ORAL ARGUMENT SCHEDULED FOR APRIL 28, 2022

No. 21-7096

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

CHRISTOPHER BEATY, Jr. and NICHOLE GARCIA, as Co-administrators of the Estate of CHRISTOPHER DAVID BEATY, Deceased, and in Their Own Right,

Plaintiffs-Appellees,

v.

FAIR ACRES GERIATRIC CENTER and DELAWARE COUNTY,

Defendants-Appellants.

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

BRIEF FOR APPELLEES

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February 18, 2022

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

Christopher Beaty, Jr., and Nichole Garcia, individually and as co-administrators of the Estate of Christopher David Beaty, (collectively "the Estate") are the Plaintiffs in the district court and are the Appellees in this Court.

Fair Acres Geriatric Center and Delaware County, doing business as Fair Acres Geriatric Center, 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 order entered by Judge Paul S. Diamond on August 5, 2021. There, the court denied Defendants' motion to dismiss the Estate's section 1983 claims, which arise out of the death of Christopher David Beaty caused by Defendants' lack of adequate infection control policies, in violation of his rights under the Federal Nursing Home Reform Amendments, 42 U.S.C. § 1396r. The order is

available on Westlaw. *See Beaty v. Delaware County*, 2021 WL 4026373 (E.D. Pa. Aug. 5, 2021).

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 Circuit Rule 28(a)(1)(C).

The Estate is aware of one pending appeal that raises the same jurisdictional question addressed below: In *Cannon v. Watermark Retirement Communities*, No. 21-7067, the Court directed the parties to address whether 42 U.S.C. § 247d-6d(e)(10) provides this Court with jurisdiction over an appeal in the same procedural posture as this one. *See Cannon*, Order dated Sept. 15, 2021. Although the cases present the same jurisdictional issue, a decision addressing the merits in *Cannon* would not resolve the merits issues in this case.

In addition, *Hereford v. Broomall Operating Company LP*, No. 22-7005, also presents the question whether a defendant may appeal an out-of-circuit district court decision to this Court under § 247-6d(e)(10). That case, however, poses an antecedent question whether that appeal, which

is from a remand order based on a lack of subject-matter jurisdiction, is barred by 28 U.S.C. § 1447(d). If the answer to that question is yes, this Court will not reach the § 247-6d(e)(10) issue in that case.

Finally, the Estate is aware of pending appeals in seven courts of appeals raising the issue whether claims like the Estate's, which are based on nursing homes' negligence in failing to take precautions to reduce the spread of the coronavirus, are claims relating to "the administration to or use by an individual of a covered countermeasure" and thus subject to immunity under the PREP Act, 42 U.S.C. § 247d-6d. These appeals include *Leroy v. Hume*, 2d Cir. No. 21-2158; *Rivera-Zayas v. Our Lady of Consolation Geriatric Care Center*, 2d Cir. No. 21-2164; *Mitchell v. Advanced HCS, LLC*, 5th Cir. No. 21-10477 (argued Jan. 31, 2022); *Perez v. Southeast SNF*, 5th Cir. No. 21-50399 (argued Dec. 6, 2021); *Hudak v. Elmcroft of Sagamore Hills*, 6th Cir. No. 21-3836; *Martin v. Petersen Health Operations, LLC*, 7th Cir. No. 21-2959; *Martin v. Filart*, 9th Cir. No. 20-56067 (argued Oct. 21, 2021); *Saldana v. Glenhaven Healthcare LLC*, 9th Cir. No. 20-56194 (argued Oct. 21, 2021); and *Schleider v. GVDB Operations, LLC*, 11th Cir. No. 21-11765.

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GLOSSARY

FNHR Amendments	Federal Nursing Home Reform Amendments, commonly referred to and referred to by the District Court and the Third Circuit as the FNHRA
HHS	Department of Health and Human Services
PREP Act	Public Readiness and Emergency Preparedness Act, commonly referred to and referred to by the District Court as the PREP Act

STATEMENT OF JURISDICTION

The United States District Court for the Eastern District of Pennsylvania has jurisdiction over this action under 28 U.S.C. §§ 1331 and 1343.

This Court lacks jurisdiction over this interlocutory appeal from the Pennsylvania district court's decision. *See infra* pp. 17–30.

STATEMENT OF THE ISSUES

(1) Whether the Public Readiness and Emergency Preparedness (PREP) Act provides this Court with jurisdiction to hear interlocutory appeals from decisions of district courts in other circuits rejecting assertions of immunity under that statute, when appeals from final decisions regarding such immunity would be heard in the regional circuit courts.

(2) Whether claims that a nursing home's inadequate infection policies led to the death of a resident from COVID-19 have a causal relationship with "the administration to or use by an individual" of a drug or device deemed a "covered countermeasure," thus triggering the liability protections of the PREP Act.

(3) Whether the district court correctly held that the Estate plausibly alleged that Defendants' policies and deliberate indifference violated Mr. Beaty's rights under the Federal Nursing Home Reform Amendments (FNHR Amendments) and caused his death.

STATUTES AND REGULATIONS

Relevant provisions of the PREP Act, 42 U.S.C. §§ 247d-6d–247d-6e, its implementing regulations, 42 C.F.R. §§ 110.10 and 110.20, and the FNHR Amendments, 42 U.S.C. § 1396r, appear in the Addendum to this brief.

STATEMENT OF THE CASE[1]

I. Fair Acres' Deliberate Indifference to the Health of its Residents and the Preventable Death of Mr. Beaty

Fair Acres Geriatric Center is a long-term skilled nursing facility in Lima, Pennsylvania, owned and operated by Delaware County, Pennsylvania. JA8, 9. When the COVID-19 pandemic began, Christopher David Beaty had resided at Fair Acres for approximately 15 years. JA8,

[1] All facts are taken from the Estate's complaint and exhibits thereto, JA7–34. In ruling on Fair Acre's Rule 12(b)(6) motion, the district court properly accepted as true all the factual allegations in that complaint. JA179 (citing *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009)).

10. Because of comorbidities and his health history, Mr. Beaty was at a heightened risk of serious illness and death from COVID-19. JA11.

Despite the risk to Mr. Beaty and other residents, and guidelines from Pennsylvania state officials, Fair Acres took few steps to prevent the spread of COVID-19 among residents. JA11. Fair Acres allowed staff and residents to intermingle throughout the facility without restrictions or precautions until June 1, 2020. JA11, 14. It failed to adopt and enforce policies for identifying, testing, and isolating residents with COVID-19 symptoms. JA14, 17, 16–17. It ignored Centers for Disease Control infection-control guidelines and did not accurately communicate about the spread of COVID-19 to public health officials, residents and their families. JA14, 18. It allowed infected staff to care for residents, and it failed to ensure that staff and residents had sufficient access to, and properly used, personal protective equipment. JA13, 16, 18–19.

As a result, by May 11, 2020, Fair Acres reported "104 confirmed resident cases of COVID-19 and 27 residents identified as 'presumed' positive based on their symptoms," and "53 confirmed employee cases of COVID-19" at the facility. JA15, 32. Still, another three weeks passed

before Fair Acres adopted policies limiting intermingling of staff and residents or requiring isolation of symptomatic residents. JA11.

On or around May 29, 2020, Fair Acres administered COVID-19 tests to Mr. Beaty and his roommate. On or around June 1, 2020, Mr. Beaty reported that his roommate was exhibiting signs of COVID-19 infection. JA11. His family reported this information to Fair Acres that same day. JA12. Nonetheless, Fair Acres did not isolate Mr. Beaty's roommate from him. *Id.* On June 2, the May 29 test results revealed that Mr. Beaty had not been positive for COVID-19 but his roommate had been. *Id.* Only then, after Mr. Beaty had been continuously exposed to a symptomatic, COVID-19 positive individual for at least four days, did Fair Acres isolate Mr. Beaty's roommate. *Id.*

Fair Acres acted too late for Mr. Beaty, who began to exhibit symptoms of COVID-19. JA12. On June 3, 2020, his condition declined, and he was sent to a hospital. *Id.* He died three days later of COVID-19. JA13.

Mr. Beaty was not the only victim of Fair Acres' indifference to COVID-19. The day after his hospitalization, Fair Acres sent residents' families a letter indicating that the number of confirmed resident cases

had more than doubled to 222 between May 11 and June 4 and that the number of confirmed employee cases had nearly doubled to 94. JA15.

II. The PREP Act and the 2020 Declaration

A. 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 (HHS) to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines." Cong. Res. Serv., *The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures* 1 (updated Jan. 13, 2022), https://crsreports.congress.gov/product/pdf/LSB/LSB10443.

The Secretary triggers the PREP Act by issuing a declaration determining that a public health emergency exists and "recommending" the "manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures." 42 U.S.C. § 247d-6d(b)(1); *see Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393, 400–01 (3d Cir. 2021). The Secretary may designate only certain drugs, biological products, and devices authorized or approved for use by the Food and

Drug Administration or the National Institute for Occupational Safety and Health as "covered countermeasures." 42 U.S.C. § 247d-6d(i)(1)(A)–(D).

Subsection (a) of the PREP Act provides "covered persons" with immunity for liability under state or federal law for "any claim for loss that has a causal relationship with the administration to or use by an individual of a [designated] covered countermeasure." *Id.* §§ 247d-6d(a)(1), (a)(2)(B). Subsection (d) creates a carveout from such 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 a three-judge court of the District Court for the District of Columbia, *id.* § 247d-6d(e).

The PREP Act also creates an administrative scheme 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. On March 10, 2020, the HHS Secretary issued a Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19. 85 Fed. Reg. 15,198 (published Mar. 17, 2020). The Declaration recommended the "manufacture, testing, development, distribution, administration, and use" of certain countermeasures to combat COVID-19: "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product." *Id.* at 15,202.

The Secretary amended the initial Declaration several times. The First Amendment expanded covered countermeasures to include certain

respiratory protective equipment. *See* 85 Fed. Reg. 21,012, 21,013–14 (Apr. 15, 2020). Later, in the Fourth Amendment's preamble, the Secretary opined 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 reflects "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). He gave 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 HHS's General Counsel. *Id.* at 79,191 & n.5. In one of those opinions, the General Counsel opined that PREP Act immunity was available to persons "using a covered countermeasure in accordance with" guidance from public health authorities, including guidance on how to prioritize scarce countermeasures like vaccines. HHS General Counsel, Advisory Opinion

20-04 at 2–7 (Oct. 22, 2020, as modified on Oct. 23, 2020).[2] The General Counsel provided "examples of program planners using covered countermeasures according to the guidance of" a public health authority that would, in his view, trigger PREP Act immunity, including the vaccination prioritization example given in the Fourth Amendment. *Id.* at 5–7.

In January 2021, the General Counsel issued a fifth advisory opinion. Advisory Opinion 21-01, JA81. The opinion purported to address whether state-court actions raising certain COVID-19-related state-law claims are properly removed to federal court based on 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 application. JA82. He opined that the PREP Act applies to claims relating to the "allocation [of a covered countermeasure] which results in non-use by some individuals," "particularly if done in

[2] The advisory opinions are available at https://www.hhs.gov/about/agencies/ogc/advisory-opinions/index.html.

accordance with a public health authority's directive," but *not* to cases where non-use was the result of "nonfeasance." JA83–84.

III. Procedural History

A. The Estate's Claims

On April 6, 2021, the Estate commenced this action in the United States District Court for the Eastern District of Pennsylvania against Fair Acres Geriatric Center and Delaware County, doing business as Fair Acres Geriatric Center (collectively, Fair Acres). JA2, JA7. The complaint asserted that Fair Acres had a "duty to comply with all provisions of the Omnibus Budget Reconciliation Act of 1987/Federal Nursing Home Reform Act, 42 U.S.C. § 1396r, 1396a(w) a[s] incorporated by 42 U.S.C. § 1396(r)," and implementing regulations issued by HHS. JA10. It identified thirty-three specific ways in which Fair Acres breached these duties, including by failing to establish, maintain, and follow an infection prevention and control program; failing to establish and follow "adequate written standards, policies, and procedures that enumerate when possible communicable diseases or infections should be reported, and who they should be reported to;" failing to establish and follow standards, policies, and procedures for when and how residents and staff members with or exposed to a communicable infection should be isolated or

otherwise prevented from exposing residents and other staff; "allowing COVID-19 infected staff to care for residents;" "failing to ensure that proper social distancing was maintained by residents and staff;" and failing to ensure that all employees had access to, were trained how to utilize, and properly utilized personal protective equipment." JA17–19.

The Estate alleged that Fair Acres' actions and inactions made its staff "less able to contain and control the spread of COVID within the facility," and were the direct and proximate cause of Mr. Beaty contracting, and dying from, COVID-19. JA23. The complaint included two claims against Fair Acres pursuant to 42 U.S.C. § 1983: one for wrongful death in the Estate's representative capacity, and one for survival on behalf of Christopher Beaty, Jr. and Nichole Garcia in their own right. JA24–25.

B. Fair Acres' Motion to Dismiss

On June 7, 2021, Fair Acres filed a motion to dismiss the action in its entirety, pursuant to Rules 12(b)(6) and 12(b)(1). JA35. Fair Acres made three PREP Act-related arguments. First, it argued that the Estate's claims were barred by subsection (a) of the PREP Act, because they relate to "the use of a test/diagnostic to diagnose the COVID-19

infection in Christopher Beaty and his roommate," JA53, and to Fair Acres' "allocation and/or non-use of covered countermeasures … meant to mitigate the spread of COVID-19," JA54. Second, it argued that the Estate did not comply with the pleading requirements for a "willful misconduct" claim pursuant to subsections (d) and (e) of the statute, and thus "any attempt to allege 'willful misconduct' … must be dismissed from Plaintiffs' Complaint." JA56–57. Third, it argued that the Estate's failure to file an administrative claim with HHS constituted a failure to exhaust administrative remedies. JA57–58.

In addition, Fair Acres argued that the Third Circuit had wrongly held that the FNHR Amendments created rights that can be enforced via section 1983 in *Grammer v. John J. Kane Regional Centers-Glen Hazel*, 570 F.3d 520 (3d Cir. 2009), and it asked the court to dismiss on the theory that "there is no enforceable individual right created by any statutory provision of the FNHRA." JA58–66. It also argued that the Estate failed to plead adequate facts to establish municipal liability under *Monell v. New York City Department of Social Services*, 436 U.S. 658 (1978). JA66–74. Finally, it argued that the Estate could not bring a wrongful death claim under Pennsylvania law. JA75–76.

The district court denied the motion in its entirety. The court held that the PREP Act did not apply to the Estate's claims. JA172–73. Citing several district courts that reached the same conclusion, the court concluded that "the term 'covered countermeasure' does not include social distancing, quarantining, or lockdowns," and held that "a defendant's *failure* to take countermeasures" does not "fall within the scope of the [PREP] Act's protection." JA172–73 (citing *Reed v. Sunbridge Hallmark Health Servs., LLC*, 2021 WL 2633156, at *4 (C.D. Cal. Jun. 25, 2021); *Lutz v. Big Blue Healthcare, Inc.*, 480 F. Supp. 3d 1207, 1216 (D. Kan. 2020); *Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 532–33 (D.N.J. 2020), *aff'd on other grounds*, 16 F.4th 393). It also rejected Fair Acres' argument that the Estate's claims had a causal relationship with the tests administered to either Mr. Beaty or his roommate. JA173.

As to Fair Acres' other arguments, the district court declined to contradict the Third Circuit's decision in *Grammer*. JA174. It held that, under that precedent, the Estate's allegations were "sufficient to state a plausible *Monell* claim," as, "[a]t the very least," the Estate had "adequately pled deliberate indifference." *Id.* Finally, it declined to

resolve Fair Acres' argument about standing to pursue the wrongful death claim at the pleading stage. JA175.

Fair Acres then filed a notice of appeal to this Court. JA176–77.

SUMMARY OF ARGUMENT

I. This Court lacks jurisdiction over this interlocutory appeal from the denial of a motion to dismiss by the United States District Court for the Eastern District of Pennsylvania. Although subsection (e)(10) of the PREP Act creates a right to interlocutory appeal to this Court from decisions denying certain motions to dismiss, that provision applies only to cases brought in the United States District Court for the District of Columbia asserting claims under the federal cause of action created by subsection (d) of the PREP Act. A contrary reading could place district courts in the impossible position of being subject to conflicting but binding precedents of two circuits.

II.A. On the merits, the district court was correct to deny Fair Acres' motion to dismiss based on the PREP Act. Contrary to Fair Acres' argument, the PREP Act does not confer immunity on entities for all claims based on their responses to pandemics. The Act confers immunity only for claims for loss that have a "causal relationship" with "the

administration to or use by an individual" of one of the drugs, medical devices, or products designated as a "covered countermeasure." The Estate's claims do not meet these requirements.

Claims based on failures to ensure social distancing or to isolate symptomatic patients have no causal relationship with covered countermeasures. Even if the Estate's complaint could be read to implicate COVID-19 testing or personal protective equipment, as Fair Acres reads it to do, the claims here would relate only to *non*-use of these measures. Extending immunity to claims where an individual died as a result of *non*-use, however, would be incompatible with both the text and purpose of the PREP Act. As dozens of district courts have recognized, multiple provisions of the statute dictate that immunity applies only where a covered countermeasure *was* administered to or used by an individual. And immunizing non-use of covered countermeasures would not advance the purpose of the Act: encouraging the manufacture, distribution, and use of those measures. HHS's nonbinding view that non-use is subject to immunity where it results from "purposeful allocation" of scarce countermeasures is untethered to the statute and, in

any event, irrelevant here, where the complaint does not allege non-use resulting from purposeful allocation.

B. Fair Acres' challenges to the adequacy of the Estate's *Monell* claims are contrary to controlling precedent both as to the pleading standards applicable to those claims, and the ability to use section 1983 to enforce the rights guaranteed to nursing home residents by the FNHR Amendments. The complaint's factual averments—including that as late as the end of May 2020, with hundreds of cases within its walls, Fair Acres failed to adopt screening, isolation, and social-distancing policies for residents and staff—plausibly allege violations of the FNHR Amendments' quality-care and infection-control provisions. Under the Third Circuit's decision in *Grammer*, which Fair Acres concedes controls, violations of these provisions are actionable under section 1983. As a municipal entity, Fair Acres may be held liable for these violations under *Monell* if the Estate proves its well-pleaded claims that the risk of harm associated with failing to adopt policies to prevent the intermingling of sick and exposed staff and residents with vulnerable residents like Mr. Beaty was so obvious that such failure constituted deliberate indifference.

ARGUMENT

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

This Court lacks jurisdiction of this appeal for two reasons. First, it is an interlocutory appeal of an order denying a motion to dismiss, which is not generally appealable as of right. *See* 28 U.S.C. § 1291. Second, it is an appeal from an order of the U.S. District Court for the *Eastern District of Pennsylvania*, despite the general rule that "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).

Fair Acres suggests that subsection (e)(10) of the PREP Act, 42 U.S.C. § 247d-6d(e)(10), provides exceptions to both these rules. Appellants' Br. 4. Subsection (e)(10), when it applies, provides a right to an interlocutory appeal of certain orders in cases under the PREP Act. That subsection is ambiguous 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 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). Because the former interpretation would place

district courts around the country in an untenable position, while the latter 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 non-subsection (d) 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 Cares Cmty. Health v. HHS*, 944 F.3d 950, 957 (D.C. Cir. 2019).

Under such an analysis, subsection (e)(10) is ambiguous. As explained above, *supra* p. 6, subsection (a) of the PREP Act creates an immunity for certain claims. Subsection (d) creates an exception to that immunity 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 1 through 9 expressly apply to "action[s] under subsection (d)." *Id.* § 247d-6d(e)(1)–(9). Those paragraphs set forth pleading requirements, 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 a motion to dismiss or an interlocutory appeal from the denial of such a motion. *Id.* § 247d-6d(e)(5), (6). 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).

Id. § 247d-6d(e)(10).

Read alone, paragraph 10 is ambiguous as to whether it, like the other provisions of subsection (e), applies only to claims brought pursuant to the subsection (d) cause of action and in the District of Columbia

district court. Because the text of paragraph 10 says nothing about what kinds of actions or which courts' decisions it applies to, it *could* be read to provide this Court with jurisdiction to hear interlocutory appeals from denials of motions to dismiss by Pennsylvania *state* courts, or even of denials of motions to dismiss filed in state administrative proceedings. Such a reading, however, would be absurd.

Paragraph 10 is best read to apply only to subsection (d) claims. The right to an interlocutory appeal provided for in subsection (e)(10) "does not stand alone," and the ten paragraphs of subsection (e) are "properly read in 'sequence' as 'integral parts of a whole.'" *Guam v. United States*, 141 S. Ct. 1608, 1613 (2021) (quoting *New Prime Inc. v. Oliveira*, 139 S. Ct. 532, 538 (2019)). The provision for "interlocutory appeals" is the last of ten provisions, nine of which indisputably address "procedures for suit" that expressly apply *only* to subsection (d) cases subject to the exclusive jurisdiction of the District Court for the District of Columbia. 42 U.S.C. § 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 substantive motions and associated interlocutory appeals discussed in the other nine paragraphs. Although the phrase "any action under subsection (d)" is not repeated in paragraph 10, an "effort to tear [paragraph 10] away from its companions based on a negative implication falters in light of the other strong textual links among them." *Guam*, 141 S. Ct. at 1615.

Reading paragraph 10 as creating a right to interlocutory appeals of motions to dismiss and for summary judgment only in cases otherwise governed by subsection (e) gives 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), the defendant could move to dismiss arguing generally that the plaintiff's claims are *not* grounded on willful misconduct and thus that "the immunity from suit conferred by subsection (a)" applies—one of the two bases of a motion for

which interlocutory appeal is permitted under paragraph 10. Or the defendant could argue that "the exclusion under subsection (c)(5)" for claims relating to certain regulated products applies—the other basis of a motion for which interlocutory appeal is permitted. If the District Court for the District of Columbia denies a motion to dismiss or for summary judgment on either of these grounds, paragraph 10 provides the defendant the right to file an interlocutory appeal in this Court. 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). That provision on its face does *not* apply in actions asserting other causes of action and brought outside the D.C. district court.

This reading is confirmed by 28 U.S.C. § 1294, which specifies that *any* appealable decision of the District Court for the Eastern District of Pennsylvania is reviewed by the Third Circuit, unless it falls under one of the specifically referenced exceptions for patent, international trade, and other subjects within the Federal Circuit's jurisdiction. 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 the 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 paragraph 10—like the other nine paragraphs of subsection (e)—to apply only to actions under subsection (d), not to actions filed in district courts outside the District of Columbia. *See Al-Bihani v. Obama*, 619 F.3d 1, 32 (D.C. Cir. 2010) ("[C]ourts construe ambiguous statutes to conform to preexisting statutes."); *cf.* 42 U.S.C. § 247d-6d(d)(1) (explicitly addressing PREP Act's interaction with Federal Tort Claims Act, 28 U.S.C. § 2679(b)(2)(B)).

Finally, under Fair Acres' interpretation of the statute, paragraph 10 provides this Court with jurisdiction over *interlocutory* appeals of decisions by any court in any case *denying* motions to dismiss or for summary judgment based on PREP Act defenses, but not over appeals

from *final* decisions (outside the District of Columbia) *granting* motions to dismiss or summary judgment, on the basis of subsection (a) immunity or on any other grounds, or, for that matter, trial judgments holding that PREP Act immunity does not apply. Those appeals would be heard in the regional circuits pursuant to 28 U.S.C. § 1294(1). Indeed, at least one such appeal is pending in the Ninth Circuit. *See Garcia v. Welltower OpCo Grp. LLC*, 9th Cir. No. 21-55224.

The Court should reject a reading of subsection (e) that would direct the appeal of an order resolving the same issues presented in a single motion to different courts, based on whether that motion was granted or denied. Such an outcome would serve no purpose. Where Congress directs appeals to a single Circuit, the purpose is to develop a uniform body of law on the relevant subject matter. *See*, *e.g.*, *United States v. Hohri*, 482 U.S. 64, 71 (1987) (noting the "evident congressional desire for uniform adjudication of Little Tucker Act claims" in channeling cases to Federal Circuit); *Nat'l Env't Dev. Ass'n's Clean Air Project v. EPA*, 891 F.3d 1041, 1053 (D.C. Cir. 2018) (noting that the Clean Air Act sends "national

issues to our circuit for uniform resolution").[3] 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.

That Congress did not intend to make this Court the sole court of appeals with the authority to interpret the PREP Act is further shown by the fact that this Court lacks jurisdiction over another category of cases requiring interpretation of the PREP Act: appeals from remand orders where a state-court defendant has invoked the PREP Act as a federal defense for purposes of the federal-officer removal statute or as a purported basis for federal question removal jurisdiction. To the extent such remand orders are appealable at all, *see* 28 U.S.C. § 1447(d), they are reviewable by regional courts of appeals. In fact, such appeals are

[3] *See*, *e.g.*, 28 U.S.C. § 1295(a)(1) (providing exclusive jurisdiction in the Federal Circuit over any "appeal from a final decision of a district court" involving claims "relating to patents or plant variety protection"); *id.* § 1292(c)(1) (providing exclusive jurisdiction in the Federal Circuit over interlocutory appeals in any cases in which it would have jurisdiction over appeals of final orders).

pending in at least six courts of appeals. *See*, *e.g.*, *Rivera-Zayas v. Our Lady of Consolation Geriatric Care Ctr.*, No. 21-2164 (2d Cir.); *Perez v. Southeast SNF*, No. 21-50399 (5th Cir.) (argued Dec. 6, 2021); *Hudak v. Elmcroft of Sagamore Hills*, No. 21-3836 (6th Cir.); *Martin v. Petersen Health Ops., LLC*, No. 21-2959 (7th Cir.); *Saldana v. Glenhaven Healthcare LLC*, No. 20-56194 (9th Cir.) (argued October 20, 2021); *Schleider v. GVDB Operations, LLC*, No. 21-11765 (11th Cir.). The parties in each case dispute the scope of the PREP Act, and the regional courts of appeals' interpretations of the PREP Act's scope will be binding on district courts within their circuits both when ruling on remand motions and when adjudicating the merits of immunity defenses where jurisdiction exists.

B. Appellants' interpretation would be unworkable for 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 Fair Acres to appeal to this Court the district court's interlocutory order denying its motion to dismiss—when the Estate's appeal of an adverse decision on the very same motion, or either party's

appeal of a final judgment, would go to the Third Circuit—would create an unworkable situation for the nation's district courts. Each of those courts (except the D.C. District Court) 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 bound only by decisions of a single court of appeals. *See*, *e.g.*, *In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171, 1176 (D.C. Cir. 1987), *aff'd sub nom. Chan v. Korean Air Lines, Ltd.*, 490 U.S. 122 (1989) ("Binding precedent for all is set only by the Supreme Court, and for the district courts within a circuit, only by the court of appeals for that circuit."); *cf. Rates Tech. Inc. v. Speakeasy, Inc.*, 685 F.3d 163, 174 n.9 (2d Cir. 2012) (noting that district courts are "bound to follow the holdings of the Federal Circuit" on issues of patent law). Under Fair Acres' interpretation of subsection (e)(10), however, district courts could be bound by precedents of two different courts of appeals on a single issue. For example, should this Court come to a different conclusion than the Fifth Circuit in the pending *Perez* appeal as to the scope of the immunity

provisions of the PREP Act, district courts within the Fifth Circuit would be in an untenable situation in future cases: If Fifth Circuit precedent required denying a motion to dismiss, but this Court's precedent 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 that untenable situation. *Cf. E. Band of Cherokee Indians v. U.S. Dep't of the Interior*, 534 F. Supp. 3d 86, 100 (D.D.C. 2021) (rejecting proffered reading where "it is not plausible that Congress intended to create such a bizarre law-school hypothetical"). For this reason, even if the statute were not ambiguous, the Estate's proposed narrower interpretation would be the best reading of the statute under the canon against absurdity. To read paragraph 10 more broadly, to direct an appeal from a district court's ruling as to a single issue raised in a motion to dismiss to different courts of appeals, depending on how the district court ruled, would be "so bizarre" and "illogical" that "Congress could not plausibly have intended" it. *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 in 28 U.S.C. § 1294, including patent cases. "[T]o avoid the risk that district courts and litigants will be forced to select from two competing lines of authority based on which circuit may have jurisdiction over an appeal that may ultimately be taken," that Court has adopted a rule where it "appl[ies] regional circuit law to nonpatent issues" and the law of the Federal Circuit to patent-specific questions. *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999) (en banc) *abrogated on other grounds by TrafFix Devices, Inc. v. Mktg. Displays, Inc.,* 532 U.S. 23, 28 (2001).

Here, no such solution to the two-master problem would be possible. Under 28 U.S.C. § 1295(a)(1), the Federal Circuit has jurisdiction over *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 Fair Acres' reading of paragraph 10, in cases arising outside of the District, this Court conducts review of PREP Act issues only in a particular procedural posture, while regional circuits

conduct review of final orders posing the same issues in other procedural postures—even in the same cases.

"When 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 under subsection (d)'s cause of action in the D.C. District Court, and not to this appeal. Accordingly, this Court lacks jurisdiction over this appeal.

II. The Pennsylvania district court correctly denied Fair Acres' motion to dismiss.

A. Standard of review

Should this Court conclude that it has jurisdiction over this interlocutory appeal, it should reduce the chances of inter-circuit friction as much as possible by adopting an approach similar to that of the Federal Circuit and applying its "own law with respect to [PREP Act] issues, but with respect to [non-PREP Act] issues … generally apply[ing] the law of the circuit in which the district court sits." *Midwest Indus.*, 175 F.3d at 1359 (in patent context); *see Russell v. United States*, 661 F.3d 1371, 1376 (Fed. Cir. 2011) (noting law of the regional circuit applies to

any "question that is not unique to cases arising under the Little Tucker Act"). Here, the law of the Third Circuit would govern to the extent that the appeal raises questions not unique to cases where a party has invoked the PREP Act, including the standards of decision for Rule 12 motions. *See*, *e.g.*, *Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253, 1257 (Fed. Cir. 2017) ("We apply regional circuit law when reviewing motions to dismiss for failure to state a claim."); *Bayer Schering Pharma AG v. Lupin, Ltd.,* 676 F.3d 1316, 1327 (Fed. Cir. 2012) ("Pleading standards are a matter of regional circuit law."). Fair Acres' brief suggests that it agrees on this point, as it concedes that the Third Circuit's decision in *Grammer* "presently controls" on the issue whether plaintiffs can bring an action pursuant to section 1983 based on a violation of the FNHR Amendments. Appellants' Br. 47.

Where the Third Circuit has jurisdiction over the interlocutory appeal of a denial of a motion to dismiss, its review is *de novo*, "accept[ing] as true all well-pled factual allegations in the complaint and all reasonable inferences that can be drawn from them." *Taksir v. Vanguard Grp.*, 903 F.3d 95, 96–97 (3d Cir. 2018) (citation omitted). Where a party seeks dismissal based on an affirmative defense, like PREP Act

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

B. The complaint does not establish that Fair Acres is entitled to immunity under the PREP Act.

PREP Act immunity applies to "any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure," 42 U.S.C. § 247d-6d(a)(2)(B), where the covered countermeasure "was administered or used" consistent with certain conditions, *id.* § 247d-6d(a)(3). The district court properly concluded that this immunity does not apply to the Estate's claims because the complaint does not allege that Mr. Beaty's death was caused by the administration to or use by an individual of any covered countermeasure. JA181–82. Rather, the Estate alleges that Mr. Beaty died as a result of Fair Acres' failure to implement adequate infection-control policies, including its failure to isolate him from his symptomatic

roommate. The district court's rejection of Fair Acres' claim to immunity was consistent with dozens of other district court decisions holding that the PREP Act is inapplicable "where a plaintiff's claim is premised on a failure to take preventative measures to stop the spread of COVID-19, as here, and where none of the alleged harm was causally connected to the administration or use of any counter-measure, which is the focus of the PREP Act." *Gwilt v. Harvard Square Ret. & Assisted Living*, 537 F. Supp. 3d 1231, 1241 (D. Colo. 2021).[4] Like those dozens of courts, this Court—

[4] *See also, e.g., Hampton v. California*, 2022 WL 195743, at *9–10 (N.D. Cal. Jan. 21, 2022); *Lilly v. SSC Houston Southwest Op. Co.*, 2022 WL 35809, at *3 (S.D. Tex. Jan. 8, 2022); *Mackey v. Tower Hill Rehab.*, 2021 WL 5050292, at *3–6 (N.D. Ill. Nov. 1, 2021); *Martin v. Petersen Health Ops.*, 2021 WL 4313604, at *10 (C.D. Ill. Sept. 22, 2021); *Lollie v. Colonnades Health Care Ctr. Ltd.*, 2021 WL 4155805, at *3–4 (S.D. Tex. Sept. 13, 2021); *Ruiz v. ConAgra Foods Packaged Foods, LLC*, 2021 WL 3056275, at *4 (E.D. Wisc. July 20, 2021); *Reed*, 2021 WL 2633156, at *4–5; *Thomas v. Century Villa Inc.*, 2021 WL 2400970, at *4 (C.D. Cal. June 10, 2021); *Maltbia v. Big Blue Healthcare, Inc.*, 2021 WL 1196445, at *5–12 (D. Kan. Mar. 30, 2021); *Gibbs v. Se. SNF LLC*, 2021 WL 1186626, at *3 (W.D. Tex. Mar. 30, 2021); *Stone v. Long Beach Healthcare Ctr.*, 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); *Smith v. Colonial Care Ctr., Inc.*, 2021 WL 1087284, at *4 (C.D. Cal. Mar. 19, 2021); *Robertson v. Big Blue Healthcare, Inc.*, 523 F. Supp. 3d 1271, 1281–86 (D. Kan. 2021); *Lyons v. Cucumber Holdings, LLC*, 520 F. Supp. 3d 1277, 1286 (C.D. Cal. 2021); *Dupervil v. Alliance Health Ops., LCC*, 516 F. Supp. 3d 238, 255–56 (E.D.N.Y. 2021); *Lutz,* 480 F. Supp. 3d at 1216–19. Fair Acres suggests that some of these courts' interpretations

if it reaches the merits—should reject Fair Acres' arguments about the "breadth" of the PREP Act and inapplicable, non-binding agency guidance.

1. The PREP Act does not apply to claims unrelated to anything that even could be considered a countermeasure.

The Estate argues that Fair Acres' negligence led to Mr. Beaty contracting COVID-19. The vast majority of the 33 acts and omissions specified in the complaint as giving rise to liability do not reference anything that could possibly be considered a covered countermeasure under the statutory definition. They include failures to adopt, implement, or follow infection-prevention protocols generally; failures to record and report and infections; failures to communicate with family members and local health-care authorities; failures to deploy social-distancing policies; and failures to isolate symptomatic patients like Mr. Beaty's roommate. *See* JA17–19 ¶¶71a–gg. But social distancing, isolation policies, and notification policies are not, and indeed cannot under the statute, be

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of the statutory provision are "inapposite" as they arose in a different procedural posture. Appellants' Br. 31 n.23. The different posture, however, does not alter the persuasiveness of the courts' reading of the same words at issue here.

"covered countermeasures." *See, e.g.*, *Ossowski v. St, Joseph Transitional Rehab. Ctr., LLC*, 2021 WL 4699235, at *3 (D. Nev. Oct. 6, 2021); *Gibbs*, 2021 WL 118662, at *3. As one district court explained, claims like these "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*, 516 F. Supp. 3d at 257. Fair Acres' brief makes no attempt to explain how such allegations fit within the scope of the PREP Act. Thus, there is no basis to dismiss those aspects of the Estate's claims.[5]

[5] If some part of the Estate's claims had the requisite causal relationship with the administration or use of covered countermeasures, the proper result would be dismissal of the Estate's claims *solely to the extent* that they relate to the use or administration of a covered countermeasure. *Cf. Jones v. Bock*, 549 U.S. 199, 221 (2007) ("As a general matter, if a complaint contains both good and bad claims, the court proceeds with the good and leaves the bad."); *In re Lord Abbett Mutual Funds Fee Litig.*, 553 F.3d 248, 257 (3d Cir. 2009) ("[a]llowing those claims that do not fall within [a federal statute's] preemptive scope to proceed, while dismissing those that do").

2. The PREP Act does not apply to claims arguably related to Fair Acres' failures to use covered countermeasures.

To the extent that the Estate alleges negligence with respect to items that *could* be covered countermeasures under the statute, such as personal protective equipment or COVID-19 testing, the allegations concern *non*-use. Claims of *non*-use, however, are not subject to PREP Act immunity. To the extent that guidance cited by Fair Acres suggests otherwise, it is both incorrect and inapplicable to this case, where there is no allegation of "purposeful allocation" of scarce materials resulting in non-use, much less any suggestion that purposeful allocation caused Mr. Beaty's death.

a. The statutory text limits immunity to claims with a causal relationship to the affirmative use of covered countermeasures.

"Statutory interpretation … begins with the text." *Ross v. Blake*, 578 U.S. 632, 638 (2016). "[I]f the text alone is insufficient to end the inquiry, [this Court] may turn to other customary statutory interpretation tools, including structure, purpose, and legislative history." *Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 637 (D.C. Cir. 2021) (cleaned up). Here, these tools indicate that only claims with a

causal relationship to the affirmative use of covered countermeasures fall within the scope of the immunity provision.

Fair Acres' argument that the statute provides immunity for decisions to take no action turns on restating the statutory text to omit important words. Fair Acres repeatedly says the statute provides for immunity for claims relating "to the 'administration' or 'use' of covered countermeasures." Appellants' Br. 22; *see also, e.g.*, *id.* at 25, 28. What the statute actually provides is immunity for claims relating to the "administration *to* or use *by an individual*" of a covered countermeasure. 42 U.S.C. §§ 247d-6d(a)(1), (2)(B) (emphasis added).

Restoring these words shows that Fair Acres relies on the incorrect meaning of the word "administration." 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. By altering the plain text of the statute, Fair Acres appears to invoke the former definition. But when the statute is read as written, only the latter definition makes sense—given the use of the prepositions "to" and "by," and the inclusion of the term "an individual." When a facility decides not

to use a covered countermeasure, it may be administering its policies, but it is not *administering a covered countermeasure to an individual*, and the countermeasure is not being *used by an individual*.

Other provisions confirm that the statutory immunity applies only to claims related to the affirmative administration or use of a covered countermeasure. For instance, the statute provides that immunity "applies only if" the countermeasure was "administered or used" during the period of the declaration, for the health condition specified in the declaration, and "administered to or used by" an individual within the population or geographic area specified in the declaration. 42 U.S.C. § 247d-6d(a)(3). In addition, licensed health professionals may only invoke PREP Act immunity if authorized to administer countermeasures "under the law of the State in which the countermeasure *was prescribed, administered, or dispensed*." *Id.* § 247d-6d(i)(8)(A) (emphasis added). And the willful misconduct federal cause of action requires proof that the underlying "injury or death was proximately caused by the administration or use of a covered countermeasure." *Id.* § 247d-6d(e)(4)(C)(i). None of these provisions would make sense if the PREP Act applied where a countermeasure was *not* administered or used.

Fair Acres suggests that the inclusion of "program planners" as "covered persons" who may be entitled to immunity in certain scenarios means that all acts relating to infection-control decisionmaking are covered by the statute. *See* Appellants' Br. 26–28 (discussing 42 U.S.C. §§ 247d-6d(i)(2)(B)(iii), (iv)). That argument conflates the question *who* may assert the immunity with the question *what claims* are within the immunity's scope. And Fair Acres' reading of the statute is not necessary to give meaning to the inclusion of program planners as potentially covered persons. Although the statute applies only to claims relating to affirmative use, a program planner could have immunity under the PREP Act from a claim, for example, that its failure to ensure appropriate training for staff administering vaccines caused a staff member to injure a patient in the process of vaccination.

Fair Acres also points to the broad meaning of the phrase "relating to." No matter how broad "relating to" may be in the abstract, however, the statute requires a connection to the affirmative use of a covered countermeasure, as demonstrated by the provisions discussed above. *See also Lopez*, 2021 WL 1121034 at *12. And despite Fair Acres' discussion of how the words "relating to" in *other* statutes have been interpreted,

Appellants Br. 29–30, in *this* statute, Congress, speaking with particularity as to the required relationship between a claim for loss and the administration or use of a covered countermeasure—has created immunity only where there is a "causal relationship with the administration to or use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(2)(B).

While Fair Acres criticizes the district court for requiring a "causal relationship," Appellants' Br. 33, it nonetheless concedes that the statute requires some "causal connection[s] between the alleged loss and the covered countermeasure," *id*. 34. And, unquestionably given the words of the statute, that causal connection must be to "the administration to or the use by an individual" of the countermeasure. 42 U.S.C. § 247d-6d(a)(1). As one court explained, "that a facility us[ed] covered countermeasures *somewhere* in the facility is [not] sufficient to invoke the PREP Act as to all claims that arise in that facility. The PREP Act still requires a causal connection between the injury and the use or administration of covered countermeasures." *Lutz*, 480 F. Supp. 3d at 1217. *Cf. Shapnik v. Hebrew Home for the Aged at Riverdale*, 535 F. Supp. 3d 301, 321 (S.D.N.Y. 2021) (rejecting argument that immunity applies

"as long as a plaintiff suffered an injury at the hands of a person charged with administering a covered countermeasure, without regard to whether there was a 'direct relationship' between the injury and the use of a covered countermeasure"). No such causal connection between the use of a covered countermeasure and Mr. Beaty's death is alleged here.

b. Immunity for claims based on use, not non-use, is consistent with the statutory purpose.

The textual limitation on immunity to scenarios where a covered countermeasure has been administered to or used by an individual is consistent with the statutory purpose. The PREP Act was intended to encourage the manufacture, distribution, and use of covered countermeasures. *See Maglioli*, 478 F. Supp. 3d at 529 (noting that the statute's "evident purpose is to embolden caregivers, permitting them to administer certain encouraged forms of care (listed COVID 'countermeasures') with the assurance that they will not face liability for having done so"). 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. Deal); *see also* 151 Cong. Rec. S14242-01 (daily ed. Dec. 21, 2005) (statement of Sen. Clinton

noting that the "provision is being billed as a simple liability protection to help those who would manufacture avian flu vaccine"). Likewise, a 2020 amendment to the PREP Act expanding the scope of potential covered countermeasures to include certain respiratory protective devices, Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, § 3101, 134 Stat. 281, 361, 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. Walden); *see also* Coronavirus Preparedness and Response: Hearing Before the H. Comm. on Oversight & Reform, Serial No. 116-96 at 43 (2020) (testimony of HHS Asst. Secretary for Preparedness and Response, urging addition of respiratory protective devices in order to boost supply). Providing immunity from suit for injuries resulting from the affirmative administration or use of covered countermeasures encourages production and use of those countermeasures. By contrast, providing immunity for *non*-administration or *non*-use "would defeat the basic purpose of the statute." *Martin*, 2021 WL 4313604, at *10.[6]

[6] HHS regulations regarding the administrative compensation scheme, promulgated pursuant to its rulemaking authority under 42

When Congress intends to immunize *inaction*, it knows how to do so. For example, in 2020, Congress separately immunized volunteer healthcare professionals for harms "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. Notably, throughout 2020, Congress debated—but did not enact—liability protections for claims like the Estate's. *See*, *e.g.*, 106 Cong. Rec. S2358 (daily ed. May 12, 2020) (Statement of Sen. 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 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.

U.S.C. § 247d-6e(b)(4), reflect a similar understanding by specifying that only "injured countermeasure *recipients*" are eligible for compensation. 42 C.F.R. § 110.10(a) (emphasis added).

c. HHS's atextual view does not support dismissal.

Fair Acres relies heavily on Advisory Opinion 21-01, issued by the HHS Office of General Counsel in January 2021. In that opinion, the General Counsel stated that he disagreed with the "'black and white' view" that PREP Act immunity cannot apply to claims relating to non-administration or non-use of a covered countermeasure. JA83. He opined that there were some "situations where a conscious decision not to use a covered countermeasure *could* relate to the administration of the countermeasure" and be subject to immunity. *Id.* (emphasis added). The General Counsel was wrong, and, in any event, his view does not support Fair Acres here.

i. HHS's view is owed no deference.

Fair Acres claims that Advisory Opinion 21-01 is "authoritative and controlling because the Secretary explicitly incorporated it into the Declaration that, by statute, defines the Act's applicability and scope." Appellants' Br. 32 (citing 42 U.S.C. §§ 247d-6d(a)(1) & (b); Fourth Amendment, 85 Fed. Reg. at 79,191). But what Fair Acres "fails to convey is that the 'incorporation' of advisory opinions mentioned in that amendment predated the advisory opinion in question here—not to mention the potential *ultra vires* ramifications of such an incorporation

by HHS as an attempted end-run around the statutorily designed, Congressionally-authorized agency powers vested in the HHS Secretary Declarations." *Ossowski*, 2021 WL 4699235, at *4.

Regardless, where, as here, a statute is unambiguous, a court owes no deference to an agency interpretation. *See, e.g.*, *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) ("If uncertainty does not exist, there is no plausible reason for deference."); *D.C. Hosp. Ass'n v. District of Columbia*, 224 F.3d 776, 780 (D.C. Cir. 2000). And where ambiguity does exist, 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, Congress has delegated to the Secretary the authority 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 define the meaning of subsection (a). *Cf.* 42 U.S.C. § 247d-6d(c)(2)(A) (providing rulemaking authority to define the term "willful misconduct").

Notably, HHS did not purport to be exercising any such authority: Advisory Opinion 21-01 explicitly states that "[i]t does not have the force or effect of law." JA85. Thus, there is no reason to depart from the general proposition that "[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 Mackey*, 2021 WL 5050292 at *5; (holding *Chevron* does not apply to Advisory Opinion 21-01's views about non-use); *Martin*, 2021 WL 4313604, at *9 (same).

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)). 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, as numerous district courts have held, Advisory Opinion 21-01 lacks any such power, "as it has neither a legal nor logical basis for reading wholesale nonuse into the statute." *Martin*, 2021 WL 4313604, at *10; *see also Mackey*, 2021 WL 5050292 at *5; *WorkCare, Inc. v. Plymouth Med., LLC*, 2021 WL 4816631, at *5 (C.D. Cal. Aug. 20, 2021). In asserting that "[p]rioritization or purposeful allocation of a Covered Countermeasure … can fall within the PREP Act" and that "there can potentially be other situations where a conscious decision not to use a covered countermeasure could relate to the administration of the countermeasure," JA83, the Advisory Opinion did not consider the relevant statutory language including the requirement of a "causal relationship" with the administration "to" or "use by an individual." Nor did it consider the statutory purpose. Indeed, the only aspect of the statute discussed was the inclusion of program planners as potential covered persons. The reasoning as to that provision is a non sequitur,

stating that "decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning," and therefore it "is expressly covered by PREP Act [*sic*]." JA84. But the statute does not "expressly cover" claims for loss relating to "program planning." It simply includes program planners among those who can invoke immunity for claims for losses caused by the use of a covered countermeasure by an individual, as discussed above. *See supra* p. 39.

ii. The Estate does not claim that Mr. Beaty died as a result of purposeful allocation of a covered countermeasure.

Even if immunity extended to claims for loss with a connection to "prioritization or purposeful allocation of a Covered Countermeasure," Appellants' Br. 22 (quoting Advisory Opinion 21-01, JA81), the Complaint does not allege any such connection. Under the Advisory Opinion's reading, immunity would be available where "(1) there are limited covered countermeasures; and (2) there was a failure to administer a covered countermeasure to one individual because it was administered to another individual." *Lyons*, 520 F. Supp. 3d at 1285. Neither element is met here. Nothing in the complaint indicates that there was a shortage of any covered countermeasure, and nothing in the

complaint alleges that Fair Acres failed to administer any covered countermeasures to Mr. Beaty because it was administering them to others. The complaint alleges that Fair Acres failed to take proper infection control measures generally. As one court explained, even under the Advisory Opinion's interpretation, "cases of general neglect [must] fall outside the protection of the PREP Act. Otherwise, the [opinion's] limiting language and illustration would be superfluous, if not confounding." *McCalebb v. AG Lynwood, LLC*, 2021 WL 911951, at *5 (C.D. Cal. Mar. 1, 2021); *see also Padilla v. Brookfield Healthcare Ctr.*, 2021 WL 1549689, at *5–6 (C.D. Cal. Apr. 19, 2021) (explaining irrelevance of Advisory Opinion 21-01 to analogous claims); *Goldblatt v. HCP Prairie Village KS OpCo LLC*, 516 F. Supp. 3d 1251, 1264 (D. Kan. 2021) (similar). *Cf. Hampton*, 2022 WL 195843, at *10 (denying motion for summary judgment where whether "defendants purposely allocated countermeasures" was a matter of disputed fact).

Fair Acres' assertion that the complaint establishes that the facility was engaged in the purposeful allocation of covered countermeasures requests that the Court draw inferences from allegations in the complaint *against* the Estate—which is impermissible on a Rule 12(b)(6)

motion. First, Fair Acres contends that allegations as to its knowledge of the number of confirmed cases in the nursing home "establish[] that Fair Acres was, in fact, testing certain of its residents and staff … and making decisions about residents' care based on that data." Appellants' Br. 38. But nothing in the complaint shows Fair Acres was testing *anyone* prior to late-May 2020, much less that its infection control policies were data-driven.[7] Next, Fair Acres asks the Court to treat the allegations that it failed to "routinely test residents" as a concession that there was a testing plan in place. Appellants' Br. 38 (citing JA18 ¶71(t)). Fair Acres' conclusion does not follow from that allegation. Moreover, even if Fair Acres had a testing plan, not all "testing" triggers PREP Act immunity—only testing that complied with the Declaration's "limitations on distribution" requirement. 42 U.S.C. § 247d-6d(b)(2)(E). And this record does not establish that any testing Fair Acres conducted was related to its performance of federal contracts or agreements, or in accordance with government instructions, as required by the Declaration. 85 Fed. Reg. at

[7] For example, the complaint alleges that Mr. Beaty's COVID-19 diagnosis was a result of a test administered by Riddle Memorial Hospital—not by Fair Acres. JA12 ¶43.

15,202.[8] *See Avicolli v. BJ's Wholesale Club, Inc.*, Civ. No. 21-1119, 2021 WL 1293397 (E.D. Pa. Apr. 7, 2021) (denying motion to dismiss where complaint did not provide a basis to infer that the Declaration's distribution requirement was met).

Fair Acres also asks the Court to infer from allegations that Fair Acres failed to have "sufficient staff or equipment (PPE)" and to "maintain infection control on the premises" that Fair Acres "was in fact using PPE … and did in fact have infection controls." Appellants' Br. 39. No such inference necessarily follows from the allegation, and, moreover, not all "infection controls" are covered countermeasures under the Declaration or statute.

Even if the complaint had alleged that Fair Acres used some covered countermeasures, denial of the motion to dismiss was proper because no allegations or facts suggest that the Estate suffered any loss caused by the "prioritization or purposeful allocation" of those countermeasures. *See Robertson*, 523 F. Supp. 3d at 1283–84. Rather, the

[8] This provision of the declaration was subsequently amended, but the amendment was explicitly not retroactive. *See* HHS, Notice of Amendment & Republished Declaration, 85 Fed. Reg. 79,190, 79,196–97, 79,198 (Dec. 9, 2020).

Estate alleges that Fair Acres' inadequate infection control measures were the result of failure to adopt and follow policies at all.

C. The Estate's *Monell* claims are adequately pleaded.

To state a claim pursuant to 42 U.S.C. § 1983, "a plaintiff must allege the violation of a right secured by the Constitution and laws of the United States, and must show that the alleged deprivation was committed by a person acting under color of state law." *West v. Atkins*, 487 U.S. 42, 48 (1988). A plaintiff cannot base a claim against a municipal entity like Fair Acres on "the unconstitutional acts of its employees just because of their employment, under a *respondeat superior* theory." *Johnson v. City of Phila.*, 975 F.3d 394, 403 (3d Cir. 2020) (citing *Monell*, 436 U.S. at 691). Rather, a plaintiff must allege that the claimed violation was "the result of a policy or custom of the governmental entity." *Natale v. Camden Cty. Corr. Facility*, 318 F.3d 575, 583 (3d Cir. 2003).

Contrary to Fair Acres' assertion, Appellants' Br. 44, *Monell* claims are not subject to a heightened pleading standard. *See Leatherman v. Tarrant Cty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168–69 (1993). Rather, the question is simply whether, "viewing the pleadings and properly associated documents in the light most favorable

to [the plaintiff]," the complaint plausibly alleges a policy or custom resulted in a violation of a federal right. *Roman v. City of Newark*, 914 F.3d 789, 802 (3d Cir. 2019); *see also Baker v. D.C.*, 326 F.3d 1302, 1307 (D.C. Cir. 2003) ("[I]f a complaint alleging municipal liability under § 1983 may be read in a way that can support a claim for relief, thereby giving the defendant fair notice of the claim, that is sufficient.").

Here, the Estate alleges that Fair Acres' actions and inactions at the policy level violated Mr. Beaty's rights under the Federal Nursing Home Reform (FNHR) Amendments and caused his death. Despite the archetypal, policy-based nature of these claims, Fair Acres argues that the complaint fails to allege the violation of an actionable federal right and fails to plausibly plead the existence of a policy or custom. But the allegations that Fair Acres violated Mr. Beaty's rights to quality care—rights that under Third Circuit precedent are enforceable via section 1983—and that such violations were part of a policy or custom easily satisfy the Rule 8 pleading standard.[9]

[9] Should the Court hold that the complaint fails for a lack of specificity as Fair Acres suggests, the Estate requests the Court direct the district court to grant leave to amend. *See Alston v. Parker*, 363 F.3d 229, 236 (3d Cir. 2004) ("Dismissal without leave to amend is justified only on the grounds of bad faith, undue delay, prejudice, or futility.").

1. The complaint plausibly alleges violations of the FNHR Amendments.

Congress passed the FNHR Amendments "to provide for the oversight and inspection of nursing homes that participate in Medicare and Medicaid programs." *Grammer*, 570 F.3d at 523. The statute imposes requirements for nursing facilities ranging from the general command that a facility "care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident," 42 U.S.C. § 1396r(b)(1)(A), to more specific requirements, relating to, for example, restraints, privacy, confidentiality, and the use of psychotropic drugs, *id.* § 1396r(c)(1)(A), visitation rights, *id.* § 1396r(c)(3), and admissions policies, *id.* § 1396r(c)(5). Particularly relevant to this case, section 1396r(d)(3) sets out requirements relating to infection control:

> A nursing facility must—
>
> (A) establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection, and
>
> (B) be designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public.

Fair Acres argues that the district court should have dismissed the case because the complaint does not include citations to the specific provisions of the FNHR Amendments that Fair Acres violated. But, as the Supreme Court has explained, no such requirement exists. In *Johnson v. City of Shelby, Mississippi*, 574 U.S. 10 (2014), the Court held that a section 1983 plaintiff need not reference even *that* statute to state a claim. The Court explained: "Federal pleading rules call for 'a short and plain statement of the claim showing that the pleader is entitled to relief'; they do not countenance dismissal of a complaint for imperfect statement of the legal theory supporting the claim asserted." *Id.* at 11 (quoting Fed. Rule Civ. Proc. 8(a)(2)). This and other courts have since consistently recognized that a plaintiff need not provide a specific statutory citation to state a claim. *See Brown v. Sessoms*, 774 F.3d 1016, 1022 (D.C. Cir. 2014); *see also Rodgers v. Lancaster Police & Fire Dep't*, 819 F.3d 205, 207 n.2 (5th Cir. 2016). The question is whether plaintiffs have sufficiently "stated the facts allegedly giving rise to liability." *Brown*, 774 F.3d at 1022.

Here, the Estate has done so. Reading the complaint in the light most favorable to the Estate, the Estate has plausibly alleged a violation

of, at the least, section 1396r(d)(3). The complaint invokes that provision by using its exact words, alleging that Fair Acres violated Mr. Beaty's rights by "failing to establish and maintain an infection prevention and control program to create a safe, sanitary and comfortable environment and prevent the development and transmission of communicable diseases and infections." JA17. This claim is supported by the factual allegations of the complaint, which states that Fair Acres failed to adopt and implement screening and isolation policies or provide adequate training regarding infection prevention and control, that there was a massive increase in COVID cases at Fair Acres in May 2020, and that Mr. Beaty contracted COVID after Fair Acres failed to isolate his symptomatic roommate. *See*, *e.g.*, JA 11–12, 14–15, 17–19. The claim is also supported by the allegations that Fair Acres violated specific HHS regulations implementing the statutory infection-control requirements. See JA22–23 (citing regulations).

These same allegations plausibly suggest violations of other rights conferred by the FNHR Amendments, including Mr. Beaty's right to be cared for "in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident," 42

U.S.C. § 1396r(b)(1)(A), to be provided services adequate "to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident," *id.* § 1396r(b)(4)(A), and to receive care "administered in a manner that enables [the facility] to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident," *id.* § 1396r(d)(1)(A).

2. Under Third Circuit precedent, the rights invoked are actionable under section 1983.

In *Grammer*, the Third Circuit held that the estate of a county nursing home resident could pursue a section 1983 claim against the facility based on its breach of the duty to ensure quality care created by section 1396r. In so doing, the court analyzed each of the "three factors courts should use to determine whether a statute conferred a federal right upon an individual," as set out in *Blessing v. Freestone*, 520 U.S. 329 (1993). *Grammer*, 570 F.3d at 525. First, it held that the provisions of the FNHRA "are obviously intended to benefit Medicaid beneficiaries and nursing home residents, not the nursing homes themselves." 570 F.3d at 527. Second, it held that the rights created by the statute "are not so 'vague or amorphous' that their enforcement would strain judicial

resources." *Id.* at 528. Third, it found "the repeated use of 'must'" "unambiguously binds" nursing homes. *Id.* Next, the court concluded that the statute contained "rights-creating language sufficient to unambiguously confer individually enforceable rights." *Id.* at 531 (citing *Gonzaga Univ. v. Doe*, 536 U.S. 273 (2002)). The court reasoned that the statute was "replete with rights-creating language." *Id.* Even though the provisions relied upon by the plaintiff in *Grammer* were "phrased in terms of responsibilities imposed on the state or the nursing home," the Third Circuit explained that "[t]he plain purpose of these provisions is to protect rights afforded to individuals." *Id.* at 529. Lastly, it held that the "larger statutory structure," which included HHS enforcement mechanisms, did not "neutralize the rights-creating language contained throughout the FNHRA." *Id.* at 531–32.

Fair Acres concedes that *Grammer* "controls," but asserts that the Estate's claims do not fall within its holding because the Third Circuit held only that "various provisions of the FNHRA," not "every" provision of the FNHR Amendments, create rights actionable under section 1983. Appellants' Br. 47. But the *Grammer* plaintiff invoked rights conferred by subsections 1396r(b)(1)(A) and 1396r(b)(4)(A), among others, 570 F.3d

at 524, and the Estate has plausibly alleged Fair Acres violated Mr. Beaty's rights under those same provisions. Moreover, nothing in *Grammer* suggests that the holding does not apply to other patient care requirements in the statute, like those governing infection control. In a non-precedential opinion, the Third Circuit itself applied *Grammer* to reverse dismissal of claims against Fair Acres based on inadequate infection control. *Robinson v. Fair Acres Geriatric Ctr.*, 722 F. App'x 194, 200 (3d Cir. 2000). And other courts of appeals, as well as district courts within the Third Circuit, have invoked *Grammer* to hold that plaintiffs may use section 1983 to enforce a range of FNHRA patient-care rights. *See*, *e.g.*, *Talevski v. Health & Hosp. Corp. of Marion Cty.*, 6 F.4th 713, 725 (7th Cir. 2021); *Anderson v. Ghaly*, 930 F.3d 1066, 1075 (9th Cir. 2019); *Alexander v. Fair Acres Geriatric Ctr.*, 2021 WL 2138794, at *3 (E.D. Pa. May 26, 2021); *Ellis v. Del. Cty.*, 2021 WL 1614401, at *2 (E.D. Pa. Apr. 26, 2021). Fair Acres offers no reason why the Third Circuit's holding does not apply here.

3. The Estate has alleged violations of Mr. Beaty's rights resulting from a policy or custom.

A plaintiff can establish a "policy or custom" for *Monell* purposes in one of three ways. First, a municipal entity may be held liable where it

"promulgates a generally applicable statement of policy and the subsequent act complained of is simply an implementation of that policy." *Natale*, 318 F.3d at 584 (citation omitted). Second, a municipality is liable where "federal law has been violated by an act of the policymaker itself." *Id.* "Finally, a policy or custom may also exist where the policymaker has failed to act affirmatively at all, though the need to take some action to control the agents of the government 'is so obvious, and the inadequacy of existing practice so likely to result in the violation of [federal] rights, that the policymaker can reasonably be said to have been deliberately indifferent to the need." *Id.* (citation omitted).

As the district court held, "at the very least, Plaintiffs have adequately pled deliberate indifference." JA183. In suggesting otherwise, Fair Acres impermissibly asks the Court to infer from the complaint that it was taking sufficient infection control measures. Appellants' Br. 41. As the Third Circuit held in rejecting such an approach to the custom or policy inquiry in another case, "[e]ven if the record can be read that way," that is "the wrong focus" at the motion to dismiss stage. *Roman*, 914 F.3d at 802. Rather, the question is "whether, viewing the pleadings and properly associated documents in the light most favorable to" the Estate,

the complaint alleges deliberate indifference. *Id.* And it does. For example, the complaint alleges that Fair Acres did not have a policy for isolating symptomatic and exposed patients and staff from others, JA18, and that this failure resulted in Mr. Beaty being "continuously and repeatedly exposed to a COVID-19 positive individual that was exhibiting known symptoms of COVID-19," his roommate, for several days. JA11–12. The complaint also alleges, for example, that Fair Acres allowed residents to intermingle with residents and staff without adequate safety precautions, allowed COVID-19 infected staff to care for residents, and failed to provide adequate personal protective equipment and related training to staff. JA18–19. These allegations are not "boilerplate," Appellants' Br. 44, but rather factual allegations that the district court properly accepted as true on a Rule 12(b)(6) motion.

Notably, this case does not involve a death in the earliest days of the pandemic. Rather, the Estate alleges Fair Acres' failures to adopt and implement policies to limit exposure to symptomatic patients continued through late-May 2020. That was more than three months after the Centers for Disease Control first recommended screening and isolation of symptomatic patients in healthcare facilities. *See* CDC, Update and

Interim Guidance on Outbreak of 2019 Novel Coronavirus (2019-nCoV), Feb. 1, 2020, https://emergency.cdc.gov/han/han00427.asp. And it was more than two months after HHS's Centers for Medicare and Medicaid Services specifically recommended that nursing homes cancel all communal and group activities, actively screen residents and staff for symptoms, and isolate symptomatic residents. *See* CMS, Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes, Mar. 13, 2020, https://www.cms.gov/files/document/qso-20-14-nh-revised.pdf.

Fair Acres' suggestion that allowing the complaint to proceed would "render every municipal- or county-run entity … liable under *Monell* for any instance in which COVID-19 was transmitted to a person in their care or custody," Appellants' Br. 43, is absurd. The Estate's complaint is not based on Fair Acres' failure "to have a perfect response to the pandemic." *Id*. It is based on Fair Acres' failure, months into the pandemic, to adopt policies as basic as isolating symptomatic residents from its other vulnerable residents—a failure that resulted in more reported COVID-19 deaths than all but two other nursing homes in America. *See* "Nearly One-Third of U.S. Coronavirus Deaths Are Linked

to Nursing Homes," *N.Y. Times*, https://www.nytimes.com/interactive/2020/us/coronavirus-nursing-homes.html (updated June 1, 2021).

Given that nearly 200 residents and staff at the facility were positive for COVID in early May 2020, Fair Acres' awareness of the increased risk to residents like Mr. Beaty, and the guidance received from public health authorities, Fair Acres' failures were "so likely to result in the violation of [federal] rights" and the need to implement different policy was "so obvious" as to constitute deliberate indifference. *Natale*, 318 F.3d at 584; *see also Bd. of Cty. Comm'rs of Bryan Cty., Okla. v. Brown*, 520 U.S. 397, 409 (1997) (noting that municipality's failure to equip employees "with specific tools to handle recurring situations" can serve as basis for *Monell* liability).

CONCLUSION

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

Respectfully submitted,

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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 12,816 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.

February 18, 2022

/s/ Adam R. Pulver
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ADDENDUM

ADDENDUM CONTENTS

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

(a) Liability protections

(1) In general

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

(2) Scope of claims for loss

…

(B) Scope

The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

(3) Certain conditions

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

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

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

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

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

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

...

(b) Declaration by Secretary

(1) Authority to issue declaration

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

(2) Contents

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

…

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

…

(c) Definition of willful misconduct

…

(2) Authority to promulgate regulatory definition

(A) In general

The Secretary, in consultation with the Attorney General, shall promulgate regulations, which may be promulgated through interim final rules, that further restrict the scope of actions or omissions by a covered person that may qualify as "willful misconduct" for purposes of subsection (d).

…

(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.

(2) Covered person

The term "covered person", when used with respect to the administration or use of a covered countermeasure, means--

(A) the United States; or

(B) a person or entity that is--

(i) a manufacturer of such countermeasure;

(ii) a distributor of such countermeasure;

(iii) a program planner of such countermeasure;

(iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or

(v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

…

(8) Qualified person

The term "qualified person", when used with respect to the administration or use of a covered countermeasure, means--

(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or

(B) a person within a category of persons so identified in a declaration by the Secretary under subsection (b).

…

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.

…

(b) Payment of compensation

…

(4) Determination of eligibility and compensation

Except as provided in this section, the procedures for determining, and for reviewing a determination of, whether an individual is an eligible individual, whether such individual has sustained a covered injury, whether compensation may be available under this section, and the amount of such compensation shall be those stated in section 239a of this title (other than in subsection (d)(2) of such section), in regulations issued pursuant to that section, and in such additional or alternate regulations as the Secretary may promulgate for purposes of this section. In making determinations under this section, other than those described in paragraph (5)(A) as to the direct causation of a covered injury, the

Secretary may only make such determination based on compelling, reliable, valid, medical and scientific evidence.

…

42 U.S.C. § 1396r Requirements for nursing facilities

…

(b) Requirements relating to provision of services

(1) Quality of life

(A) In general

A nursing facility must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident.

…

(4) Provision of services and activities

(A) In general

To the extent needed to fulfill all plans of care described in paragraph (2), a nursing facility must provide (or arrange for the provision of)—

(i) nursing and related services and specialized rehabilitative services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident;

(ii) medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident;

(iii) pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident;
(iv) dietary services that assure that the meals meet the daily nutritional and special dietary needs of each resident;

(v) an on-going program, directed by a qualified professional, of activities designed to meet the interests and the physical, mental, and psychosocial well-being of each resident;

(vi) routine dental services (to the extent covered under the State plan) and emergency dental services to meet the needs of each resident; and

(vii) treatment and services required by mentally ill and mentally retarded residents not otherwise provided or arranged for (or required to be provided or arranged for) by the State.

The services provided or arranged by the facility must meet professional standards of quality.

…

(d) Requirements relating to administration and other matters

(1) Administration

(A) In general

A nursing facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident (consistent with requirements established under subsection (f)(5)).

…

(3) Sanitary and infection control and physical environment

A nursing facility must--

(A) establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection, and

(B) be designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public.

…

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).

…