ORAL ARGUMENT NOT YET SCHEDULED

No. 21-7017

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

LANE HATCHER, individually and in a representative capacity for all persons identified by K.S.A. 60-1902 and as an heir-at-law to deceased Amanda L'Heureux,

Plaintiff-Appellee,

v.

HCP PRAIRIE VILLAGE KS OPCO LLC, doing business as Brighton Gardens of Prairie Village, and SUNRISE SENIOR LIVING MANAGEMENT, INC.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Kansas

BRIEF FOR APPELLEE

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

Lane Hatcher, individually and in a representative capacity for all persons identified by K.S.A. 60-1902 and as an heir-at-law to deceased Amanda L'Heureux, is the plaintiff in the district court and is the appellee in this Court.

HCP Prairie Village KS OpCo LLC, doing business as Brighton Gardens of Prairie Village, and Sunrise Senior Living Management, Inc., 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 interlocutory memorandum opinion and order issued by Judge Sam A. Crow of the United States District Court for the District of Kansas on January 27, 2021, which, in relevant part, denied Defendant-Appellants' motion to dismiss Plaintiff-Appellee's Kansas tort law claims based on injuries to her mother in January 2019 and April 2020, which ultimately resulted in her death in April 2020.

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). In addition to the pending appeal in *Garcia v. Welltower OpCo Group*, 9th Cir. No. 21-55224, cited by Appellants (at ii), Appellee's counsel is aware of the following pending appeals raising related issues as to the scope of the liability protections provided by the PREP Act, 42 U.S.C. § 247d-6d(a):

U.S. Court of Appeals for the Second Circuit:

- 21-505 – *Dupervil v. Alliance Health Operations, LLC* (held in abeyance)

U.S. Court of Appeals for the Third Circuit:

- 20-2833 – *Estate of Maglioli v. Alliance HC Holdings LLC* (consolidated with 20-2834 *Estate of Kaegi v. Alliance HC Holdings LLC*) (argument scheduled, June 23, 2021)
- 20-3287 – *Sherod v. Comprehensive Healthcare Management Services LLC* (motion to dismiss pending)

U.S. Court of Appeals for the Fifth Circuit:

- 21-10477 – *Mitchell v. Advanced HCS, LLC*
- 21-50399 – *Perez v. Southeast SNF* (consolidated with 21-50412 – *Strait v. Southeast SNF*; 21-50413 – *Salinas v. Southeast SNF*)

U.S. Court of Appeals for the Ninth Circuit:

- 20-56067 – *Martin v. Filart* (consolidated with 20-56078 – *Martin v. Serrano Post Acute*)
- 20-56194 – *Saldana v. Glenhaven Healthcare LLC*
- 21-55185 – *Lyons v. Cucumber Holdings, LLC*
- 21-55302 – *Estate of McCalebb v. AG Lynwood, LLC*
- 21-55377 – *Smith v. Colonial Care Center*
- 21-55400 – *Martin v. Serrano Post Acute LLC* (consolidated with 21-55403 – *Martin v. Filart*)
- 21-55402 – *Ivey v. Serrano Post Acute LLC*
- 21-55454 – *Nava v. ReNew Health Group, LLC*
- 21-55468 – *Winn v. California Post Acute, LLC*
- 21-55561 – *Golbad v. GHC of Canoga Park, LLC*

U.S. Court of Appeals for the Eleventh Circuit:

- 21-11765 – *Schleider v. GVDB Operations, LLC*

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GLOSSARY

CARES Act	Coronavirus Aid, Relief, and Economic Security 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

Appellee Lane Hatcher agrees with Appellants that the United States District Court for the District of Kansas has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1), because the parties are citizens of different states and Ms. Hatcher seeks damages in excess of $75,000, exclusive of interest and costs. Ms. Hatcher disagrees with Appellants' suggestion that the district court also has jurisdiction on the ground that this action, involving only claims for wrongful death and negligence under Kansas state law, raises a "substantial federal question." Appellants' Br. at 1. *See D.C. Ass'n of Chartered Pub. Schs. v. Dist. of Columbia*, 930 F.3d 487, 492 (D.C. Cir. 2019) (holding a federal defense does not create a substantial federal question under *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 315 (2005)); *Becker v. Ute Indian Tribe of the Uintah & Ouray Rsrv.*, 770 F.3d 944, 947 (10th Cir. 2014) (same). This disagreement, however, is irrelevant to this appeal.

This Court lacks jurisdiction over this interlocutory appeal from the Kansas district court's decision, as explained in detail below. *See* Argument, pp. 15–28. Appellants' 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 would yield chaos in the district courts.

STATEMENT OF THE ISSUES

(1) Whether the PREP Act provides for an interlocutory appeal to this Court from a decision by any of the nation's 94 district courts rejecting an assertion of immunity under that statute.

(2) Whether tort claims alleging that inadequate staffing and medical care at a skilled nursing facility led to the death of a resident from COVID-19 have a causal relationship to the administration or use of a drug or device deemed a "covered countermeasure" by the Secretary of the Department of Health and Human Services, thus triggering the liability protections of the PREP Act.

STATUTES AND REGULATIONS

Relevant provisions of the PREP Act, 42 U.S.C. §§ 247d-6d–247d-6e, and implementing regulations, 42 C.F.R. §§ 110.10 and 110.20, appear in the Addendum to this brief.

STATEMENT OF THE CASE

I. Brighton Gardens' Understaffing Leading to the Death of Amanda L'Heureux

From January 2019 through April 2020, Amanda L'Heureux lived at Brighton Gardens of Prairie Village, a skilled nursing facility in Prairie Village, Kansas. JA30. Brighton Gardens is owned and operated by Appellant HCP Prairie Village KS OpCo LLC, which is controlled by Appellant Sunrise Senior Management, Inc.[1] *Id.*; JA31–33. Shortly after Ms. L'Heureux moved to Brighton Gardens, the facility's nursing staff dropped her and/or permitted her to fall during a botched transfer, causing her to fracture her hip. JA30. That injury, and complications from resulting surgery, limited her mobility and increased her risk of respiratory infection. JA31.

Throughout Ms. L'Heureux's time at Brighton Gardens, the facility was understaffed. JA38. The facility had too few registered nurses and inadequately supervised nursing aides and licensed practical nurses. The facility also failed to use adequate assistive devices or develop and implement fall prevention policies. JA38; JA40–41; JA46–47. These shortcomings all contributed to Ms. L'Heureux's 2019 fall. JA38.

[1] Appellants are referred to collectively as Brighton Gardens.

Brighton Gardens' understaffing also contributed to inadequate infection-control measures when the COVID-19 pandemic began in 2020. JA38–39; JA40–41. First, Brighton Gardens allowed staff who showed symptoms of COVID-19, or otherwise felt ill, to continue to work and interact with residents. *Id*. Second, because of understaffing, Brighton Gardens did not adequately clean and disinfect common areas to reduce the risk of transmission of the coronavirus. *Id.* Third, Brighton Gardens' screening of staff members, via temperature checks, was inefficient and potentially led to cross-contamination. *Id.* Finally, Brighton Gardens failed to develop a plan to assess and address Ms. L'Heureux's increased risk of infection as a result of her limited mobility. JA40–41.

On April 14, 2020, Ms. L'Heureux began exhibiting symptoms of COVID-19. JA31. Two days later, she tested positive for COVID-19. *Id.* On April 24, 2020, Brighton Gardens belatedly transferred Ms. L'Heureux to a hospital, where she died of COVID-19 two days later. *Id.*

In this lawsuit, Ms. L'Heureux's daughter, Lane Hatcher, alleges that the injuries Ms. L'Heureux suffered as a result of the 2019 botched transfer increased her susceptibility to COVID-19 and thus directly contributed to her death. JA31. She also alleges that Brighton Gardens'

inadequate infection control measures, including its failures to prevent symptomatic staff from interacting with patients, directly caused or contributed to her mother's infection with the virus and death. JA39, 41, 47, 50. Finally, she alleges that Brighton Gardens provided inadequate care for Ms. L'Heureux *after* she contracted COVID-19—including by failing to timely report to a physician changes in her condition, failing to carry out her physician's directions, and failing to timely transfer Ms. L'Heureux to a hospital—and that this inadequate care, not the use (or non-use) of any covered countermeasure, contributed to Ms. L'Heureux's death. JA41; *see also* JA31, 47, 50.

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 [Health and Human Services] 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 Mar. 19, 2021), https://crsreports.congress.gov/product/pdf/LSB/LSB10443. The

Secretary triggers the Act's provisions by formally declaring a public-health emergency and "recommending" the "manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures." 42 U.S.C. § 247d-6d(b)(1).

"Covered countermeasures" include certain drugs, biological products, and devices authorized for emergency use, 42 U.S.C. § 247d-6d(i)(1)(A)–(C). In 2020, Congress amended the statute, first in the Families First Coronavirus Response Act, and again in the Coronavirus Aid, Relief, and Economic Security (CARES) Act, to also make respiratory protective devices approved by the National Institute of Occupational Safety and Health covered countermeasures in limited circumstances. Pub. L. No. 116-127, § 6005, 134 Stat. 178, 207 (2020); Pub. L. No. 116-136, § 3103, 134 Stat. 281, 361 (2020), *codified at* 42 U.S.C. § 247d–6d(i)(1)(D).

Subsection (a) of the PREP Act limits liability by making "a covered person" "immune from suit and liability under Federal and State law" for claims with a "causal relationship with the administration to or use by an individual of a covered countermeasure," subject to certain conditions. 42 U.S.C. §§ 247d-6d(a)(1), (a)(2)(B), (a)(3). Subsection (d) 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 carve-out, the statute creates an "exclusive Federal cause of action," *id.*, and provides special procedures for their adjudication, with exclusive jurisdiction in the District Court for the District of Columbia, *id.* § 247d-6d(e).

The PREP Act also 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). HHS regulations specify that eligibility for compensation is limited to "injured countermeasure recipients" and their survivors, 42 C.F.R. § 110.10(a), and define "covered injuries" as excluding "injur[ies] sustained as the direct result of the covered condition or disease for which the countermeasure was administered or used … (e.g., if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease)," *id.* § 110.20(d).

B. The COVID-19 PREP Act Declaration and Amendments

On March 17, 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. 85 Fed. Reg. 15,198, 15,198 (Mar. 17, 2020). The Secretary later amended the initial Declaration several times. In April 2020, the First Amendment expanded covered countermeasures to include certain respiratory protective equipment, based on the CARES Act. *See* 85 Fed. Reg. 21,012, 21,013–14 (Apr. 15, 2020).

The Fourth Amendment, signed December 3, 2020, included the Secretary's view that "[w]here there are limited Covered Countermeasures, not administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute 'relating to … the administration to … an individual' under 42 U.S.C. 247d-6d," where it is a result of "prioritization or purposeful allocation … particularly if done in accordance with a public health authority's directive." 85 Fed. Reg. 79,190, 79,194 (Dec. 9, 2020). The Fourth Amendment used as an example the decision to vaccinate a more-vulnerable individual instead of a less-vulnerable individual. *Id.* The

Fourth Amendment also incorporated by reference four advisory opinions previously issued by the HHS Office of General Counsel. *Id.* at 79,191; 79,191 n.5. In the only one of those opinions addressed by Brighton Gardens, Advisory Opinion 20-04 (JA229), the General Counsel had opined that PREP Act immunity was available as a defense to claims based on program planners' purposeful allocation of scarce countermeasures consistent with Centers for Disease Control direction that resulted in certain individuals not being administered the countermeasure. JA234.

In the waning days of the last administration, the General Counsel issued a fifth advisory opinion. *See* HHS General Counsel, Advisory Opinion 21-01 (Jan. 8, 2021), JA237.[2] The opinion purported to address the question whether state court actions raising state-law claims are properly removed to federal court on the basis of a defendant's assertion of a PREP Act defense. *Id.* In expressing his view that "the PREP Act is a [c]omplete [p]reemption statute," the General Counsel also discussed "whether the non-use of a covered countermeasure triggers" the statute's

[2] Each of the five advisory opinions states that it "sets forth the current views" of the General Counsel, is "not a final agency action or a final order," and "does not have the force or effect of law." *See*, *e.g.*, JA241.

application. JA238. In his view, the PREP Act applies to claims relating to the "allocation [of a covered countermeasure] which results in non-use by some individuals," but *not* to cases where non-use was the result of "nonfeasance." JA240.

III. Procedural History

This action was commenced in the United States District Court for the District of Kansas on August 3, 2020, by Appellant Lane Hatcher, Ms. L'Heureux's surviving daughter and Special Administrator of Ms. L'Heureux's estate, in her individual capacity, as a representative of all heirs under Kansas law, and on behalf of the estate. JA7; JA31. The operative complaint was filed on November 30, 2020, and includes claims for wrongful death and negligence under Kansas state law. JA9; JA39–51. The complaint alleges that Brighton Gardens' negligence caused Ms. L'Heureux to fall in January 2019, to contract the coronavirus, and to die from COVID-19. JA39–51.

On December 14, 2020, Brighton Gardens moved to dismiss the operative complaint on the grounds that (1) Ms. Hatcher's claims fell within the scope of PREP Act subsection (a)'s immunity provision, and/or that they fell within the subsection (d) exclusion from that provision but

did not meet the special requirements for bringing such claims contained in subsection (e), JA61; (2) Brighton Gardens was immune from suit pursuant to Kansas Executive Order 20-26, JA76–80; and (3) Ms. Hatcher failed to sufficiently plead causation between the 2019 fall and Ms. L'Heureux's 2020 death from COVID-19, JA80–81.

The district court denied the motion to dismiss on January 27, 2021. JA261. As to Brighton Gardens' PREP Act arguments, the district court concluded that Ms. Hatcher had "plausibly alleged facts describing a loss which is *not* caused by or related to and does not arise out of or result from the administration of use of a 'covered countermeasure.'" JA270. The court explained that the possibility that Brighton Gardens may have used covered countermeasures did not immunize it from *all* claims arising out of the pandemic, but only those with a "direct connection" to the administration or use of such covered countermeasures—none of which were asserted in Ms. Hatcher's complaint. JA273. It also rejected the arguments that "all actions or 'non-actions' related to infection control are protected by PREP Act immunity," and that once a facility engages in a "recommended activity" to minimize the spread of COVID-19, it is immune from all claims regarding COVID-19. JA273–75. Finally,

the court found that neither the Fourth Amendment to the Secretary's Declaration nor any of the General Counsel's advisory opinions had any relevance to this case, because Ms. Hatcher did not claim that her mother's "death was caused by a decision to ration a covered product or allocate a covered countermeasure to some but not others," JA275, or was caused "during the administration of a covered countermeasure," JA276. The court also rejected Brighton Gardens' state-law arguments. JA276–278.

Brighton Gardens filed a notice of appeal to this Court on February 19, 2021. JA280. Invoking Tenth Circuit precedent, *McCauley v. Halliburton Energy Services, Inc.*, 413 F.3d 1158, 1161–62 (10th Cir. 2005), Ms. Hatcher moved the district court for an order certifying the notice as frivolous. JA11. On April 6, 2021, the district court denied that motion, stating that it "does not endorse defendants' position but will not certify defendants' appeal as frivolous" in light of the "little case law interpreting" subsection (e)(10) of the PREP Act. JA11 (Dkt. 60.)

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 District of Kansas. While subsection (e)(10) of the PREP Act creates a right to interlocutory appeals to this Court of decisions denying certain motions to dismiss, its text is best read, like the text of every other provision of subsection (e), to apply 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. Brighton Gardens' 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 Brighton Gardens' motion to dismiss. Ms. Hatcher's claims do not have "a causal relationship with the administration to or use by an individual of a covered countermeasure." They therefore are not subject to the immunity provided by subsection (a) of the PREP Act.

The complaint alleges Brighton Gardens was negligent in three ways: (1) in causing Ms. L'Heureux to fall and fracture her hip in January 2019; (2) in following staffing policies that resulted in inadequate infection control measures; and (3) in failing to provide Ms. L'Heureux adequate medical care *after* she contracted COVID-19. The alleged

negligence has nothing to do with the administration or use of the specific drugs and devices deemed covered countermeasures. Brighton Gardens points to scattered references in the complaint that could suggest that the facility was using covered countermeasures, but those references do not mean that Ms. Hatcher's claims have a causal relationship with such use—particularly in the posture of a motion to dismiss where all inferences are to be made in Ms. Hatcher's favor. And neither the plain language of the statute nor HHS interpretations of it support Brighton Gardens' argument that it is immune from any and all claims relating to its negligence in stopping the spread of COVID-19 merely because it used some covered countermeasures. As the district court below, and more than twenty other district courts have held, the PREP Act's immunity provision does not apply to claims based on general neglect of facilities like Brighton Gardens in failing to prevent the spread of COVID-19.

The district court also correctly declined to dismiss Ms. Hatcher's claims based on Brighton Gardens' negligence that caused her January 2019 injuries. The complaint plausibly alleged that those injuries increased Ms. Hatcher's susceptibility to COVID-19.

Finally, the district court was not required to address separately Brighton Gardens' alternative argument that Ms. Hatcher's claims fell under the subsection (d) exception to subsection (a), and thus that they were subject to the exclusive jurisdiction of the District Court for the District of Columbia. Because subsection (a) did not apply to Ms. Hatcher's claims, the claims could not fall within the subsection (d) exception.

ARGUMENT

I. This Court lacks jurisdiction to review the Kansas 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 District of Kansas. Subject to three exceptions, none of which applies here, such "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 Tenth Circuit.

Brighton Gardens 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. Brighton Gardens 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. 7, 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 Kansas *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, 2021 WL 2044537, at *4 (May 24, 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*, 2021 WL 2044537, at *5.

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 issues 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 issue on 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*, 2021 WL 2044537, at *3 (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 District of Kansas is reviewed by the Tenth 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) (addressing interaction with Federal Tort Claims Act, 28 U.S.C. § 2679(b)(2)(B)).

Finally, under Brighton Gardens' 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. Those appeals would be heard in the regional circuits pursuant to 28 U.S.C. § 1294(1). Indeed, in the only case Ms. Hatcher is aware of where a district court granted a motion to dismiss based on the legal theory asserted by Appellants here, the appeal is pending in the Ninth Circuit Court of Appeals. *See Garcia v. Welltower OpCo Grp. LLC*, 9th Cir. Appeal No. 21-55224.

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 "evident congressional desire for uniform adjudication of Little Tucker Act claims" in channeling cases to Federal Circuit); *Nat'l Env't Dev. Ass'n's Clean Air Project v. Env't Prot. Agency*, 891 F.3d 1041, 1053 (D.C. Cir. 2018) (noting Clean Air Act sends "national issues to our circuit for uniform resolution"). To achieve this objective, Congress directs to the chosen 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 any 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 72 (noting "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.[3]

[3] Paragraph (10) also does not give this Court authority to hear 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 of such orders are pending in at least five other courts of appeals. *See, e.g.*, *Dupervil v. Alliance Health Operations, LLC*, No. 21-505 (2d Cir.); *Est. of Maglioli v. Alliance HC Holdings LLC*, No. 20-2833 (3d Cir.) (argument scheduled for June 23, 2021); *Mitchell v. Advanced HCS, LLC*, No. 21-10477 (5th Cir.); *Martin v. Filart*, No. 20-56067 (9th Cir.); *Schleider v. GVDB Operations, LLC*, No. 21-11765 (11th Cir.). In each case, the defendants-appellants argue that claims similar to Ms. Hatcher's are within the scope of the PREP Act's immunity provision. Those courts' interpretations of the PREP Act's scope will be binding on district courts within their circuits both when ruling on

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 Brighton Gardens to appeal to this Court the district court's interlocutory order denying its motion to dismiss, even though Ms. Hatcher would have appealed an adverse decision on the very same motion to the Tenth Circuit, would create an unworkable situation for the 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.*, *United States v. Spedalieri*, 910 F.2d 707, 709 n.2 (10th Cir. 1990) ("A district court must follow the precedent of this circuit, regardless of its views concerning the advantages of the precedent of our sister circuits."); *cf. Rates Tech. Inc. v.*

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remand motions and when adjudicating the merits of immunity defenses where jurisdiction exists.

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). Under Brighton Gardens' 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 issue a ruling on the merits in this case and reach a different conclusion than the Ninth Circuit in the pending *Garcia* appeal 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 required granting that same motion, the decision 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 unworkable situation. *Cf. E. Band of Cherokee Indians & Cherokee Nation v. U.S. Dep't of the Interior*, 2021 WL 1518379, at *9 (D.D.C. Apr. 16, 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,

Ms. Hatcher'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 rulings as to the issues raised in a single 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 (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 Brighton Gardens' 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 Kansas district court correctly denied Brighton Gardens' motion to dismiss.

A. Standard of Review

Should this Court conclude that it has jurisdiction over this interlocutory appeal from the decision of the Kansas 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, described above, and apply its "own law with respect to [PREP Act] issues, but with respect to [non-PREP Act] issues … generally apply 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 Tenth 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 appropriate pleading standards and 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 Tenth Circuit has jurisdiction over the interlocutory appeal of a denial of a motion to dismiss, its review is *de novo*, "accepting as true all well-pleaded factual allegations in the complaint and viewing the allegations in the light most favorable to the non-moving party." *Wilson v. Montano*, 715 F.3d 847, 852 (10th Cir. 2013); *see also Vila v. Inter-American Inv. Corp.*, 570 F.3d 274, 278 (D.C. Cir. 2009) (applying same standard).

B. Ms. Hatcher's claims do not have a causal relationship with the administration or use of a covered countermeasure.

Brighton Gardens argues that the Kansas district court should have dismissed Ms. Hatcher's complaint because her claims are completely barred by the immunity provision of subsection (a) of the PREP Act. Subsection (a) creates an affirmative defense, with four elements: A plaintiff's claim must be (1) against a "covered person," (2) "for loss," (3)

"arising out of, relating to, or resulting from the administration to or the use by an individual," (4) of a covered countermeasure subject to a declaration of the HHS Secretary. 42 U.S.C. § 247d-6d(a)(1). As the district court held, the latter two elements are lacking here.

Ms. Hatcher's claims concern (1) Brighton Gardens' responsibility for Ms. L'Heureux's January 2019 fall; (2) Brighton Gardens' negligence and recklessness in allowing exposed or symptomatic staff members to continue to provide direct care; (3) Brighton Gardens' failures to assess Ms. L'Heureux's heightened risk of infection and to take appropriate remedial measures; and (4) Brighton Gardens' failure to provide appropriate medical care to Ms. L'Heureux *after* she contracted the coronavirus. The claims do not relate to covered countermeasures, much less have a causal relationship with their administration or use, as required to trigger either subsection (a) or subsection (d) of the PREP Act. *See* 42 U.S.C. § 247d-6d(a)(2)(B) (limiting scope of subsection (a) immunity to claims that have "a causal relationship with the administration to or use by an individual of a covered countermeasure"). Given the lack of any relationship between Ms. Hatcher's claims and the administration or use of any "covered countermeasure," the PREP Act no

more bars Ms. Hatcher's claims than it would negligence claims based on a slip-and-fall in Brighton Gardens' parking lot.[4]

1. Claims relating to Ms. L'Heureux's January 2019 fall or post-COVID-19 diagnosis medical care are unrelated to COVID-19 countermeasures.

Ms. Hatcher brings claims based on Brighton Gardens' negligence in causing her mother to fall and injure herself in January 2019, and in providing deficient care *after* Ms. L'Heureux contracted COVID-19. *See, e.g.*, JA41, 47, 48–51. Brighton Gardens does not attempt to identify a causal relationship between these claims and the administration or use of covered countermeasures for COVID-19, and with good reason. Brighton Gardens' inadequate fall prevention measures in January 2019 have no relationship whatsoever to those drugs, biological products, and medical devices the HHS Secretary deemed COVID-19 countermeasures

[4] Even if some part of Ms. Hatcher's claims had the requisite causal relationship with the administration or use of covered countermeasures, the proper result would be dismissal of Ms. Hatcher's claims *solely to the extent* that they relate to the use or administration of a covered countermeasure. *Cf. Garley v. Sandia Corp.*, 236 F.3d 1200, 1214 (10th Cir. 2001) (holding tort claim was preempted only with respect to one "factual predicate" and thus claim should only be dismissed in part); *Hogarth v. Kan. & Okla. R.R. LLC*, 2020 WL 3639744 (D. Kan. July 6, 2020) (dismissing negligence claim only to extent it was based on violation of Locomotive Inspection Act).

more than a year later. Covered countermeasures designed to minimize the *spread* of COVID-19 are irrelevant to claims based on the inadequate care Brighton Gardens provided to Ms. L'Heureux after her diagnosis, including Brighton Gardens' failure to keep her physician apprised of changes in her condition and to timely transfer her to a facility that could provide appropriate medical care as her condition worsened. And there are no allegations that covered countermeasures were used to *treat* Ms. L'Heureux or that use of covered countermeasures caused her death. Even under Brighton Garden's expansive theories of PREP Act immunity, the district court correctly denied the motion to dismiss these claims.

2. Claims based on Brighton Gardens' negligent infection control lack a causal relationship to the administration or use of covered countermeasures.

Ms. Hatcher claims that Brighton Gardens' negligence in 2020 led to her mother contracting COVID-19. Ms. Hatcher's claims are not based on any allegation that Brighton Gardens used any of the drugs, biological products, or devices deemed "covered countermeasures" in a way that caused her mother harm. Rather, she alleges that persistent understaffing led Brighton Gardens to allow exposed or symptomatic

staff to continue to interact with patients, and to fail to take proper infection control measures due to a lack of supervision, staffing, and training. As one district court explained in holding that similar claims do not fall under the PREP Act, "even if Plaintiff could have brought claims that fall under the PREP Act given the alleged actions or inactions of Defendants, Plaintiff's actual claims facially rest on an alleged duty arising from or related to proper standards of general medical and nursing care, not the administration or use of certain drugs, biological products, or devices, i.e., the countermeasures covered under the PREP Act." *Dupervil v. All. Health Operations, LCC*, 2021 WL 355137, at *13 (E.D.N.Y. Feb. 2, 2021).

Attempting to rewrite Ms. Hatcher's claims, Brighton Gardens describes them as based on "the affirmative use or administration of thermometers, disinfectants, and COVID-19 testing," Appellants' Br. 33; *see also id.* at 23–32, and on its "activities and decisions as to how [unspecified] countermeasures are allocated and dispensed," *id.* at 34; *see also id.* 32–41. These arguments rely on both inaccurate characterizations of the complaint and misreadings of the law.

a. Ms. Hatcher's claims do not relate to the "affirmative use or administration" of covered countermeasures.

Brighton Gardens characterizes Ms. Hatcher's claims about the facility's understaffing and resulting inadequate infection control as claims based on the affirmative use or administration of diagnostic tests, disinfectants, or thermometers. In so doing, Brighton Gardens asks the Court to disregard the familiar motion to dismiss standard and draw numerous inferences *against* Ms. Hatcher, the non-moving party, contrary to the plain meaning of her complaint. *See, e.g.*, *Brokers' Choice of Am., Inc. v. NBC Universal, Inc.*, 861 F.3d 1081, 1105 (10th Cir. 2017) (on motion to dismiss, court must "make all reasonable inferences in favor of the *non-moving* party").

First, Brighton Gardens argues that its decisions "as to when, how, and under what circumstances a diagnostic test was administered to Ms. L'Heureux and others is protected under the PREP Act." Appellants' Br. 25. Whether or not true, that statement has nothing to do with the claims Ms. Hatcher has brought. The operative complaint refers to COVID-19 testing only twice: It states that Ms. L'Heureux tested positive for COVID-19 on April 16, 2020. JA31. And it states that a Brighton Gardens

staff member who reported symptoms of COVID-19 on April 16 and 17, 2020, tested positive for COVID-19 on April 22, 2020—six days after Ms. L'Heureux tested positive.[5] Neither of these allegations suggests that Ms. Hatcher's claims have a causal relationship with Brighton Gardens' decisions about how to administer COVID-19 tests to her—or to anyone.

Grasping at straws, Brighton Gardens points to allegations in the complaint that it acted negligently "[b]y failing to provide adequate assistive devices to prevent injuries and infection," JA41 (¶ 76(i)), and "[b]y failing to adequately, timely and consistently prevent, assess, and treat [Ms. L'Heureux]'s risk for falls and infection," JA41 (¶ 76(m)), JA47 (¶ 102 (m)). Those allegations have nothing to do with COVID-19 tests. The term "assistive device" does not encompass diagnostic testing.[6] And

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[5] In any event, the allegation a staff member "tested positive" does not mean that *Brighton Gardens* administered the test in question.

[6] *See* U.S. Nat'l Library of Med., "Assistive devices," *MedlinePlus*, Apr. 13, 2021, https://medlineplus.gov/assistivedevices.html (assistive devices are "tools, products or types of equipment that help you perform tasks and activities"); *see also* Ashley L. Schoenfisch, et al., Use of Assistive Devices to Lift, Transfer, and Reposition Hospital Patients, 68 Nursing Research 3 (2019), https://www.safety.duke.edu/sites/default/files/Use_of_Assistive_Devices_to_Lift_Transfer.pdf; Ass'n of Occ. Health Profs. in Healthcare, *Beyond Getting Started - A Resource Guide: Implementing a Safe Patient Handling and Mobility Program in the*

COVID-19 tests are not used in assessing or addressing "risk for falls and infection." The district court was correct not to infer that these allegations were referring to Brighton Gardens' administration or use of COVID-19 diagnostic tests.

Next, Brighton Gardens argues that Ms. Hatcher's allegation that it failed to "adequately clean and disinfect common areas to reduce transmission of infection" means that her claims are based on the administration or use of a covered countermeasure: disinfectant. Appellants' Br. 25 (quoting JA39 (¶ 66(c)). Generally, however, cleaning supplies are not covered countermeasures—they are not drugs, biological products, or medical devices. Brighton Gardens argues that some disinfectant could hypothetically be a "qualified pandemic product" used to prevent COVID-19 transmission and thus a covered countermeasure, Appellants' Br. 25, but there is no evidence that any disinfectants actually meet that definition set out in the PREP Act—much less any disinfectants used by Brighton Gardens. To be a qualified pandemic

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Acute Care Setting 26, https://www.aohp.org/aohp/Portals/0/Documents/ToolsForYourWork/BGSpublication/20-06%20BGS%20Safe%20Patient%20Handling.pdf (discussing use of assistive devices in patient handling).

product, something must be a drug, biological product, or medical device, and approved, cleared, or authorized for use by the FDA. 42 U.S.C. § 247d-6d(i)(7). Nothing in the complaint would allow the district court to infer that Ms. Hatcher's claims involve the "affirmative" use of a disinfectant that meets this standard, particularly because Ms. Hatcher's sole reference to cleaning was about a *lack* of adequate cleaning.

Last, Brighton Gardens argues that actions relating to "when, how, and under what circumstances thermometers were administered to Ms. L'Heureux and other individuals at the Facility were protected acts under the Act." Appellants' Br. 28. Yet the complaint contains no claims concerning the use of thermometers as to Ms. L'Heureux. Although Ms. Hatcher referenced thermometer use as part of her claim that, because of understaffing, Brighton Gardens allowed symptomatic staff to continue to interact with patients, her claim that the staff was negligent in recording what thermometers revealed is not a challenge to "when, how, and under what circumstances" thermometers were used. Rather, it is a challenge to Brighton Gardens' failure to take appropriate responsive action *after* using thermometers. *See* JA39 (¶ 66(e)) (alleging "lack of supervision of nursing aides and [licensed practical nurses] which

resulted in … staff members – between April 29 to May 5 2020 – on five occasions failing to record a temperature"). And even if the complaint could reasonably be read to challenge how Brighton Gardens used thermometers on *staff*, that would not make Ms. L'Heureux an "injured countermeasure recipient"—who, as indicated in HHS regulations, are the only victims that have lost the right to judicial remedies in exchange for an administrative one. *See* 42 C.F.R. § 110.10.

Because Ms. Hatcher's claims lack a causal relationship with the "affirmative use" of any covered countermeasures, the district court properly denied the motion to dismiss.

b. Ms. Hatcher's claims of neglect and inaction do not relate to the administration or use of covered countermeasures.

As the district court below, JA273, and more than 20 other district courts have held, the PREP Act does not bar claims like Ms. Hatcher's, that "refer to policies and a failure to protect, not to any covered countermeasure, *i.e.*, drug, product, or device." *Smith v. Colonial Care Ctr., Inc.*, 2021 WL 1087284, at *4 (C.D. Cal. Mar. 19, 2021); *see also Dupervil,* 2021 WL 335137, at *13; *Gunter v. CCRC Opco-Freedom Square, LLC*, 2020 WL 8461513, at *3–4 (M.D. Fla. Oct. 29, 2020)

(holding that claims based on "the Defendants' negligent conduct in failing to properly staff the Facility, failing to effectively communicate with residents and families, failing to provide necessary medical supplies to the staff, reducing the cleaning practices in the Facility, and failing to properly use resident's funds" did not fall within the scope of the PREP Act). Thus, although Brighton Gardens argues that the PREP Act broadly bars any claims based on "the alleged failures to act or inaction described in the Amended Complaint," Appellants' Br. 30, "the square peg of Plaintiffs' allegations does not fit into the round hole of the PREP Act's definition of a covered countermeasure." *Smith*, 2020 WL 1087284, at *13.[7]

[7] *See also Thomas v. Century Villa Inc.*, 2021 WL 2400970, at *4 (C.D. Cal. June 10, 2021); *Brannon v. J. Ori, LLC*, 2021 WL 2339196, at *3 (E.D. Tex. June 8, 2021); *Forman v. C.P.C.H., Inc.* 2021 WL 2209308, at *2 (C.D. Cal. June 1, 2021); *Gwilt v. Harvard Square Ret. & Assisted Living*, 2021 WL 2373768, at *3 (D. Colo. May 7, 2021); *Evans v. Melbourne Terrace RCC, LLC*, 2021 WL 1687173, at *2 (M.D. Fla. Apr. 29, 2021); *Shapnik v. Hebrew Home for the Aged at Riverdale*, 2021 WL 1614818, at *15–16 (S.D.N.Y. Apr. 26, 2021); *Padilla v. Brookfield Healthcare Ctr.*, 2021 WL 1549689, at *5–6 (C.D. Cal. Apr. 19, 2021); *Hopman v. Sunrise Villa Culver City*, 2021 WL 1529964, at *5–6 (C.D. Cal. Apr. 16, 2021); *Winn v. Cal. Post Acute LLC*, 2021 WL 1292507, at *4 (C.D. Cal. Apr. 6, 2021); *Nava v. Parkwest Rehab. Ctr. LLC*, 2021 WL 1253577, at *2–3 (C.D. Cal. Apr. 5, 2021); *Maltbia v. Big Blue Healthcare, Inc.*, 2021 WL 1196445, at *5–12 (D. Kan. Mar. 30, 2021); *Gibbs v. Se.*

i. Whether Brighton Gardens engaged in recommended activities is irrelevant.

Brighton Gardens argues that it is immune under the PREP Act from liability for its failures to act because it was engaged in "recommended activities." Appellants' Br. 30–32. As the district court explained, even if Brighton Gardens were engaged in recommended activities, "all the requirements of the PREP Act must be met" in order for the facility to invoke the statute's immunity provision. JA274. Because Ms. Hatcher's claims do not relate to the administration or use of a covered countermeasure, whether or not Brighton Gardens was engaged in "recommended activities" is irrelevant.

SNF LLC, 2021 WL 1186626, at *3 (W.D. Tex. Mar. 30, 2021); *Stone v. Long Beach Healthcare Ctr., LLC*, 2021 WL 1163572, at *4–5 (C.D. Cal. Mar. 26, 2021); *Lopez v. Life Care Ctrs. of Am.*, 2021 WL 1121034, at *7–15 (D.N.M. Mar. 24, 2021); *McCalebb v. AG Lynwood, LLC*, 2021 WL 911951, at *5 (C.D. Cal. Mar. 1, 2021); *Robertson v. Big Blue Healthcare, Inc.*, 2021 WL 764566, at *7–8 (D. Kan. Feb. 26, 2021); *Lyons v. Cucumber Holdings, LLC*, 2021 WL 364640, at *5 (C.D. Cal. Feb. 3, 2021); *Goldblatt v. HCP Prairie Vill. KS OPCO LLC*, 2021 WL 308158, at *9–11 (D. Kan. Jan. 29, 2021); *Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC*, 2020 WL 6140474, at *1 (W.D. Pa. Oct. 16, 2020); *Eaton v. Big Blue Healthcare, Inc.,* 480 F. Supp. 3d 1184, 1192–95 (D. Kan. 2020); *Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 528–33 (D.N.J. 2020).

The term "recommended activities" does not appear in the PREP Act. Two places in the statute come closest. First, subsection (b)(1) provides the HHS Secretary authority to issue a declaration "recommending … 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." 42 U.S.C. § 247d-6d(b)(1). Brighton Gardens' assertion—which is entitled to no consideration on a motion to dismiss—that it was acting in "accordance with public health guidance issued by various federal and state agencies throughout the pandemic," Appellants' Br. 30, has no relevance to whether Ms. Hatcher's claims are causally related to administration or use of covered countermeasures recommended in the HHS Secretary's PREP Act Declaration.

Second, subsection (c)(4) provides immunity for willful misconduct claims based on the administration or use of a covered countermeasure, where such administration or use was in compliance with "recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in the declaration." 42 U.S.C. § 247d-6d(c)(4). Again, this provision has relevance only if a claim

has a causal connection with the administration or use of a covered countermeasure. Ms. Hatcher's claims do not.

ii. The claims do not challenge the administration of covered countermeasures to individuals.

Brighton Gardens suggests that all of its actions and inactions relating to COVID-19 collectively constituted the "administration" of covered countermeasures and, therefore, that it is immune under the PREP Act for any claims relating to COVID-19. Appellants' Br. 33–36. The statute does not support such a reading.

Subsection (a) provides immunity for claims relating to "*the administration to* or the *use by* an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(1) (emphasis added). The word "administration" is capable of different meanings. To "administer" something can mean "to manage or supervise the execution, use, or conduct of," or it can mean "to provide or apply; dispense." Merriam-Webster.com Dictionary, https://www.merriam-webster.com/dictionary/administer. In asking the Court to apply the PREP Act to all claims "relating to management and operation of countermeasure programs generally," Appellants' Br. 34, Brighton Gardens appears to invoke the former definition. But in the context of the PREP Act, only

the latter definition makes sense—given the use of the preposition "to," and the relationship between "administration to" and "use by." Drugs are often "administered to" individuals by health care providers; devices are often "used by" individuals directly. Including both terms in the statute ensures coverage in both scenarios.

The notion that the PREP Act creates immunity for injuries not directly related to the affirmative use of a covered countermeasure is further undercut by other aspects of the Act, which limit its application to claims based on the actual administration or use of a covered countermeasure. *See, e.g.*, 42 U.S.C. § 247d-6d(a)(3) (noting immunity applies only where "the countermeasure was administered or used" under certain conditions); *id.* § 247d-6e(b)(1) (for purposes of administrative remedy, authorizing compensation for injuries "directly caused by the administration or use of a covered countermeasure").

Reading the "administration" of a covered countermeasure to refer to the affirmative delivery of a covered countermeasure is consistent with the Act's purpose.[8] The Act was intended to encourage the manufacture

[8] HHS regulations regarding the administrative compensation scheme, promulgated pursuant to the Secretary's rulemaking authority

and distribution of covered countermeasures. Supporters explained that the bill was designed to ensure that a pandemic flu "vaccine gets developed and to make sure doctors are willing to give it when the time comes." 151 Cong. Rec. H12244-03 (daily ed. Dec. 18, 2005) (statement of Rep. Nathan Deal); *see also* 151 Cong. Rec. S14242-01 (daily ed. Dec. 21, 2005) (statement of Sen. Hillary Clinton noting that the "provision is being billed as a simple liability protection to help those who would manufacture avian flu vaccine"). Likewise, the addition of certain approved respiratory protective devices to the scope of covered countermeasures last March was designed to "boost the availability and supply of critically needed respirator [masks]." 166 Cong. Rec. H1675-09 (daily ed. Mar. 13, 2020) (statement of Rep. Greg Walden); *see also* Coronavirus Preparedness and Response: Hearing Before the H. Comm. on Oversight & Reform, Serial No. 116-96 at 43 (2020) (testimony of Dr. Robert Kadlec, HHS Asst. Secretary for Preparedness and Response, urging addition of respiratory protective devices to PREP Act in order to

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under 42 U.S.C. § 247d-6e(b)(4), reflect a similar focus on affirmative uses of covered countermeasures, by deeming only "injured counter-measure recipients"—not *non*-recipients or anyone else—eligible for compensation through the PREP Act's administrative compensation scheme. 42 C.F.R. § 110.10(a).

boost supply). Immunity for injuries resulting from the affirmative administration or use of a covered countermeasure protects manufacturers and encourages production; immunity for claims based on the non-use of covered countermeasures, or on patient care and staffing decisions unrelated to covered countermeasures, does not.

When Congress intends to provide immunity for things other than affirmative actions, it knows how to do so. For example, in the CARES Act, Congress immunized volunteer healthcare professionals for harm caused by "an act *or omission* of the professional in the provision of health care services during the public health emergency with respect to COVID–19." Pub. L. No. 116-136, § 3215(a), 134 Stat. at 374 (emphasis added). If providing immunity for an act necessarily confers immunity for the failure to act, the term "or omission" would be superfluous. Throughout 2020, Congress debated—but ultimately did not enact—liability protections for claims like Ms. Hatcher's. *See*, *e.g.*, 106 Cong. Rec. S2358 (daily ed. May 12, 2020) (Statement of Sen. Mitch McConnell, discussing legislation to "raise the liability threshold for COVID-related malpractice lawsuits" and to "create a legal safe harbor" for entities that are "following public health guidelines to the best of their ability"). The

subsequent debate over whether to immunize entities that failed to take adequate infection control measures confirms that Congress had not already created such immunity through the PREP Act in 2005 or amendment earlier in 2020. *See Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001) (noting Congress does not "hide elephants in mouseholes").

Ms. Hatcher alleges that Brighton Gardens failed to develop an adequate plan to address her mother's increased susceptibility to COVID-19, allowed symptomatic staff to interact with patients, and otherwise failed to take adequate steps to prevent the transmission of the coronavirus. She does not allege that Brighton Gardens "administered" covered countermeasures to her mother, and her claims do not relate to Brighton Gardens' administration of covered countermeasures to any other individual. Accordingly, her claims are not barred by the PREP Act.

iii. HHS interpretations do not support Brighton Gardens.

To support its theory of immunity, Brighton Gardens relies heavily on statements by HHS and argues that these statements must be afforded "controlling weight" under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843–44 (1984). *See*

Appellants' Br. 36. HHS's interpretations, however, are nowhere near as broad as Brighton Gardens suggests, and they do not support Brighton Gardens' view that all of its actions and inactions regarding COVID-19 infection control are part of its "administration" of a covered countermeasure. Moreover, HHS's interpretations are not "controlling." HHS's musings on hypothetical scenarios are not entitled to *Chevron* deference, and its statements lack persuasive value given the agency's complete failure to examine the text and structure of the Act.

First, Brighton Gardens selectively quotes the Secretary's definition of the term "administration" in the initial PREP Act Declaration. Appellants' Br. 34 (citing 85 Fed. Reg. at 15,200). The full text of the Secretary's definition reflects a narrower view. The Secretary stated:

> 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.

85 Fed. Reg. at 15,200. Even under this view, immunity applies only to decisions that "directly relate" to the affirmative "physical provision of a

countermeasure to a recipient." Brighton Gardens makes no attempt to explain how Ms. Hatcher's claims of, for example, persistent understaffing, generally inadequate infection control policies, and allowing symptomatic employees to continue to interact with patients "directly relate" to such a "physical provision." And on a motion to dismiss, there is no basis to infer that they do.

Second, Brighton Gardens points to advisory opinions issued by HHS's General Counsel, which generally opine that claims relating to "non-use" of covered countermeasures may fall within the scope of PREP Act immunity where non-use is the result of a purposeful prioritization of limited resources. Appellants' Br. 34–35. In the cited portion of Advisory Opinion 20-04, the General Counsel discussed the example of a patient turned away from a pharmacy that has limited doses of a COVID-19 vaccine, who later develops COVID-19 and dies. *See* JA234. The General Counsel opined that the PREP Act immunity would apply to a wrongful death suit against the pharmacy because its "prioritization" of limited doses constitutes the administration of those doses. *Id.* In Advisory Opinion 21-01, the General Counsel stated his view that immunity applies to claims arising out of non-use of covered

countermeasures when the claims relate to "allocation which results in non-use," but *not* to claims of "nonfeasance … that [] result[] in non-use." JA239.

In neither opinion did the General Counsel examine the text or purpose of the PREP Act. More importantly, whether or not those views are correct, the scenarios have nothing to do with this case. The complaint does not allege that Ms. L'Heureux contracted COVID-19 because Brighton Gardens prioritized the distribution of covered countermeasures to others and failed to administer countermeasures to her. Rather, it alleges that as a result of understaffing, Brighton Gardens failed generally to take proper infection control measures and allowed symptomatic staff to continue to work. As one court explained, even under the General Counsel's interpretation, "cases of general neglect [must] fall outside the protection of the PREP Act. Otherwise, the [opinions'] limiting language and illustration would be superfluous, if not confounding." *McCalebb*, 2021 WL 911951, at *5; *see also Padilla*, 2021 WL 1549689, at *5–6 (explaining Advisory Opinion 21-01 is irrelevant to analogous claims); *Goldblatt*, 2021 WL 308158, at *10 (addressing similar claims and stating "while Secretary Azar reads

the PREP Act's immunity to cover a species of 'inaction' claims, that species hasn't presented itself in this case").

Because none of the cited materials supports Brighton Gardens' theory of PREP Act immunity, the Court need not address Brighton Gardens' passing invocation of *Chevron* deference. In any event, *Chevron* deference does not apply to either the Secretary's or HHS General Counsel's interpretation of the terms "administration" and "use." An "administrative implementation of a particular statutory provision qualifies for *Chevron* deference [only] when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). Here, although HHS has issued regulations implementing the PREP Act, HHS has not issued regulations defining the terms "administration or use." And while the PREP Act allows the Secretary to issue a declaration "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," 42 U.S.C. § 247d-6d(b)(1), this authority does not carry with it the authority to announce definitions of the words "administration" or "use" that carry the force of law. *Cf.* 42 U.S.C. §247d-6d(c)(2)(A) (providing rulemaking authority to define the term "willful misconduct").

With respect to the General Counsel's opinions, "[i]nterpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference." *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000); *see also Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 643 (2013). The very case on which the General Counsel relies for his authority to issue advisory opinions, *see* JA235, 241, states that advisory opinions "are not entitled to any deference in the federal courts." *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 645 (6th Cir. 2004). Each of the five advisory opinions accordingly states that "[i]t does not have the force or effect of law." JA235, 241.

Where an "agency enunciates its interpretation through informal action that lacks the force of law, [this Court] accept[s] the agency's interpretation only if it is persuasive." *Mount Royal Joint Venture v.*

Kempthorne, 477 F.3d 745, 754 (D.C. Cir. 2007) (citing *Mead*, *Christensen*, and *Skidmore v. Swift Co.*, 323 U.S. 134 (1944)); *see also Wos*, 568 U.S. at 587. In that situation, courts' treatment of an agency's interpretation "depend[s] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Skidmore*, 323 U.S. at 140. Here, to the extent that the HHS materials indicate that the PREP Act provides immunity for claims based on anything other than the administration or use of a covered countermeasure, HHS was opining on hypothetical scenarios, without any examination of the statutory text, history, or purpose.[9] Accordingly, not even *Skidmore* deference is due.

[9] The one district court that deferred to the General Counsel's view and concluded that claims like Ms. Hatcher's are within the scope of the PREP Act similarly failed to address the text or purpose of the statute. *See Garcia v. Welltower OpCo Grp. LLC*, 2021 WL 492581, at *7–9 (C.D. Cal. Feb. 10, 2021). *But see Parr v. Palm Garden of Winter Haven, LLC*, 2021 WL 1851688, at *2 (M.D. Fla. May 10, 2021) (noting that "all of the federal district court decisions reported on Westlaw that cite to and consider *Garcia* have declined to follow its lead").

3. The inapplicability of the PREP Act affirmative defense need not be pleaded.

Contrary to Brighton Gardens' suggestion, Appellants' Br. 41–42, Ms. Hatcher had no burden to plead facts to show that the PREP Act did *not* apply. *See Rivero v. Bd. of Regents of Univ. of N.M.*, 950 F.3d 754, 759–60 (10th Cir. 2020) ("A plaintiff has no burden to anticipate an affirmative defense and plead facts negating it."); *see also de Csepel v. Republic of Hungary*, 714 F.3d 591, 607–08 (D.C. Cir. 2013) ("[A]lthough it is certainly true that plaintiffs must plead the elements of their *claims* with specificity, they are 'not required to negate an affirmative defense in their complaint.'" (quoting *Flying Food Grp., Inc. v. NLRB*, 471 F.3d 178, 183 (D.C. Cir. 2006)). Rather, a motion to dismiss based on subsection (a) of the PREP Act, like any other motion to dismiss based on an affirmative defense, should be granted only if the elements of the defense "appear[] plainly on the face of the complaint itself." *Ullery v. Bradley*, 949 F.3d 1282, 1288 (10th Cir. 2020).

C. Ms. Hatcher pleaded a plausible causal link between the 2019 fall and her mother's death.

Separate from its PREP Act arguments, Brighton Gardens argues that the district court should have dismissed Ms. Hatcher's claims based on the facility's negligence in causing her mother to fall and fracture her

hip in January 2019, because she did not adequately plead causation. Appellants' Br. 44–45.[10] The district court correctly held that Ms. Hatcher's complaint met the applicable pleading standard.

In the operative complaint, Ms. Hatcher alleges that, as a result of a botched transfer, her mother fractured her hip, leading to two surgeries and an infection in the surgical wound. JA30 (¶¶ 2–4). These injuries left her "less mobile and at a higher risk of contracting a respiratory infection

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[10] To the extent Brighton Gardens suggests Ms. Hatcher's complaint should have been dismissed because she "fail[ed] to identify an applicable standard of care" or a breach of that standard as elements of her Kansas tort claims, Appellants' Br. 41, that argument is not properly before the Court. It appears nowhere in Appellants' Statement of Issues, *see* Fed. R. App. P. 28(a)(5), or in any developed form in Brighton Gardens' appellate brief. *Cf. Bronson v. Swensen*, 500 F.3d 1099, 1105 (10th Cir. 2007) ("[C]ursory statements, without supporting analysis and case law, fail to constitute the kind of briefing that is necessary to avoid application of the forfeiture doctrine."). Moreover, this argument was not raised below. In the district court, Brighton Gardens' only argument about the sufficiency of the factual allegations of Ms. Hatcher's claims was limited to two paragraphs asserting that the complaint lacked sufficient detail regarding a causal link between the botched transfer in 2019 and Ms. Hatcher's death in 2020. *See* JA80–81. But the standard of care, breach of that standard, and causation are distinct elements of a negligence claim. *See Montgomery v. Saleh*, 466 P.3d 902, 907 (Kan. 2020). Because Brighton Gardens did not argue that the complaint was deficient as to the duty and breach elements of the tort claims, any such argument has been forfeited in this Court. *See Trans-W. Petroleum, Inc. v. United States Gypsum Co.*, 830 F.3d 1171, 1175 (10th Cir. 2016) ("As a general rule, a federal appellate court does not consider an issue not passed upon below." (citation omitted)).

like Covid-19." JA31 (¶ 6). The complaint alleges that the "fracture caused by Brighton Gardens" thus "directly contributed" to Ms. L'Heureux's "contraction of Covid-19 and ultimately her death." *Id.* (¶ 11). These allegations are sufficient to meet the requirements of Federal Rule of Civil Procedure 8.

At the motion to dismiss stage, the question is whether "the plaintiff has provided 'enough facts to state a claim to relief that is plausible on its face.'" *Hogan v. Winder*, 762 F.3d 1096, 1104 (10th Cir. 2014) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 547 (2007)). As the district court held, it is more than plausible that immobility is "a COVID-19 risk factor" and thus contributed to Ms. L'Heureux's illness and eventual death. JA301 (citing *United States v. Walls*, 2020 WL 6390597, at *9 (W.D. Pa. Nov. 2, 2020); *Malam v. Adducci*, 2020 WL 1934895, at *4–5 (E.D. Mich. Apr. 22, 2020)).[11] In the *Walls* case, for example, the district court cited Centers for Disease Control guidance for the proposition that "'people who have limited mobility' could be at

[11] Brighton Gardens criticizes the district court's citation to these cases on the grounds that they are "detention/prison cases where the plaintiff sought early release based on COVID-19." Appellants' Br. 44 n.54. That distinction is irrelevant; both cases acknowledge the link between limited mobility and increased risk of COVID-19 transmission.

increased risk of becoming infected." 2020 WL 6390597, at *8 (quoting Ctrs. for Disease Control & Prevention, *Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19)* (Oct. 27, 2020 version), https://stacks.cdc.gov/view/cdc/96080. That the link between immobility and COVID-19 infection risk has been recognized by the Centers for Disease Control and district courts around the country after reviewing scientific evidence belies Brighton Gardens' assertion that "such causation is implausible." Appellants' Br. 49; *see People First of Ala. v. Merrill*, 491 F. Supp. 3d 1076, 1095–96 (N.D. Ala. 2020), *appeal pending* (finding that people with limited mobility are at increased risk of contracting COVID-19); *United States v. Jackson*, 2020 WL 6110998, at *3 (D.S.C. Oct. 16, 2020) (noting that mobility limitations present "increased risk of serious illness from COVID-19"); *Malam v. Adducci*, 2020 WL 1809675, at *4 (E.D. Mich. Apr. 9, 2020) (finding limited mobility placed individual at "high risk of severe illness from COVID-19").

In her complaint, Ms. Hatcher was not required to plead scientific detail about how decreased mobility leads to an increased risk of COVID-19 transmission. Whether or not the injuries Brighton Gardens caused

Ms. L'Heureux in January 2019 played a role in her contracting COVID-19 in 2020 is a factual issue, and, as this case proceeds, Brighton Gardens will have an opportunity to challenge and rebut any evidence Ms. Hatcher puts forth. But if Brighton Gardens "really wishes to dispute the facts alleged in a complaint, a motion to dismiss surely isn't the proper way to go about it." *Ute Indian Tribe of the Uintah v. Myton*, 835 F.3d 1255, 1261 (10th Cir. 2016) (Gorsuch, J.).

D. After holding that the claims alleged are not within the scope of subsection (a), the district court properly declined to consider Brighton Gardens' argument under subsection (d).

Finally, Brighton Gardens briefly argues that Ms. Hatcher's claims should be viewed as "willful misconduct" claims subject to the exclusive federal cause of action created by subsection (d) of the PREP Act. Reframing the claims in that fashion, Brighton Gardens argues that the action should have been dismissed for failure to exhaust administrative remedies pursuant to 42 U.S.C. § 247d-6e(d)(1), and because Ms. Hatcher "filed suit in the wrong forum." Appellants' Br. 46. Brighton Gardens also argues that the district court erred by failing to address this argument under Federal Rule of Civil Procedure 12(b)(1). Appellants' Br. 46–47. This argument fails to acknowledge the relationship between the

immunity provision of subsection (a) and the exception to that immunity created by subsection (d).

As discussed above, subsection (a) of the PREP Act defines a set of claims as to which immunity generally applies, and subsection (d) carves out a subset of such claims as to which there is no immunity, but rather an exclusive federal cause of action governed by specific procedures. If Ms. Hatcher's claims do not fall under subsection (a), then as a matter of law they cannot be within the exception to subsection (a) created by subsection (d). And if they are not within that exception, they cannot be subject to the administrative exhaustion requirement or venue limitations that apply to subsection (d) claims.

As Brighton Gardens acknowledged below, JA58, whether a preemption defense applies to Ms. Hatcher's state-law claims is a question reviewed under Rule 12(b)(6). *See Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1341 (10th Cir. 2015) (citing *Jones v. Bock*, 548 U.S. 199, 212–15 (2007)). Once the district court analyzed that threshold legal question and concluded that the PREP Act did not apply because Ms. Hatcher's claims do not relate to the use or administration of a covered countermeasure (under subsection (a)), there was no need to consider

Brighton Gardens' argument that Ms. Hatcher's claims were ones for "willful misconduct" relating to the use or administration of a covered countermeasure (under subsection (d)).[12]

The district court was not required to address this issue separately under Rule 12(b)(1). Brighton Gardens points to no evidence beyond the four corners of the complaint that it asked the district court to consider but that the court disregarded.[13] The issue was a purely legal one. Thus,

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[12] Brighton Gardens misquotes the district court as having "incorrectly stated" that "Defendants do not contend that [the willful misconduct] provision directly applies to warrant the dismissal of this action." Appellants' Br. 46 (citing JA274). The bracketed language does not accurately reflect the district court's opinion; the provision being discussed was subsection (c)(4) of the Act, 42 U.S.C. § 247d(c)(4)), which provides immunity for certain willful misconduct claims where a covered person was complying with government directives. *See* JA274. The district court was correct that Brighton Gardens did "not contend that [subsection (c)(4)] directly applies to warrant dismissal of the action." *Id.* Indeed, if Brighton Gardens were correct that Ms. Hatcher's claims fall under subsection (d), the Kansas district court would have lacked jurisdiction to determine whether the subsection (c)(4) defense applied.

[13] While Brighton Gardens included a request "for oral argument and/or jurisdictional hearing" with its motion to dismiss, it did not indicate what, if any, evidence would be adduced at such a hearing. *See* JA81–82. Brighton Gardens does not challenge the district court's denial of that request, JA263 n.3, and has thus forfeited any argument that the district court was required to hold such a hearing. *Cf. Breakthrough Mgmt. Grp., Inc. v. Chukchansi Gold Casino & Resort*, 629 F.3d 1173,

treating Brighton Gardens' motion as a facial attack under Rule 12(b)(1) would not have affected the court's review. *See Safe Streets Alliance v. Hickenlooper*, 859 F.3d 865, 877–78 (10th Cir. 2017) ("[A] facial attack on the complaint's allegations as to subject matter jurisdiction questions the sufficiency of the complaint, and the district court must accept the allegations in the complaint as true." (marks and citation omitted)); *see also Schmitz v. Colorado State Patrol*, 841 F. App'x 45, 54 (10th Cir. 2020) (noting that review of Rule 12(b)(1) facial attacks "mirrors how we assess Rule 12(b)(6) motions").

That said, should this Court reverse the district court on the issue whether subsection (a) applies to Ms. Hatcher's claims, it should remand to the district court to determine in the first instance which, if any, claims fall within subsection (d). Any such claims would be dismissed without prejudice for lack of subject matter jurisdiction. This Court should decline to make that determination in the first instance, particularly because Brighton Gardens failed to provide any argument in its opening brief as to which, if any, of Ms. Hatcher's claims seek relief for "willful

1188–89 (10th Cir. 2010) (district court's handling of jurisdictional hearing subject to abuse-of-discretion review).

misconduct"—a term that, under the statute, applies to intentional acts or omissions, and requires a showing of more than "negligence in any form or recklessness." 42 U.S.C. § 247d-6d(c)(1)(A)–(B).[14] *See, e.g.*, *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1108 (10th Cir. 2017) ("Because the district court did not consider this question and it has not been fully briefed on appeal, we leave this question for the district court to address on remand.").

CONCLUSION

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

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[14] Brighton Gardens inaccurately states that "[i]ronically, the District Court found there were sufficient allegations of willful misconduct in the Amended Complaint to deny immunity" under Kansas Executive Order 20-26. Appellants' Br. 46 (citing JA277). In the cited portion of its opinion, the district court stated Ms. Hatcher's "allegations are sufficient at this stage to describe a plausible claim of *gross negligence and recklessness*," and thus fell within the exception to immunity conferred by the Executive Order. JA277 (emphasis added). While Executive Order 20-26 contains an exception to immunity for gross negligence and recklessness, subsection (d) of the PREP Act does not. *Compare* Kan. Exec. Order 20-26 (Apr. 22, 2020) ¶5, https://governor.kansas.gov/wp-content/uploads/2020/04/EO-20-26-Executed.pdf with 42 U.S.C. §247d-6d(c)(1)(B) (explicitly stating willful misconduct exception does *not* apply to "negligence in any form or recklessness").

Respectfully submitted,

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June 14, 2021

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 12,997 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.

June 14, 2021

/s/ Adam R. Pulver
Adam R. Pulver

ADDENDUM

ADDENDUM

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).

...

(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.

…

(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.

…

(5) Exclusion for regulated activity of manufacturer or distributor

(A) In general

If an act or omission by a manufacturer or distributor with respect to a covered countermeasure, which act or omission is alleged under subsection (e)(3)(A) to constitute willful misconduct, is subject to regulation by this chapter or by the Federal Food, Drug, and Cosmetic Act, such act or omission shall not constitute "willful misconduct" for purposes of subsection (d) if--

(i) neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission; or

(ii) such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy.

…

(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.

…

(7) Qualified pandemic or epidemic product

The term "qualified pandemic or epidemic product" means 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))2 that is--

(A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured--

(I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or

(II) to limit the harm such pandemic or epidemic might otherwise cause;

(ii) a product 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 a product described in clause (i); or

(iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and

(B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 262 of this title;

(ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act; or

(iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act.

…

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.

…

42 C.F.R. § 110.10 Eligible requesters.

(a) The following requesters may, as determined by the Secretary, be eligible to receive benefits from this Program:

(1) Injured countermeasure recipients, as described in § 110.3(n);

(2) Survivors, as described in § 110.3(cc) and § 110.11; or

(3) Estates of deceased injured countermeasure recipients through individuals authorized to act on behalf of the deceased injured countermeasure recipient's estate under applicable State law (i.e., executors or administrators).

…

42 C.F.R. § 110.20 How to establish a covered injury.

(a) General. Only serious injuries, as described in § 110.3(z), or deaths are covered under the Program. In order to be eligible for benefits under the Program, a requester must submit documentation showing that a covered injury, as described in § 110.3(g), was sustained as the direct result of the administration or use of a covered countermeasure pursuant to the terms of a declaration under section 319F–3(b) of the PHS Act (including administration or use during the effective period of the declaration) or as the direct result of the administration or use of a covered countermeasure in a good faith belief that it was administered or used pursuant to the terms of a declaration (including administration or use during the effective period of the declaration). A requester can establish that a covered injury was sustained by demonstrating to the

Secretary that a Table injury occurred, as described in paragraph (c) of this section. In the alternative, a requester can establish that an injury was actually caused by a covered countermeasure, as described in paragraph (d) of this section. The Secretary may obtain the opinions of qualified medical experts in making determinations concerning covered injuries.

…

(d) Injuries resulting from the underlying condition for which the countermeasure was administered or used. An injury sustained as the direct result of the covered condition or disease for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (e.g., if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease).

…