state, local, and tribal authorities and institutions or organizations acting on behalf of those governmental entities.

For governmental program planners only, liability immunity is afforded only to the extent they obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles. This last limitation on distribution is intended to deter program planners that are government entities from seizing privately held stockpiles of Covered Countermeasures. It does not apply to any other Covered Persons, including other program planners who are not government entities.

Section VIII. Category of Disease, Health Condition, or Threat

The Secretary must identify in the Declaration, for each Covered Countermeasure, the categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure. In Section VIII of the Declaration, the Secretary states that the disease threat for which he recommends administration or use of the Covered Countermeasures is COVID–19 caused by SARS-CoV-2 or a virus mutating therefrom.

Section IX. Administration of Covered Countermeasures

The PREP Act does not explicitly define the term ''administration'' but does assign the Secretary the responsibility to provide relevant conditions in the Declaration. In Section IX of the Declaration, the Secretary defines ''Administration of a Covered Countermeasure,'' as follows:

Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.

The definition of ''administration'' extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a Declaration issued under the Act. Under the definition, these liability claims are precluded if they allege an injury caused by a countermeasure, or if the claims are due to manufacture, delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a Declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

Section X. Population

The Secretary must identify, for each Covered Countermeasure specified in a Declaration, the population or populations of individuals for which liability immunity is in effect with respect to administration or use of the countermeasure. Section X of the Declaration identifies which individuals should use the countermeasure or to whom the countermeasure should be administered—in short, those who should be vaccinated or take a drug or other countermeasure. Section X provides that the population includes ''any individual who uses or who is administered a Covered Countermeasure in accordance with the Declaration.''

It should be noted that under the PREP Act, liability protection extends beyond the Population specified in the Declaration. Specifically, liability immunity is afforded (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population, and (2) to program planners and qualified persons when the countermeasure is either used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population. Section X of the Declaration includes these statutory conditions in the Declaration for clarity.

Section XI. Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in the Declaration, the geographic area or areas for which liability immunity is in effect, including, as appropriate, whether the Declaration applies only to

individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area. Section XI of the Declaration provides that liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation. This could include claims related to administration or use in countries outside the U.S. It is possible that claims may arise in regard to administration or use of the Covered Countermeasures outside the U.S. that may be resolved under U.S. law.

In addition, the PREP Act specifies that liability immunity is afforded (1) to manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas, and (2) to program planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas. Section XI of the Declaration includes these statutory conditions in the Declaration for clarity.

Section XII. Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act. Section XII of the Declaration extends the effective period for different means of distribution of Covered Countermeasures through October 1, 2024.

Section XIII. Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective time period of the Declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including accepting returns of Covered Countermeasures, and for other Covered Persons to take appropriate actions to limit administration or use of the Covered Countermeasure. In addition, the PREP Act specifies that, for Covered Countermeasures that are subject to a Declaration at the time they are obtained for the Strategic National Stockpile (SNS) under 42 U.S.C. 247d-6b(a), the effective period of the Declaration extends through the time the countermeasure is used or administered. Liability immunity under the provisions of the PREP Act and the conditions of the Declaration continue during these additional time periods. Thus, liability immunity is afforded during the ''Effective Time Period,'' described under Section XII of the Declaration, plus the ''Additional Time Period'' described under Section XIII of the Declaration.

Section XIII of the Declaration provides for 12 months as the Additional Time Period of coverage after expiration of the Declaration. Section XIII also explains the extended coverage that applies to any product obtained for the SNS during the effective period of the Declaration.

Section XIV. Countermeasures Injury Compensation Program

Section 319F–4 of the PHS Act, 42 U.S.C. 247d-6e, authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure. Compensation under the CICP for an injury directly caused by a Covered Countermeasure is based on the requirements set forth in this Declaration, the administrative rules for the Program, and the statute. To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.'' The administrative rules for the Program further explain the necessary requirements for eligibility under the CICP. Please note that, by statute, requirements for compensation under the CICP may not align with the requirements for liability immunity provided under the PREP Act. Section XIV of the Declaration, ''Countermeasures Injury Compensation Program,'' explains the types of injury and standard of evidence needed to be considered for compensation under the CICP.

Further, the administrative rules for the CICP specify that if countermeasures are administered or used outside the United States, only otherwise eligible individuals at United States embassies, military installations abroad (such as military bases, ships, and camps) or at North Atlantic Treaty Organization (NATO) installations (subject to the NATO Status of Forces Agreement) where American servicemen and servicewomen are stationed may be considered for CICP benefits. Other individuals outside the United States may not be eligible for CICP benefits.

Section XV. Amendments

Section XV of the Declaration confirms that the Secretary may amend any portion of this Declaration through publication in the **Federal Register.**

Declaration

Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID–19.

I. Determination of Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that the spread of SARS-CoV–2 or a virus mutating therefrom and the resulting disease COVID–19 constitutes a public health emergency.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend, under the conditions stated in this Declaration, the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures.

IV. Liability Immunity

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this Declaration is in effect for the Recommended Activities described in Section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' ''qualified persons,'' and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I have determined that the following additional persons are qualified persons: (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and

volunteers, following a Declaration of an emergency; (b) any person

authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act; and (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the

FD&C Act.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS-CoV–2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or

(b) 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.

As used in this Declaration, the terms Authority Having Jurisdiction and Declaration of Emergency have the following meanings:

i. The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, tribal, state, or federal boundary lines) or functional (*e.g.,* law enforcement, public health) range or sphere of authority.

ii. A Declaration of Emergency means any Declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a federal Declaration in support of an Emergency Use Authorization under Section 564 of the FD&C Act unless such Declaration specifies otherwise;

I have also determined that, for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is COVID–19 caused by SARS-CoV–2 or a virus mutating therefrom.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in any designated geographic area; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for Covered Countermeasures through means of distribution, as identified in Section VII(a) of this Declaration, other than in accordance with the public health and medical response of the Authority Having Jurisdiction and extends through October 1, 2024.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a Declaration and lasts through (1) the final day the emergency Declaration is in effect, or (2) October 1, 2024, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional 12 months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at the toll-free number 1–855–266–2427 or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

Amendments to this Declaration will be published in the **Federal Register**, as warranted.

Authority: 42 U.S.C. 247d–6d.

Dated: March 10, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–05484 Filed 3–12–20; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–18–423: NIDDK Multi-Center Clinical Study Implementation Planning Cooperative Agreements (U34) in Digestive Diseases.

Date: May 22, 2020.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–7682, *campd@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 10, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05361 Filed 3–16–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Small Business: Cardiovascular Sciences, March 19, 2020 08:00 a.m. to March 20, 2020, 01:00 p.m., Embassy Suites Alexandria Old Town, 1900 Diagonal Road, Alexandria, VA 22314 which was published in the **Federal Register** on February 20, 2020, 85 FR 9791.

The meeting location is being held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, at 09:00 a.m. The meeting date remains the same. The meeting is closed to the public.

Dated: March 11, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05417 Filed 3–16–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, PAR 19–059: Global Noncommunicable Diseases and Injury Across the Lifespan (R21), March 23, 2020, 8:00 a.m. to 5:00 p.m., at the Hotel Palomar, 2121 P Street NW, Washington, DC 20037, which was published in the **Federal Register** on February 25, 2020, 85 FR 10708.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The format of the meeting has been changed to a Video Assisted Meeting. The meeting date and time remain the same. The meeting is closed to the public.

Dated: March 11, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05419 Filed 3–16–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Consortium for the Study of Chronic Pancreatitis, Diabetes, and Pancreatic Cancer Clinical Centers Special Emphasis Panel.

Date: April 2, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.