No. 22-2757

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

ZANE CAGLE, individually and in a representative capacity for all persons identified by RSMo 537.080,

Plaintiff-Appellee,

v.

NHC HEALTHCARE-MARYLAND HEIGHTS, LLC, *et al.*,

Defendants-Appellants.

On Appeal from the United States District Court
for the Eastern District of Missouri
Case No. 4:21-cv-01431
Hon. Ronnie L. White, U.S.D.J.

BRIEF OF APPELLEE

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SUMMARY OF THE CASE AND REQUEST FOR ORAL ARGUMENT

Plaintiff-Appellee Zane Cagle, a Missouri citizen, brought this Missouri tort law action in Missouri state court, against a nursing home and related individuals and entities—Missouri and non-Missouri citizens. The complaint alleges that Defendants-Appellants failed to take adequate measures to prevent the spread of COVID-19 and to provide appropriate medical care to Mr. Cagle's father, a resident who died of COVID-19 that he contracted at the nursing home.

Defendants removed the action to federal district court on four theories, each of which was properly rejected in the remand order defendants now appeal, and none of which raises novel or complex issues. Defendants invoke "snap removal," but that doctrine is irrelevant here, where 28 U.S.C. § 1332's requirement of complete diversity is not satisfied. Defendants also make arguments based on complete preemption, the *Grable* doctrine, and federal-officer jurisdiction. Those arguments, however, are indistinguishable from those rejected by four courts of appeals in similar cases, and the federal-officer argument is barred by this Court's recent precedent. Accordingly, no more than 10 minutes of oral argument per side is necessary.

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STATEMENT OF JURISDICTION

Appellee agrees with Appellants that this Court has appellate jurisdiction. The district court, however, correctly concluded that it lacked subject-matter jurisdiction for the reasons explained below.

STATEMENT OF ISSUES

1. Whether "snap removal," which provides an exception to the forum-defendant rule of 28 U.S.C. § 1441(b)(2), allows a federal court to exercise diversity jurisdiction where the named parties are not completely diverse and the action is therefore outside the court's original jurisdiction under 28 U.S.C. § 1332(a).

- *In re Levy,* 52 F.4th 244 (5th Cir. 2022)
- *Pecherski v. Gen. Motors Corp.*, 636 F.2d 1156 (8th Cir. 1981)
- *Pullman Co. v. Jenkins*, 305 U.S. 534 (1939)
- 28 U.S.C. § 1332(a)(1)

2. Whether the PREP Act, 42 U.S.C. §§ 247d-6d & 247d-6e, a statute that provides immunity against claims for injuries caused by the "administration to or use by an individual" of certain "covered countermeasures," completely preempts state-law claims where the only connection to such countermeasures is their non-use.

- *Martin v. Petersen Health Operations, LLC*, 37 F.4th 1210 (7th Cir. 2022)
- *Mitchell v. Advanced HCS, L.L.C.*, 28 F.4th 580 (5th Cir. 2022)

- *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679 (9th Cir. 2022)
- *Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393 (3d Cir. 2021).

3. Whether a defendant's intent to raise a PREP Act defense to a state-law claim is sufficient to trigger federal jurisdiction under the "substantial federal question" or "*Grable*" doctrine.

- *Martin v. Petersen Health Operations, LLC*, 37 F.4th 1210 (7th Cir. 2022)
- *Mitchell v. Advanced HCS, L.L.C.*, 28 F.4th 580 (5th Cir. 2022)
- *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679 (9th Cir. 2022)
- *Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393 (3d Cir. 2021)

4. Whether non-binding federal COVID-19-related guidance converted the entire nursing home industry into an "extension of the federal government" and converted all nursing home operations into actions taken "under" federal officer direction, as required to invoke the federal-officer removal statute, 28 U.S.C. § 1442(a)(1).

- *Watson v. Philip Morris Cos.*, 551 U.S. 142 (2007)
- *Buljic v. Tyson Foods, Inc.*, 22 F.4th 730 (8th Cir. 2021)
- *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679 (9th Cir. 2022)
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STATEMENT OF THE CASE

I. The PREP Act and the 2020 Declaration

A. Enacted in 2005 "[t]o encourage the expeditious development and deployment of medical countermeasures during a public health emergency, the Public Readiness and Emergency Preparedness Act (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, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures 1 (2022).[1]

The Secretary can trigger 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," under certain conditions. 42 U.S.C. § 247d-6d(b)(1). 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

[1] https://crsreports.congress.gov/product/pdf/LSB/LSB10443.

Occupational Safety and Health as "covered countermeasures." *Id.* § 247d-6d(i)(1)(A)–(D).

Subsection (a) of the PREP Act provides "covered person[s]" with immunity from liability under state or federal law for "any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure." *Id.* §§ 247d-6d(a)(1), (a)(2)(B). The statute imposes conditions that limit this immunity, *id.* § 247d-6d(a)(3), and authorizes the Secretary to impose further limitations, *id.* §§ 247d-6d(a)(5), (b)(2).

Subsection (d) of the statute creates a carve-out from the subsection (a) immunity for suits brought against covered persons "for death or serious physical injury proximately caused by willful misconduct." *Id.* § 247d-6d(d)(1). The term "willful misconduct" is defined only to include acts or omissions taken "intentionally to achieve a wrongful purpose," "knowingly without legal or factual justification," and "in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." *Id.* § 247d-6(c)(1)(A). For claims within the carve-out, the statute creates an "exclusive Federal cause of action," *id.* § 247d-6d(d)(1), and provides special adjudicatory procedures

and exclusive jurisdiction in a three-judge court of the District Court for the District of Columbia, *id.* § 247d-6d(e). Such claims are governed by the substantive law "of the State in which the alleged willful misconduct occurred." *Id.* § 247d-6d(e)(2).

The statute also creates an administrative fund, available to those who suffered injuries "directly caused by the administration or use of a covered countermeasure." 42 U.S.C. § 247d-6e(a).

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 "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 15,201–02.

The Secretary has subsequently amended the Declaration ten times.[2] The First Amendment expanded covered countermeasures to include certain respiratory protective equipment. *See* 85 Fed. Reg. 21,012, 21,014 (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 "[p]rioritization or purposeful allocation … particularly if done in accordance with a public health authority's directive." 85 Fed. Reg. 79,190, 79,197 (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 Office of General Counsel (OGC). *Id.* at 79,191 & n.5. In one of those opinions, OGC opined that PREP Act immunity was available to persons "using a covered

[2] All of the Amendments are available at https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx.

countermeasure in accordance with" guidance from public health authorities, including guidance on how to prioritize scarce countermeasures like vaccines. OGC, Advisory Opinion 20-04, at App. 153, R. Doc. 1-12, at 4 (Oct. 22, 2020, as modified on Oct. 23, 2020).

On January 8, 2021, OGC issued Advisory Opinion 21-01, opining that "the PREP Act is a '[c]omplete [p]reemption' [s]tatute" and that it applies to situations where a covered person makes a decision regarding allocation of covered countermeasures that "results in non-use by some individuals," but *not* where non-use is the result of "nonfeasance." App. 159–61, R. Doc. 1-13, at 2–4. The Advisory Opinion also asserted that "substantial federal question" jurisdiction exists in any case where a defendant invokes the PREP Act. App. 161–62, R. Doc. 1-13, at 4–5 (citing *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005)). Like the previous advisory opinions, it stated that it "set[] forth the [then-]current views" of OGC, was "not a final agency action or a final order," and did "not have the force or effect of law." App. 162, R. Doc. 1-13, at 5.

II. The Federal-State Pandemic Response

Since January 2020, federal agencies, including HHS's Centers for Disease Control and Prevention (CDC) and Centers for Medicare and Medicaid Services (CMS), have issued guidance to long-term care facilities regarding COVID-19 infection control and the applicability of existing regulations. *See, e.g.*, CDC & CMS, COVID-19 Long-Term Care Facility Guidance (LTC Guidance) (Apr. 2, 2020);[3] CDC, Coronavirus Disease 2019 (COVID-19) Preparedness Checklist for Nursing Homes and other Long-Term Care Settings (Preparedness Checklist) (Mar. 13, 2020).[4] These guidance documents explicitly indicated that state and local governments would retain their roles as primary protectors of public health. The LTC Guidance provided "recommendations to State and local governments and long-term care facilities," and urged facilities and state and local governments to work together. LTC Guidance 1. The Preparedness Checklist recommended that "[i]nformation from state, local, tribal, and territorial health departments, emergency management

[3] https://www.cms.gov/files/document/4220-covid-19-long-term-care-facility-guidance.pdf.

[4] https://www.cdc.gov/coronavirus/2019-ncov/downloads/novel-coronavirus-2019-Nursing-Homes-Preparedness-Checklist_3_13.pdf.

agencies/authorities, and trade organizations should be incorporated into the facility's COVID-19 plan," and that facilities should "actively obtain information from state, local, tribal, and territorial resources to ensure that the facility's plan complements other community and regional planning efforts." Preparedness Checklist 1. *See also* CMS, Toolkit on State Actions to Mitigate COVID-19 Prevalence in Nursing Homes 3 (Version 26 Mar. 2022) (compiling "many creative plans that state governments and other entities have put into operation").[5]

Consistent with HHS's expectations, Missouri took several actions to address COVID-19 in nursing homes by ensuring that its public health agencies were "strategically aligned with [their] federal and national partners." Mo. Dep't of Health & Senior Servs. (DHSS), News Release, DHSS Director Williams meets at White House to discuss federal, state and local health officials' strategic alignment on COVID-19 (Feb. 27, 2020).[6] In March 2020, for example, DHSS "instruct[ed] facilities to impose restrictions on visitors," to cancel communal dining and all group

[5] https://www.cms.gov/files/document/covid-toolkit-states-mitigate-covid-19-nursing-homes.pdf.

[6] https://health.mo.gov/news/newsitem/uuid/ffc9eb47-c189-4cc7-8a24-6130a710dbb3.

activities, and to "implement active screening of residents and staff." DHHS, Memo from Director Randall Williams re: COVID-19 Visitor Restrictions (Mar. 13, 2020).[7] DHSS also issued detailed instructions for evaluation of potential COVID-19 cases in health care settings. DHSS, Health Update: Criteria to Guide Evaluation and Laboratory Testing for COVID-19 (Mar. 24, 2020).[8] And in April 2020, DHSS issued an extensive list of steps facilities should take to limit the spread of COVID-19. DHSS, Missouri Interim Guidance for Long Term Care Facilities with Confirmed COVID-19 Cases (Apr. 1, 2020).[9]

III. NHC's Inadequate Infection Control Policies and Willis Cagle's Death

In April 2020, Willis Marion Cagle moved into NHC Healthcare-Maryland Heights, a nursing home located in Bridgeton, Missouri. App. 40, 52, R. Doc. 1, at 30, R. Doc. 1-1, at 11. Although the dangers of COVID-19 were by then well known, NHC failed to take basic steps to prevent

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[7] https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/pdf/ltc-memo.pdf.

[8] https://health.mo.gov/emergencies/ert/alertsadvisories/pdf/update32320.pdf.

[9] https://ltc.health.mo.gov/wp-content/uploads/sites/18/2020/04/COVID-19-LTCF-Guidance-4.1.2020.pdf.

spread of COVID-19 at the facility, including by failing to screen residents and staff for COVID-19 symptoms, failing to adopt and maintain infection control procedures, failing to quarantine residents with COVID-19 symptoms from other vulnerable residents, and failing to follow social distancing guidelines. App. 52–54, R. Doc. 1-1, at 11–13.

NHC-Maryland Heights confirmed the first positive cases of COVID-19 within its walls in May 2020, and Willis tested positive within weeks. App. 52, R. Doc. 1-1, at 11. His condition worsened, and NHC failed to provide him with appropriate medical care. *Id.* His family insisted he be transported to a hospital, where he died from COVID-19 on June 12, 2020. App. 52–54, R. Doc. 1-1, at 11–13. By February 2021, 273 residents and 91 staff members at NHC-Maryland Heights had tested positive for COVID-19; 48 had died. App 52, R. Doc. 1-1, at 11.

IV. Procedural History

A. State court proceedings

Plaintiff-Appellee Zane Cagle, Willis's adult son, commenced this action in the Circuit Court of St. Louis County, Missouri, on August 27, 2021. App. 42, 45, R. Doc. 1-1 at 1, 4. Mr. Cagle's state court petition brought three claims under Missouri law: (1) for wrongful death based on NHC's negligence; (2) for negligence per se based on NHC's violations of

several Missouri regulations governing residential care facilities; and (3) for survival pursuant to R.S. Mo. § 537.021, again invoking NHC's negligence. App. 52–58, R. Doc. 1-1, at 11–17.

The state court petition named sixteen defendants, in addition to anonymous Doe defendants. Defendants NHC Healthcare-Maryland Heights, LLC; NHC/OP, LP; NHC/Delaware, Inc.; and National Healthcare Corporation (Delaware) (collectively "NHC" or "the corporate defendants") are citizens of Delaware and Tennessee. *See* App. 400, R. Doc. 27, at 5. Mr. Cagle alleges, and NHC does not dispute, that eleven of the twelve individual defendants—NHC-Maryland Heights administrators and staff—are residents of Missouri. App. 48–49, R. Doc. 1-1, at 7-8.

On November 10, 2021, the state court issued summonses for the corporate defendants and two of the individual defendants who reside in Missouri, Susan Morley-Taylor and Jeffrey Loraine. App. 69–70, R. Doc. 1-8, at 1–2. The corporate defendants were successfully served on November 23, 2021, but the summonses for Morley-Taylor and Loraine were returned non est. App. 452–55, R. Doc. 35-2, at 1–4.

B. District court proceedings

Before Mr. Cagle could complete service on Morley-Taylor and Loraine, NHC removed the action to the United States District Court for the Eastern District of Missouri. App. 11, R. Doc. 1, at 1. NHC's removal notice invoked four theories. First, it asserted diversity jurisdiction pursuant to 28 U.S.C. § 1332(a)(1) and § 1441(a). App. 13, R. Doc. 1, at 3. Second, it asserted that the PREP Act completely preempted all of plaintiff's claims, thus converting those claims into ones arising under federal law for purposes of 28 U.S.C. § 1331. App. 13, 18–28, R. Doc. 1, at 3, 8–18. Third, it asserted "embedded federal question" jurisdiction under *Grable*. App. 28–29, R. Doc. 1, at 18-19. Fourth, it claimed that removal was appropriate under the federal-officer removal statute, 28 U.S.C. § 1442(a)(1), as "the unique regulatory context and scheme related to COVID-19" made NHC "an extension of the Federal Government and its agencies and officers." App. 30–38, R. Doc. 1, at 20-28.

Mr. Cagle moved to remand. App. 381, R. Doc. 21, at 1. As to diversity jurisdiction, he explained that named defendants Morley-Taylor's and Loraine's Missouri citizenship destroyed complete diversity, regardless of whether they had been served. App. 381–83, 385–89, R. Doc.

21, at 1–3, R. Doc. 22, at 1–5. As to federal-question jurisdiction, Mr. Cagle explained that a potential federal defense does not create jurisdiction, and that his claims were not completely preempted by the PREP Act, both because the claims are outside the scope of the statute and because that statute cannot completely preempt claims for negligence where it provides no substitute cause of action. App. 391–92, R. Doc. 22, at 7–8. Finally, he argued that the regulatory relationship between NHC and federal agencies did not satisfy the "acting under" requirement of the federal-officer removal statute. App. 392–93, R. Doc. 22, at 8–9.

In opposing remand, NHC invoked the doctrine of "snap removal," suggesting that the doctrine allows for removal where complete diversity is lacking if the non-diverse defendants have not yet been served. App. 398–402, R. Doc. 27, at 3–7. As to its other jurisdictional arguments, it stated that, "for sake of brevity," it was primarily "incorporat[ing] the arguments and citations made in" the removal notice and "only reiterate[d] portions." App. 402 n.8, 409 n.13, R. Doc. 27, at 7, 14. In a footnote addressing federal-officer removal jurisdiction, it acknowledged this Court's decision in *Buljic v. Tyson Foods, Inc.*, 22 F.4th 730 (8th Cir.

2021), but contended that "any portions which may be analogized/applicable … are in error." App. 412 n.20, R. Doc. 27, at 17.

While briefing on the remand motion was underway, Missouri citizen defendants Morley-Taylor and Loraine were served. App. 436–41, R. Doc. 32, at 1, R. Doc. 32-1, at 1–2, R. Doc. 33, at 1, R. Doc. 33-1, at 1–2. On July 20, 2022, the district court granted the motion to remand, rejecting each of NHC's theories. Add. 1, R. Doc. 50, at 1. As to diversity, the court declined to adopt the "snap removal" theory and held that removal based on diversity was barred by 28 U.S.C. § 1441(b)(2), the forum-defendant rule. Add. 7–9, R. Doc. 50, at 7-9. The court also held that NHC had failed to meet its burden to establish that the amount in controversy exceeds $75,000. Add. 9, R. Doc. 50, at 9. The court did not reach Mr. Cagle's argument that the lack of complete diversity barred jurisdiction under 28 U.S.C. § 1332(a)(1).

Turning to NHC's federal-question arguments, the court rejected NHC's complete preemption argument on the ground that Mr. Cagle's claims were outside the scope of the PREP Act because he did "not suggest that [his father]'s death was causally connected to Defendants' administration or use of any drug, biological product, or device (i.e., a

covered countermeasure[])." Add. 16, R. Doc. 50, at 16 (citing 42 U.S.C. § 247d-6d(a)(2)(B); case citations omitted).

Next, the court held that *Grable* was inapplicable because the only federal issue raised by NHC was a "potential defense," not an aspect of plaintiff's claim. Add. 19–20, R. Doc. 50, at 19–20.

Finally, citing precedent including this Court's decision in *Buljic*, 22 F.4th at 742, and the Supreme Court's decision in *Watson v. Philip Morris Cos.*, 551 U.S. 142 (2007), the court found that NHC was "not 'acting under' a federal officer at the time that Willis contracted COVID-19," and thus that the federal-officer removal statute did not apply. Add. 23, R. Doc. 50, at 23.

SUMMARY OF ARGUMENT

Appellants present this Court with four theories of jurisdiction without so much as acknowledging several recent appellate decisions rejecting those same theories—including *this* Court's decision in *Buljic*, on which the district court relied in its order of remand. These decisions—along with other decisions of this Court and the Supreme Court—demonstrate that Appellants' arguments are incorrect and that the district court's remand order should be affirmed.

First, the theory behind "snap removal" is that the forum-defendant rule of 28 U.S.C. § 1441(b)(2)—which bars the removal of cases where diversity jurisdiction otherwise exists pursuant to 28 U.S.C. § 1332(a) where a defendant is a citizen of the forum state—does not apply where the forum defendant has not yet been served. Section 1441(b)(2) is a *limit* on diversity jurisdiction, not an expansion of it; it explicitly applies only where the requirements of section 1332(a) are "otherwise" met. One of those requirements is complete diversity among all *named* parties, not just those served. Thus, neither the forum-defendant rule nor any interpretation of it can create diversity jurisdiction in cases like this one, where complete diversity among named parties is lacking.

Second, as four courts of appeals have held, the PREP Act does not completely preempt claims like Mr. Cagle's. The statute applies only where a plaintiff asserts an injury with "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), a specified drug or device used in a manner recommended by the HHS Secretary. Mr. Cagle does not allege that his father's death had any such relationship. But even where the PREP Act's immunity provision applies, the Act does not create federal jurisdiction

through complete preemption. Even under the statute's narrow cause of action for claims alleging "willful misconduct" in the use of a covered countermeasure—which NHC does *not* suggest Mr. Cagle alleges here—Congress has explicitly preserved state law, while providing a federal forum for resolution of state-law claims. The provision of such a limited federal-court remedy is not the same as the complete displacement of state law and the substitution of a uniform body of federal law that is the hallmark of complete preemption statutes. Additionally, Congress's decision to provide federal jurisdiction over one set of claims related to covered countermeasures (i.e., willful-misconduct claims) does not demonstrate that Congress implicitly created federal jurisdiction over *other* claims related to countermeasures. NHC cannot overcome the exceptionally strong presumption against complete preemption this Court applies.

Third, again as four courts of appeals have held, an asserted PREP Act defense does not satisfy the requirements of "substantial federal question" or "*Grable*" jurisdiction. A defendant's intent to raise a federal immunity defense does not evidence that a significant, disputed federal issue is an element of the plaintiff's state-law claim. Moreover, the

assumption of federal jurisdiction over all state-law malpractice claims related to COVID-19 would massively disrupt the state-federal judicial balance.

Finally, under this Court's recent decision in *Buljic*, Supreme Court precedent, and the decisions of sister circuits, neither federal guidance, NHC's participation in a "critical infrastructure" industry, nor the fact that NHC could qualify as a "program planner" under the PREP Act establish that NHC was in the sort of subordinate relationship with the federal government necessary to invoke the federal-officer removal statute.

STANDARD OF REVIEW

This Court reviews a district court's remand order *de novo*. *Buljic*, 22 F.4th at 738.

ARGUMENT

I. The lack of complete diversity among named defendants means there is no diversity jurisdiction.

NHC argues that there is diversity jurisdiction over this action because it engaged in "snap removal." NHC Br. 15–23. Whether the district court correctly rejected a reading of the forum-defendant rule that allows for snap removal, Add. 7–9, R. Doc. 50, at 7-9, is irrelevant,

however. Regardless of whether the Court might otherwise adopt the snap removal theory, diversity jurisdiction is lacking here because there is no complete diversity among the named parties, as required by section 1332(a)(1). *See Pullman Co. v. Jenkins*, 305 U.S. 534, 538 (1939).

"Defendants may remove a[] [state-court] action on the basis of diversity of citizenship if there is complete diversity between all named plaintiffs and all named defendants, *and* no defendant is a citizen of the forum State." *Lincoln Property Co. v. Roche*, 546 U.S. 81, 84 (2005) (emphasis added). The first of these two distinct requirements, complete diversity between named parties, is a jurisdictional requirement of section 1332(a)(1), and it applies both to original and removal jurisdiction. The latter requirement, the "forum-defendant rule" of section 1441(b)(2), applies only to removal. The concept of "snap removal" relates solely to this second requirement, and refers to the scenario where a defendant "remove[s] an action before a named co-defendant, who is a citizen of the forum, has been served." *In re Levy*, 52 F.4th 244, 247 (5th Cir. 2022). According to some courts, the prohibition on removal of section 1441(b)(2) does not apply in that situation. *See id.*; *see also* Wright & Miller, 14C Fed. Prac. & Proc. Juris. § 3723 (Rev. 4th ed. 2022)

(suggesting that section 1441(b)(2) "implies that a *diverse but resident* defendant who has not been served may be ignored in determining removability" (emphasis added)).

As its plain text states, however, section 1441(b)(2) applies only in "action[s] otherwise removable … under section 1332(a)." Thus, snap removal has no relevance in cases where named parties are *not* completely diverse, as the Fifth Circuit—which *has* endorsed snap removal—explained recently in rejecting a party's misplaced invocation of that theory similar to NHC's argument here. *See Levy*, 52 F.4th at 247–48.

Levy's conclusion is consistent with this Court's holding forty years ago that "section 1441(b) did not change the removal requirement set forth in *Pullman* that a court, in determining the propriety of removal based on diversity of citizenship, must consider all named defendants, regardless of service." *Pecherski v. Gen. Motors Corp.*, 636 F.2d 1156, 1160–61 (8th Cir. 1981). NHC suggests that *Pecherski* is no longer good law, citing to it with the parenthetical "abrogated by amendment." NHC Br. 20. But no amendment to either section 1332 or section 1441 has abrogated *Pecherski*'s relevant holding: that section 1441(b) only applies

where the complete diversity requirement of section 1332(a)(1) is satisfied.[10] To the contrary, the 2011 amendment to section 1441 reinforces this holding by making express that the forum-defendant rule is relevant only to civil actions "otherwise removable solely on the basis of the jurisdiction under section 1332(a)." *See* Federal Courts Jurisdiction & Venue Clarification Act of 2011, Pub. L. No. 112-63, Title I, § 103, 125 Stat. 758, 759, *codified at* 28 U.S.C. § 1441(b)(2).

The Supreme Court's holding in *Pullman* that complete diversity is required of *named* parties, not just served ones, likewise remains good law. *See, e.g.*, *Lincoln Prop. Co.*, 546 U.S. at 84; *Northport Health Servs. of Ark., LLC v. Rutherford*, 605 F.3d 483, 486 (8th Cir. 2010). Thus, district courts throughout this Circuit, like the Fifth Circuit in *Levy*, have repeatedly rejected arguments like NHC's that attempt to export snap removal from section 1441(b) to the complete diversity analysis under

[10] One district court, in addressing issues relating to fictitious defendants, stated in a footnote that *Pecherski* was "overruled" by 1988 amendments to section 1441 that expressly addressed fictitious defendants. *See Payich v. GGNSC Omaha Oak Grove, LLC*, 2012 WL 1416693, at *3 n.1 (D. Neb. Apr. 24, 2012) (referencing Judicial Improvements and Access to Justice Act of 1988, Pub. L. No. 100–702, Title X, § 1016(a), 102 Stat. 4642, 4669). Neither this case nor the relevant holding in *Pecherski* implicates those amendments.

section 1332(a). *See, e.g.*, *Allison v. Shelton*, 2022 WL 4245535, at *4 (W.D. Ark. Sept. 15, 2022); *Taylor v. Clark Equip. Co.*, 2022 WL 1640372, at *6 (E.D. Mo. May 24, 2022); *Spreitzer Props., LLC v. Travelers Corp*, 2022 WL 1137091, at *7 (N.D. Iowa Apr. 18, 2022); *see also Woods v. Ross Dress for Less, Inc.*, 833 F. App'x 754, 759 (10th Cir. 2021). The cases cited by NHC do not suggest otherwise and in fact make clear that snap removal is available only where there is complete diversity among all named parties. *See, e.g.*, *Tillman v. BNSF Ry. Co.*, 2021 WL 842600, at *3 (E.D. Mo. Mar. 5, 2021) (holding that *Pecherski* did not bar removal where there was "complete diversity between plaintiff and defendants"), *discussed in* NHC Br. 18–19; *Breitweiser v. Chesapeake Energy Corp.*, 2015 WL 6322625, at *2 n.6 (N.D. Tex. Oct. 20, 2015) (explaining why "[s]nap removals can occur only in removal cases based solely on diversity jurisdiction where complete diversity exists"), *cited in* NHC Br. 17; *Johnson v. Emerson Elec. Co.*, 2013 WL 5442752, at *3 (E.D. Mo. Sept. 30, 2013) (distinguishing *Pecherski* as inapplicable "where complete diversity exists"), *cited in* NHC Br. 19; *Brake v. Reser's Fine Foods, Inc.*, 2009 WL 213013, at *2 (E.D. Mo. Jan. 28, 2009) (similar), *cited in* NHC Br. 19–20.

Here, as NHC concedes, the plaintiff and two of the named defendants, Morley-Taylor and Loraine, are Missouri citizens. *See* NHC Br. at 17–18. Thus, there is no complete diversity and no jurisdiction under 28 U.S.C. § 1332.

II. The PREP Act does not completely preempt Mr. Cagle's claims.

Although Mr. Cagle's well-pleaded complaint asserts only Missouri-law claims, NHC argues that the claims arise under federal law for purposes of 28 U.S.C. § 1331 because they are "completely preempted" by the PREP Act. NHC's complete preemption argument fails both because Mr. Cagle's claims based on NHC's inadequate infection-control policies are outside the scope of the PREP Act and because that statute does not completely preempt all claims within the scope of its ordinary immunity provision.

A. Mr. Cagle's claims are not within the ambit of the PREP Act.

As the district court concluded, it is unnecessary to determine whether the PREP Act is a complete preemption statute because Mr. Cagle's claims are outside the PREP Act's scope. Add. 16–17, R. Doc. 50, at 16-17. *Cf. Griffioen v. Cedar Rapids & Iowa City Ry. Co.*, 785 F.3d 1182, 1192 (8th Cir. 2015) (reversing denial of remand motion without

resolving whether Interstate Commerce Commission Termination Act (ICCTA) completely preempts claims within its scope, because, even if it did, the defendant had "not established that the [plaintiff]'s claims fall within the scope of those so preempted").

The PREP Act's immunity provision, its exception to immunity for willful misconduct, and its administrative compensation fund all apply only to claims for losses with "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). Here, the district court correctly recognized Mr. Cagle does *not* allege that his father died because of the "administration to or use by an individual of a covered countermeasure." Add. 16–17, R. Doc. 50, at 16-17. Rather, he alleges that Willis died because NHC "negligently failed to follow proper infection control protocols" and because NHC "failed to timely intervene to obtain medical attention for Willis." App. 52, R. Doc. 1-1, at 11.

The district court's conclusion that such claims lie outside the scope of the statute is consistent with decisions of dozens of courts recognizing the inapplicability of the PREP Act "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." *Gwilt v. Harvard Sq. Retirement & Assisted Living*, 537 F. Supp. 3d 1231, 1240 (D. Colo. 2021).[11] As the Seventh Circuit explained, such claims "are not even arguably preempted" by the PREP Act, as the only relationship they conceivably have with covered countermeasures is with their *non*-use—contrary to the Secretary's recommendations. *Martin*, 37 F.4th at 1213. An allegation of injury resulting from *non*-use "is the opposite of a contention that a covered countermeasure caused harm." *Id.* at 1214; *see also Manyweather*, 40 F.4th at 245–46 (holding similar failure-to-use

[11] *Accord, e.g., Martin v. Petersen Health Ops., LLC*, 37 F.4th 1210, 1213 (7th Cir. 2022); *Manyweather v. Woodlawn Manor, Inc.*, 40 F.4th 237, 245–46 (5th Cir. 2022); *Arbor Mgmt. Servs., LLC v. Hendrix*, 875 S.E.2d 392, 397 (Ga. Ct. App. 2022); *Whitehead v. Pine Haven Operating LLC*, 75 Misc. 3d 985, 991–92 (N.Y. Sup. Ct. 2022); *Testa v. Broomall Operating Co.*, 2022 WL 3563616, at *4–5 (E.D. Pa. Aug. 18, 2022); *Yarnell v. Clinton No. 1, Inc.*, 591 F. Supp. 3d 432, 439 (W.D. Mo. 2022); *Walsh v. SSC Westchester Operating Co.*, 592 F. Supp. 3d 737, 743–46 (N.D. Ill. 2022); *Pirotte v. HCP Prairie Village KS OPCO, LLC*, 580 F. Supp. 3d 1012, 1025–27 (D. Kan. 2022); *Ruiz v. ConAgra Foods Packaged Foods, LLC*, 2021 WL 3056275, at *4–5 (E.D. Wisc. July 20, 2021); *Roderick v. Life Care Ctrs. of Am.*, 2021 WL 6337496, at *2 (E.D. Tenn. Apr. 30, 2021); *Lyons v. Cucumber Holdings, LLC*, 520 F. Supp. 3d 1277, 1286 (C.D. Cal. 2021); *Dupervil v. Alliance Health Ops., LLC*, 516 F. Supp. 3d 238, 255–56 (E.D.N.Y. 2021), *vacated as moot*, 2022 WL 3756009 (2d Cir. Aug. 1, 2022).

claims outside the PREP Act's scope). The conclusion that the PREP Act applies only where a plaintiff claims that *use* of a covered countermeasure caused injury is supported by the statute's text and purpose. And to the extent administrative authority cited by NHC can be read to suggest otherwise, this Court owes it no deference.

1. The PREP Act applies only to claims alleging that the use or administration of a covered countermeasure caused injury to an individual.

"Interpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context of the statute, and consulting any precedents or authorities that inform the analysis." *Dolan v. U.S. Postal Serv.*, 546 U.S. 481, 486 (2006), *quoted in Sanzone v. Mercy Health*, 954 F.3d 1031, 1040 (8th Cir. 2020). Here, the PREP Act's text, purpose, and context confirm that only claims with a causal relationship to actual use of covered countermeasures fall within the statute's scope.

Throughout its brief, NHC suggests the statute applies to "claims related to the administration or use of certain covered countermeasures." NHC Br. 5; *see also, e.g.*, *id.* 12, 27, 28, 29. But this paraphrasing omits important words of the statute. The text actually limits the applicability of each of the statute's operative provisions to "claim[s] for loss that ha[ve] 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) (emphasis added). Restoration of the "causal relationship" language, and the prepositions "to" and "by an individual" makes NHC's broad interpretation of the statute—based on the word "administration"—untenable. *See Manyweather,* 40 F.4th at 245–46 (noting that the "causal relationship" language narrows the broad "relating to" language and makes clear that the statute only applies to claims based on actual use of countermeasures). To "administer" can mean "to manage or supervise the execution, use, or conduct of" something, or it can mean "to provide or apply: DISPENSE." Merriam-Webster Online Dictionary.[12] Here, only the latter definition of the word makes sense. When a facility does *not* use a covered countermeasure, it is not administering a covered countermeasure *to an individual*, nor is a countermeasure being used *by an individual*.

Other statutory provisions confirm that the Act cannot sensibly be read to apply where a countermeasure was *not* administered or used. For instance, the statute provides for immunity "only if" the countermeasure

[12] https://www.merriam-webster.com/dictionary/administer.

was "administered or used" during the period of the declaration, for the condition specified in the declaration, and "administered to or used by" an individual within the population or area specified in the declaration. 42 U.S.C. § 247d-6d(a)(3). Similarly, healthcare professionals only obtain 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). These provisions cannot function if the statute applies, as NHC suggests, when no countermeasure was administered or used at all.

NHC contends that the fact that the statute "refers to both 'acts and omissions' eight times" means that "affirmative acts alone are not required." NHC Br. 43. Each of the eight provisions NHC points to, however, refers to what can constitute "willful misconduct" under the statute. For example, subsection (e)(3) uses the phrase "act or omission" in setting out pleading standards for willful misconduct claims, requiring a plaintiff to plead with particularity, among other things:

> 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[.]

42 U.S.C. § 247d-6d(e)(3)(A) (emphasis added).[13] As the statutory language shows, the reference to an "act or omission" does not eliminate the requirement that the covered countermeasure must have been "administered to or used by" the victim. Instead, it recognizes that an omission may result in a countermeasure being administered or used improperly—for example, if a facility manager's deliberate failure to provide proper training to employees administering vaccines causes an employee to nick a patient's artery while administering the vaccine, or if a provider's intentional failure to sterilize equipment between uses causes a patient to contract an infectious disease during vaccination. In such scenarios, a covered countermeasure would be used, and a complaint could allege an omission by the facility constituting willful misconduct in relation to its use. This reading, unlike NHC's, gives meaning to each phrase in the statute.

If the PREP Act's text left any ambiguity as to its scope, its purpose confirms that it applies only where an injury was caused by actual use—

[13] NHC suggests that the Third Circuit in *Maglioli* held that the "PREP Act applies to 'acts and omissions.'" NHC Br. 43. The only references to omissions in *Maglioli* are in quotations of the statute with respect to the elements of willful misconduct. *See Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393, 401, 410 (3d Cir. 2021).

not non-use—of covered countermeasures. The PREP Act was intended to encourage the manufacture, distribution, and use of covered countermeasures. *See Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 529 (D.N.J. 2020) (noting 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"), *aff'd on other grounds*, 16 F.4th 393 (3d Cir. 2021). Supporters explained that the bill would ensure that a pandemic flu "vaccine gets developed and [that] doctors are willing to give it." 151 Cong. Rec. H12244-03 (daily ed. Dec. 18, 2005) (statement of Rep. Deal); Assessing the Nat'l Pandemic Flu Preparedness Plan: Hearing Before the H. Comm. on Energy & Commerce, Serial No. 109-59 at 20 (Nov. 8, 2005) (statement of HHS Secretary Leavitt) ("[T]he threat of liability exposure is too often a barrier to willingness to participate in the vaccine business.").[14] 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

[14] https://www.govinfo.gov/content/pkg/CHRG-109hhrg26891/pdf/CHRG-109hhrg26891.pdf.

Economic Security Act, Pub. L. No. 116-136, § 3103, 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 (Mar. 11, 2020) (testimony of HHS Asst. Secretary Kadlec, urging addition of respiratory protective devices to boost supply).[15] Immunity from suit for injuries resulting from the affirmative administration or use of covered countermeasures encourages production and use of those countermeasures. By contrast, immunity for decisions *not* to administer or use covered countermeasures "would defeat the basic purpose of the statute." *Martin v. Petersen Health Ops., LLC*, 2021 WL 4313604, *10 (C.D. Ill. Sept. 22, 2021), *aff'd*, 37 F.4th 1210 (7th Cir. 2022).

Throughout 2020, Congress debated—but did not enact—liability protections for claims like Mr. Cagle's. *See*, *e.g.*, 166 Cong. Rec. S2358 (daily ed. May 12, 2020) (statement of Sen. McConnell, discussing

[15] https://www.govinfo.gov/content/pkg/CHRG-116hhrg40428/pdf/CHRG-116hhrg40428.pdf.

legislation to "raise the liability threshold for COVID-related malpractice lawsuits" and to "create a legal safe harbor" for entities "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 indicates that the PREP Act did not already provide immunity.

2. Administrative authority does not suggest that the PREP Act applies.

NHC contends that the Secretary's PREP Act Declaration and General Counsel's advisory opinions somehow expanded the scope of PREP Act immunity to the claims here. The cited materials do not purport to do so, however, and, in any event, nothing in those documents is entitled to deference from this Court.

NHC relies on two HHS documents that, at most, support the idea that the PREP Act may apply to a claim based on an injury caused by the decision to administer or use a covered countermeasure to one individual, but not another. In the Fourth Amendment to the Declaration, the Secretary adopted a new definition of the term "Administration of the Covered Countermeasure":

> physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure

> programs, or management and operation of locations for the purpose of distributing and dispensing countermeasures.

85 Fed. Reg. at 79,197. This text does not indicate that the statute applies to decisions not to deliver, distribute, or dispense countermeasures at all, much less that it applies to failures to do so based on negligence. To the contrary, HHS's explanation for this change in the accompanying preamble stated that it was intended "to make explicit that there can be situations where not administering a covered countermeasure to a *particular individual* can fall within the PREP Act and this Declaration's liability protections." 85 Fed. Reg. at 79,194 (emphasis added).

The narrow scope of the definitional change is consistent with OGC Advisory Opinion 21-01, which NHC selectively quotes in its brief, at 43 (quoting App. 161, R. Doc. 1-13, at 4). In that explicitly non-binding guidance document, the General Counsel asserted that the "language of the PREP Act itself supports a distinction between allocation which results in non-use by some individuals," which he opined could in certain circumstances fall within the scope of the statutory immunity, "and nonfeasance … that also results in non-use," which cannot. App. 161, R. Doc. 1-13, at 4.

Whether or not the OGC's view is correct does not matter here, where Mr. Cagle alleges his father died, as the district court put it, "because Defendants failed to take preventative measures to stop the entry and spread of COVID-19 within the facility," Add. 16, R. Doc. 50, at 16, not because of NHC's purposeful allocation decisions with regard to the specific drugs and devices deemed covered countermeasures. *See Estate of McCalebb v. AG Lynwood, LLC*, 2021 WL 911951, at *5 (C.D. Cal. Mar. 1, 2021) (concluding that claims of "general neglect" do not fall within the scope of the statute, even under HHS's view). HHS has never suggested that the PREP Act applies to such a situation.

As explained above (at 27–33), the text and purpose of the PREP Act unambiguously demonstrate that only claims based on injuries caused by the actual administration to or use of a covered countermeasure fall under the statute. *See Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 175 (2016) (stating "we do not defer to the agency when the statute is unambiguous"). Were there ambiguity, however, HHS's interpretation would not control, as there is no evidence "that Congress delegated authority to the agency generally to make rules carrying the force of law," nor that HHS's interpretation "was

promulgated in the exercise of [such] authority." *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). The Secretary did not, and could not, purport to be exercising any such delegated authority here.

Without citing to any statutory provision, NHC says there is "clear congressional authorization for HHS to define terms in the context of each public health threat and to implement the PREP Act." NHC Br. 43 (citations omitted).[16] But Congress only delegated the Secretary 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). In giving the Secretary the power to specify which administrations or uses of covered countermeasures are subject to immunity, Congress did not give

[16] NHC cites *Maglioli* for the proposition that Congress granted the HHS Secretary the authority to "control the scope" of the PREP Act. NHC Br. 43. But *Maglioli* simply notes, in explaining how the statute operates generally, that "[t]he Secretary controls the scope of immunity through the declaration and amendments, *within the confines of the PREP Act*." 16 F.4th at 401 (emphasis added). This statement reflects that the Secretary has to issue a declaration for the statute to be operative—not that the Secretary has authority to alter the meaning of the statute's words.

him the power to define the terms "administration" or "use." *Cf. id.* § 247d-6d(c)(2)(A) (providing rulemaking authority to define "willful misconduct").[17]

Where a statute is ambiguous, "an agency's non-binding opinion is accorded weight 'depend[ing] 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.'" *Dominguez-Herrera v. Sessions*, 850 F.3d 411, 415 (8th Cir. 2017) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). Here, the agency has not addressed the relevant statutory language, including the requirement of a "causal relationship" with the administration "to" or "use by an individual," and it has not considered the statute's purpose of stimulating manufacture and use. Any conclusion the agency reached without doing so is not entitled to deference.

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[17] In a footnote, NHC incorrectly states that "courts cannot question the scope set by HHS." NHC Br. 43 n.5 (citing 42 U.S.C. § 247d-6d(b)(7)). The cited provision sets aside the presumption of judicial reviewability of final agency action as to PREP Act declarations. *See Maglioli*, 16 F.4th at 403. It does not mean that courts are required to accept HHS's statutory interpretations in *other* judicial proceedings and does not mean "that the Secretary's interpretation of the PREP Act has the force of law." *Mackey v. Tower Hill Rehab., LLC*, 569 F. Supp. 3d 740, 748 n.7 (N.D. Ill. 2021).

B. The PREP Act does not completely preempt negligence claims relating to the administration or use of covered countermeasures.

Because Mr. Cagle's claims do not relate to an injury caused by the administration to or use by an individual of a covered countermeasure, the Court need not determine whether the PREP Act completely preempts any claims that do. Even so, as the Third, Fifth, Seventh, and Ninth Circuits and dozens of district courts around the country have held, the PREP Act does not completely preempt all claims where its ordinary immunity provision may apply. *See, e.g.*, *Martin*, 37 F.4th at 1213–14; *Mitchell v. Advanced HCS, L.L.C.*, 28 F.4th 580, 586–88 (5th Cir. 2022); *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679, 687–88 (9th Cir. 2022), *cert. denied*, 2022 WL 17085186 (Nov. 21, 2022); *Maglioli*, 16 F.4th at 406–13; *Buhlig v. Walgreen Co.*, 2022 WL 4534445, at *2 (W.D. Mo. Sept. 20, 2022); *Mancinelli v. Hillcrest Millard, LLC*, 2022 WL 3009750, at *1–2 (D. Neb. May 19, 2022); *Yarnell*, 591 F. Supp. 3d at 438–39; *Fisher v. Rome Ctr. LLC*, 2022 WL 16949603, at *6–9 (N.D.N.Y. Nov. 15, 2022); *Massamore v. RBRC, Inc.*, 595 F. Supp. 3d 594, 599–602 (W.D. Ky. 2022); *Dorsett v. Highlands Lake Ctr., LLC*, 557 F. Supp. 3d 1218, 1228–35 (M.D. Fla. 2021).

"Complete preemption provides a narrow exception to the general rule that, absent diversity, a case filed in state court is not removable to federal court unless it affirmatively alleges a federal claim." *Bates v. Mo. & N. Ark. R. Co.*, 548 F.3d 634, 636 (8th Cir. 2008) (citing *Beneficial Nat'l Bank v. Anderson,* 539 U.S. 1, 7–8 (2003)). There is an "exceptionally strong presumption against complete preemption," and the doctrine only applies "where a federal statute completely displaces state law and it is clear Congress meant the federal statute to be the exclusive cause of action for the type of claim asserted." *Johnson v. MFA Petroleum Co.,* 701 F.3d 243, 250 (8th Cir. 2012) (cleaned up). Such clear intent is lacking "when there is no substitute federal cause of action." *Id.* at 252.

The PREP Act fails both steps of the inquiry: It does not wholly displace state law and replace it with uniform federal substantive law, and it does not provide a substitute cause of action in the vast majority of cases where its ordinary preemption provision applies. To the extent federal agencies have conclusorily asserted otherwise, those views are owed no deference.

1. The PREP Act does not entirely displace state law.

Complete preemption is rare. The Supreme Court has recognized only three statutes with the requisite force to give rise to it: section 301 of the Labor Management Relations Act (LMRA), section 502(a) of the Employee Retirement Income Security Act (ERISA), and sections 85 and 86 of the National Bank Act. *Beneficial*, 539 U.S. at 6–8, 11.[18] Where these statutes completely preempt state-law claims, such claims are transformed into ones for a violation of federal law. A state-law claim that is completely preempted by ERISA, for example, becomes one based on a violation of duties imposed by ERISA—and not any other independent legal duty. *See Aetna Health Inc. v. Davila*, 542 U.S. 200, 210 (2004). A state-law claim that is completely preempted by the LMRA is one "controlled by [the] federal substantive law" that exclusively governs covered collective bargaining agreements. *Avco Corp. v. Aero Lodge No. 735, Int'l Ass'n of Machinists & Aerospace Workers*, 390 U.S. 557, 560 (1968). And a state-law claim that is completely preempted by

[18] This Court "has additionally recognized complete preemption in certain particular areas of 'special federal interest,'" finding the high standard satisfied by provisions of the now-repealed Federal Railroad Safety Act, the Railway Labor Act, and the Indian Gaming Regulatory Act. *Johnson*, 701 F.3d at 248 (citations omitted).

the National Bank Act is one governed by federal "substantive limits on the rates of interest that national banks may charge." *Beneficial*, 539 U.S. at 9.

Unlike these statutes, the PREP Act creates no substantive standards whose violation gives rise to a cause of action independent of state law. It is, "at its core, an immunity statute; it does not create rights, duties, or obligations." *Dorsett*, 557 F. Supp. 3d at 1230 (citation omitted); *see Gwilt*, 537 F. Supp. 3d at 1249. Where a state law claim meets the requirements of subsection (a) of the PREP Act, one of two things happens. *First*, where the three criteria for willful misconduct are met, rather than displacing state law, the statute expressly preserves state law and provides a federal venue for adjudicating state-law claims. *See* 42 U.S.C. § 247d-6d(e)(2) (providing that *state* law is the source of "[t]he substantive law for decision" in a subsection (d) action). "By incorporating state law into the federal action, the Act does not entirely displace state law, making the Act unlike other instances of complete preemption." *Matthews v. Centrus Energy Corp.*, 15 F.4th 714, 721 (6th Cir. 2021) (discussing similar feature of the Price-Anderson Act). Complete preemption, which posits that state law has been wholly displaced in

order to provide for uniform substantive and procedural law, *see Beneficial*, 539 U.S. at 10, cannot exist where state law continues to apply. *Second*, as to claims within the scope of subsection (a) that do not allege willful misconduct, the statute "does not transform the plaintiff's state-law claims into federal claims but rather extinguishes them altogether." *Rivet v. Regions Bank of La.*, 522 U.S. 470, 476 (1998). In neither set of circumstances does the PREP Act ever transform state-law claims into purely federal ones, and thus the statute cannot create complete preemption. *Saldana*, 27 F.4th at 688 (concluding that these features demonstrate that "the PREP Act is not a complete preemption statute").

2. The PREP Act does not provide a federal cause of action for negligence-based claims.

In addition to failing to create a uniform substantive standard to resolve all claims relating to covered countermeasures, as NHC concedes, the PREP Act does not provide a federal cause of action for claims, like Mr. Cagle's, that are grounded in negligence. As this Court has explained, without a federal cause of action that embodies the claims at issue, "complete preemption is off the table." *Krakowski v. Allied Pilots Ass'n*, 973 F.3d 833, 837 (8th Cir. 2020).

"The scope of complete preemption turns primarily on the provision creating the federal cause of action—not on an express preemption provision." *Griffioen*, 785 F.3d at 1190. Nonetheless, NHC's complete preemption argument is based upon the latter, emphasizing how "expansive," "sweeping," and "broad" the statute's ordinary preemption provisions are. NHC Br. 28–30. But Congress's intention to eliminate liability for a broad set of claims in a wide range of scenarios is not relevant to the complete preemption inquiry. "Congress has the power to eliminate state-law remedies and causes of action without providing federal substitutes, but when it does so, the presumption is that preemption serves only as a defense, not as a basis for removal to federal court." *Griffioen*, 785 F.3d at 1192. Something more is required for complete preemption.

That something more cannot be, as NHC suggests, NHC Br. 30, the existence of the subsection (e) administrative compensation scheme. As the Third Circuit observed in rejecting similar reliance on that provision, "neither the Supreme Court nor any circuit court has extended complete preemption to a statute because it created a compensation fund." *Maglioli*, 16 F.4th at 412. Rather, as the Second Circuit explained, the

Supreme Court's *Beneficial* decision "makes clear" that "removal of state-law claims based on complete preemption becomes possible … because a federal statute with completely preemptive force also gives rise to original federal jurisdiction, and as a consequence allows removal under 28 U.S.C. § 1441." *Sullivan v. Am. Airlines, Inc.*, 424 F.3d 267, 276 (2d Cir. 2005) (discussing *Beneficial*, 539 U.S. at 8). As one scholar has put it, the federal judicial cause of action serves as "the hinge on which the door to the federal courthouse swings." Gil Seinfeld, *The Puzzle of Complete Preemption*, 155 U. Pa. L. Rev. 537, 567 (2007), *quoted in Griffioen*, 785 F.3d at 1190. An administrative remedy cannot serve as that hinge, though, because it does not provide a basis for a federal *court*'s jurisdiction.[19] Additionally, as a question of congressional intent, a

[19] In *Griffioen*, the Court expressly declined to decide whether an administrative cause of action can ever trigger complete preemption, basing its decision on the fact that the plaintiff's claims could not have been brought pursuant to the administrative cause of action at issue in that case. 785 F.3d at 1190 n.3. Some of this Court's case law can be read to suggest that the administrative mechanism in the Railway Labor Act suffices to create complete preemption, but at least one judge of this Court has suggested any such conclusion is inconsistent with the Supreme Court's decision in *Beneficial*. *See Richardson v. BNSF Ry. Co.*, 2 F.4th 1063, 1073 (8th Cir. 2021) (Colloton, J., concurring). And in dicta in a footnote in *Krakowski*, the Court has suggested that any complete preemption effect of the Railway Labor Act arises not from its

congressional decision that certain claims should be resolved outside of *any* court is not evidence that Congress intended to make those same "claims removable to federal court." *Maglioli*, 16 F.4th at 412; *see Mitchell*, 28 F.4th at 587.

The only access to federal courts created by the PREP Act comes from subsection (d), where Congress provided for adjudication of state-law claims in the District Court for the District of Columbia when specific statutory elements of "willful misconduct" are met. But that provision cannot serve as the basis for *other* federal district courts to adjudicate *other* state-law claims via the doctrine of complete preemption.[20]

As the Third, Fifth, Seventh, and Ninth Circuits agree, Congress's decision to create a federal cause of action for the adjudication of *some* countermeasure-related claims is not evidence that Congress intended to

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administrative remedies, but from the statute's provision for judicial review of those remedies. 973 F.3d at 837 n.1. The PREP Act explicitly provides, though, that there is no judicial review of any determination relating to the compensation fund. 42 U.S.C. § 239a(f)(2), *incorporated by* 42 U.S.C. § 247d-6e(b)(4).

[20] Mr. Cagle's negligence claims plainly do not allege the elements of a subsection (d) willful misconduct claim, and NHC does not suggest otherwise. *See* 42 U.S.C. § 247d-6d(c)(1) (setting out elements of willful misconduct).

provide a federal forum for the adjudication of *all* countermeasure-related claims. To the contrary, "[t]he provision of one specifically defined, exclusive federal cause of action undermines [the] argument that Congress intended the Act to completely preempt all state-law claims related to the pandemic." *Saldana*, 27 F.4th at 688. As the Fifth Circuit noted, in other statutes, Congress has created a general, federal cause of action that can be used to adjudicate whether a state-law claim is barred. *Mitchell*, 28 F.4th at 587–88 (discussing ICCTA and Air Transportation Safety and System Stabilization Act). In the PREP Act, it did not do so, choosing instead to create a federal cause of action only for claims based on a "subset of potential wrongs." *Martin*, 37 F.4th at 1213. Claims based on *other* wrongs cannot be completely preempted by that cause of action. As the Third Circuit explained, while it is true that "[t]he elements of the state cause of action need not 'precisely duplicate' the elements of the federal cause of action for complete preemption to apply," "complete preemption does not apply when federal law creates an entirely *different* cause of action from the state claims in the complaint." *Maglioli*, 16 F.4th at 411 (quoting *Davila*, 542 U.S. at 216). Claims of ordinary negligence, like those brought by Mr. Cagle, are entirely different from allegations

that a covered person acted "intentionally to achieve a wrongful purpose." 42 U.S.C. § 247d-6d(c)(1)(A)(i). Congress provided federal jurisdiction only over cases where a plaintiff asserts the latter claim.

NHC asserts that, in holding that the PREP Act's exclusive cause of action cannot completely preempt claims that could not be brought pursuant to that cause of action, the Third Circuit's *Maglioli* decision is contrary to *Davila*, because if *any* claim that implicates the PREP Act's liability protections is completely preempted, *all* such claims must be. NHC Br. 31–32. Not so. As *Davila* reaffirmed, for a claim to be completely preempted by ERISA, the key questions are whether a plaintiff "could have brought his claim under ERISA § 502(a)(1)(B)," and whether "there is no other independent legal duty that is implicated by a defendant's actions." *Davila*, 542 U.S. at 210. There, although the state-law claim had *additional* elements beyond those of a section 502(a)(1)(B) claim, the duty it sought to enforce was not independent of the terms of an ERISA plan, and there was no dispute that the claim could *also* have been brought under § 502(a)(1)(B). The Court did not suggest, however, that *any* claim against an ERISA plan was completely preempted by § 502(a)(1)(B).

In holding that a claim that could *not* have been brought pursuant to subsection (d) of the PREP Act cannot be preempted by that provision, *Maglioli* (like *Mitchell* and *Martin*) is consistent with this Court's precedent. In *Griffioen*, the Court considered whether the ICCTA completely preempted certain claims relating to the construction and maintenance of railway bridges. Like the PREP Act, that statute has a broader express preemption provision, and a narrower exclusive remedial provision. The former preempts all state remedies "with respect to regulation of rail transportation." 49 U.S.C. § 10501(b), *quoted in Griffioen*, 785 F.3d at 1189. The latter, on the other hand, provides for a cause of action before the Surface Transportation Board for "violations of the ICCTA's substantive provisions or accompanying regulations." *Griffioen*, 785 F.3d at 1191. Assuming without deciding that the administrative cause of action could completely preempt some set of claims, the Court held it could only do so with respect to claims that could be brought pursuant to that administrative cause of action, *i.e.*, as claims for violations of the ICCTA's substantive provisions. *Id.* at 1192.

Similarly, in *Krakowski*, the Court declined to find the Railway Labor Act could completely preempt a claim between an airline employee

and his union. Regardless of whether the Act substantively preempted the employee's state-law claims based on a violation of a collective-bargaining agreement, the Court held those claims could not be completely preempted because the employee could not have brought them under the Railway Labor Act's cause of action, which is only available for disputes between employees and carriers. 973 F.3d at 837.

So too here, Mr. Cagle's inability to bring his claims as PREP Act subsection (d) claims means that statute cannot completely preempt those claims.

3. No deference is owed to administrative views as to whether the statute provides for complete preemption.

NHC argues that this Court should defer to the federal government's view, as expressed in the preamble to the Fifth Amendment to the PREP Act Declaration, the HHS General Counsel Advisory Opinion 21-01, and a district court statement of interest, that the PREP Act completely preempts claims within the scope of its immunity provisions. NHC Br. 34–39.[21] But as four courts of appeals have held,

[21] NHC states that "two administrations have consistently advocated for a federal forum for PREP Act claims," NHC Br. 38, but the only document it cites that uses the phrase "complete preemption" and

those "lightly developed" views are owed no deference at all. *Maglioli*, 16 F.4th at 403; *see also Martin*, 37 F.4th at 1214; *Mitchell*, 28 F.4th at 585 n.3; *Saldana*, 27 F.4th at 687–88. As the Third Circuit explained, "the scope of federal courts' jurisdiction is a legal issue that is the province of the courts, not agencies." *Maglioli*, 16 F.4th at 404. *Cf. Iowa League of Cities v. EPA*, 711 F.3d 844, 872 (8th Cir. 2013) (stating that "the rationale for granting deference to administrative decisions is simply not applicable where the topic of [this Court's] review … is not a matter that Congress has committed to the agency's discretion," or that falls within "an area uniquely falling within [the agency's] expertise"). "Federal

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that was issued after the current administration took office is the Fifth Amendment to the Declaration, 86 Fed. Reg. 7872, 7874 (Feb. 2, 2021), *cited in* NHC Br. 37. Not only was this document signed by the Acting HHS Secretary on January 28, 2021, only one week after President Biden was sworn in, but, as several courts have explained, in context, its reference to "complete preemption" is obviously "not to the doctrine of complete preemption for purposes of federal-question jurisdiction, but rather to ordinary, defensive preemption." *Leroy v. Hume*, 554 F. Supp. 3d 470, 478 (E.D.N.Y. 2021) (citation omitted); *see also, e.g.*, *Stone v. Long Beach Healthcare Ctr., LLC*, 2021 WL 1163572, at *6 n.5 (C.D. Cal. Mar. 26, 2021). And despite the clear judicial consensus that has developed since that date, the United States has not filed a brief as amicus curiae in any of the eight courts of appeals that have considered or are considering appeals from district court decisions finding no complete preemption. *See Martin*, 37 F.4th at 1214 (noting lack of federal amicus participation). This silence is not "consistent advocacy" of NHC's view.

courts routinely conclude that no deference is owed such interpretations." *Maglioli*, 16 F.4th at 404 (collecting cases). Moreover, to the extent the cited documents provide any reasoning at all, "[t]he reasoning is thin," with little to no discussion of relevant cases. *Martin*, 37 F.4th at 1214; *see also Maglioli*, 16 F.4th at 404 ("Even if HHS has something valuable to say on the matter, we do not find it in these statements.").

III. There is no *Grable* jurisdiction.

NHC also argues that this action, and any case in which a party invokes the PREP Act as an immunity defense, falls into the "special and small category of cases in which arising under jurisdiction still lies" despite the absence of a federal-law claim, because of the presence of a substantial federal question. *Gunn v. Minton*, 568 U.S. 251, 258 (2013) (cleaned up). *See* NHC Br. 44–47. But "substantial federal question" or "*Grable*" jurisdiction exists only where a federal issue is "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn,* 568 U.S. at 258 (citing *Grable,* 545 U.S. at 313–14); *see also Great Lakes Gas Transmission Ltd. P'ship v. Essar Steel Minn. LLC*, 843 F.3d 325, 331–32 (8th Cir. 2016) (discussing four requirements).

NHC does not address the four *Grable* requirements. And as every federal appellate court to consider whether *Grable* provides jurisdiction in similar cases has concluded, these requirements are not satisfied here. *See, e.g.*, *Martin,* 37 F.4th at 1214–15; *Mitchell*, 28 F.4th at 588–89; *Saldana*, 27 F.4th at 688–89; *Maglioli*, 16 F.4th at 413.

To begin with, the *complaint* does not "necessarily raise" any issues of federal law and, therefore, raises no "substantial" or "actually disputed" issues of federal law. A federal question is necessarily raised when it is an "essential element" of a plaintiff's state-law claim. *Cent. Iowa Power Coop. v. Midwest Indep. Transmission Sys. Operator, Inc.*, 561 F.3d 904, 914 (8th Cir. 2009) (citations omitted). The well-pleaded complaint rule determines whether the federal question is such an essential element. *See Moore v. Kansas City Pub. Schs.*, 828 F.3d 687, 691–93 (8th Cir. 2016). NHC does not identify any federal question that is an element of Mr. Cagle's Missouri well-pleaded state-law claims. The sole federal question it identifies is the application of the PREP Act—a statute that, as the district court recognized, Add. 19, R. Doc. 50, at 19, NHC seeks to inject into the case as a *defense*. But a federal immunity defense, no matter how broad that defense may be, "is not a sufficient

basis to find embedded federal question jurisdiction." *Saldana*, 27 F.4th at 688; *accord Mitchell*, 28 F.4th at 589; *Maglioli*, 16 F.4th at 413. *Cf. Oglala Sioux Tribe v. C & W Enterp., Inc.*, 487 F.3d 1129, 1131–32 (8th Cir. 2007) (holding that a federal immunity defense does not create federal jurisdiction).

That "the PREP Act is a national security statute," NHC Br. 44, does not mean that all pandemic-related tort claims are "inherently federal [in] nature," and thus belong in federal court. *Id.* 45. The mere existence of a federal substantive policy interest does not create a federal question. *See Caterpillar Inc. v. Williams*, 482 U.S. 386, 399 (1987). *Grable* requires "a serious federal interest in claiming the advantages thought to be inherent in a federal forum," 545 U.S. at 313, and the mere desire to have federal courts interpret federal law is not such an interest. Crucially, "[t]he state court in which the personal-injury suit was lodged is competent to apply federal law, to the extent it is relevant." *Empire Healthchoice Assur., Inc. v. McVeigh*, 547 U.S. 677, 701 (2006). *Cf. Arbor Mgmt. Servs.*, 875 S.E.2d at 395–98 (state court application of PREP Act); *Whitehead*, 75 Misc. 3d at 991–93 (same).

This case also fails the fourth *Grable* requirement, which asks whether adjudication of the issue in federal court would disrupt the federal-state balance approved by Congress. Enforcing health-care providers' duties of care is a "bread-and-butter state court issue," *Central Iowa*, 561 F.3d at 914, as states have "special responsibility for maintaining standards among members of the licensed professions," *Gunn*, 568 U.S. at 264 (citation omitted). Shifting all malpractice claims relating to COVID-19 to federal court would ignore Congress's specific judgment in the PREP Act that federal jurisdiction extends over only a narrow category of state-law cases: claims brought by plaintiffs alleging "willful misconduct" arising out of injuries caused by the use or administration of covered countermeasures. Assuming jurisdiction over an *additional* category of state-law cases would not be "consistent with congressional judgment about the sound division of labor between state and federal courts." *Grable*, 545 U.S. at 313.

Contrary to NHC's suggestion, NHC Br. 45–46, HHS's cursory assertions that *Grable* applies are owed no deference both because the issue is one of federal-court jurisdiction, *see* *supra* p. 50, and because HHS's brief analysis is unpersuasive "given [its] conclusory invocation of

Grable without supporting legal analysis." *Thomas v. Pomona Healthcare & Wellness Ctr.*, 2022 WL 845349, at *3 (C.D. Cal. Mar. 22, 2022) (collecting cases); *see also Maglioli*, 16 F.4th at 403–04.

IV. NHC is not entitled to invoke federal-officer removal jurisdiction.

Finally, NHC contends federal jurisdiction was appropriate under the federal-officer removal statute. The conclusory arguments NHC presents have been rejected not only by four courts of appeals in cases involving nursing homes, but also by this Court in a recent decision addressing a similar context.

To establish jurisdiction under 28 U.S.C. § 1442(a)(1), a private party must show "(1) it acted under the direction of a federal officer, (2) there is a causal connection between [its] actions and the official authority, (3) [it] has a colorable federal defense to the plaintiffs' claims, and (4) [it] is a 'person,' within the meaning of the statute." *Buljic*, 22 F.4th at 738. NHC has not met its burden as to the first three elements.

A. NHC was not acting under federal officer direction.

"[N]ot all relationships between private entities and the federal government satisfy" the "acting under" requirement of the statute. *Id.* Rather, a private entity must be involved in "an effort to *assist*, or to help

carry out, the duties or tasks of the federal superior." *Watson*, 551 U.S. at 152. "[T]he help or assistance necessary to bring a private person within the scope of the statute does *not* include simply *complying* with the law," and thus "compliance (or noncompliance) with federal laws, rules, and regulations" does not meet the statutory requirement, "even if the regulation is highly detailed and even if the private firm's activities are highly supervised and monitored." *Id.* at 152–153.

Despite the Supreme Court's holding in *Watson*, NHC argues that federal regulation of "long-term care facilities, skilled nursing facilities, nursing homes, and the healthcare personnel working there" somehow meets the statutory standard, because that regulation was "complex, unprecedented, and has pervaded virtually every aspect of the day-to-day operations of these facilities." NHC Br. 50. But even if this claim of pervasive regulation, for which NHC cites nothing but a CMS document that is directed at state agencies and is specifically described as "guidance,"[22] were true, "[t]he fact that an entity … is subject to pervasive

[22] CMS, Ref: QSO-20-28-NH, Nursing Home Five Star Quality Rating System updates, Nursing Home Staff Counts, and Frequently Asked Questions (Apr. 24, 2020), https://www.cms.gov/files/document/qso-20-28-nh.pdf (revised version cited in NHC Br. 50).

federal regulation alone is not sufficient to confer federal jurisdiction." *Buljic*, 22 F.4th at 739. By statute and regulation, facilities like NHC are heavily regulated by the federal government as a condition of their receipt of Medicare and Medicaid funding, including with respect to infection control. *See, e.g.*, 42 U.S.C. §§ 1395i-3(d)(3)(A), 1396r(d)(3)(A); 42 C.F.R. § 483.80. Even if the federal government issued *more* directives to regulated entities as a result of the pandemic, it was not asserting a different kind of control than it previously had under these laws. *See Martin*, 37 F.4th at 1212–13; *Mitchell*, 28 F.4th at 590–91; *Saldana*, 27 F.4th at 685; *Maglioli*, 16 F.4th at 405–06; *see also* Add. 22–23, R. Doc. 50, at 22–23 (collecting cases). Any difference in the relationship between regulators and NHC before and after the onset of the pandemic was "one of degree, not kind." *Watson*, 551 U.S. at 157.

NHC also cannot rely on the fact that nursing homes, like participants in dozens of other industries, were designated "critical infrastructure" by a 2013 federal emergency planning document. NHC Br. 50. In *Buljic*, this Court explicitly held that such a designation—there, for participants in the food and agriculture sector—is not evidence of a subservient relationship like that required to fulfill the "acting

under" element of the statute. "[T]hat an industry is considered critical does not necessarily mean that every entity within it fulfills a basic governmental task or that workers within that industry are acting under the direction of federal officers." 22 F.4th at 740. Particularly given that the 2013 document "identified scores of categories of workers, including dentists, automotive repair workers, news reporters, and funeral home workers," "[i]t cannot be that the federal government's mere designation of an industry as important—or even critical—is sufficient to federalize an entity's operations and confer federal jurisdiction." *Id.*; *see also Mitchell*, 28 F.4th at 590 (rejecting "critical infrastructure" argument); *Saldana*, 27 F.4th at 685 (same); *Maglioli*, 16 F.4th at 406 (same). NHC makes no effort to distinguish *Buljic*, and its holding plainly governs.

NHC additionally suggests that the PREP Act and the Secretary's declaration somehow brought it under the direction of a federal officer. NHC Br. 50–51. This argument appears to rest on the notion that NHC, like any other nursing home operator, could qualify as a "program planner" under the statute. But while "program planners" may qualify for PREP Act immunity, 42 U.S.C. § 247d-6d(i)(2)(B)(iii), no statutory provision, or anything else, delegates authority or otherwise places all

"program planners" into a subservient relationship with the federal government. Given the broad statutory definition of "program planner" to include virtually every state, local, and tribal government and public health employee thereof, *id.* § 247d-6d(i)(6), such a delegation would be a massive disruption of our federal scheme. *Cf. Maglioli*, 16 F.4th at 400 ("There is no COVID-19 exception to federalism."). The notion that the pandemic response brought nursing homes under the control of the federal government is also flatly inconsistent with the repeated, explicit statements of federal agencies that emphasized the primacy of state and local regulators, discussed above. *See supra* p. 8.

B. There is no connection between NHC's negligence and official authority.

Since NHC "was not 'acting under' federal authority," it cannot satisfy the second element of the statute, a causal connection between such actions and the injuries alleged. *Graves v. 3M Co.*, 17 F.4th 764, 769 (8th Cir. 2021). Moreover, NHC is not being sued for actions it undertook pursuant to guidance issued by federal agencies. If anything, it is being sued for *ignoring* state and federal guidance. *See, e.g.*, App. 52, R. Doc. 1-1, at 11. NHC's unsupported assertion in its brief that it "carr[ied] out

CDC, CMS, and HHS directives," and that doing so caused Willis's death, NHC Br. 53, does not meet NHC's burden.

C. NHC lacks a colorable federal defense.

Lastly, NHC lacks a colorable federal defense. The only such defense NHC invokes is the PREP Act's immunity defense. *See* NHC Br. 55. But, as explained above, at 10–11, the complaint does not allege that Willis's death had 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). Mr. Cagle's claims are "not even arguably preempted" by the PREP Act. *Martin*, 37 F.4th at 1213.

CONCLUSION

The Court should affirm the decision below.

Respectfully submitted,

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1. 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), it contains 12,228 words.

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December 28, 2022

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I hereby certify that on December 28, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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