No. 21-3836

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

LAURA HUDAK, Executrix of the Estate of William P. Koballa,
Plaintiff-Appellee,

v.

ELMCROFT OF SAGAMORE HILLS, ELMCROFT BY ECLIPSE SENIOR LIVING, ECLIPSE SENIOR LIVING, INC., ECLIPSE PORTFOLIO OPERATIONS, LLC, ECLIPSE PORTFOLIO OPERATIONS II, LLC, and JAMIE ASHLEY COHEN,
Defendants-Appellants.

On Appeal from the United States District Court
for the Northern District of Ohio, Eastern Division
No. 5:21-cv-0060
Hon. Sara Lioi, District Judge

BRIEF OF PLAINTIFF-APPELLEE LAURA HUDAK

Patrick T. Murphy
Christian D. Foisy
DWORKEN & BERNSTEIN CO., L.P.A.
1468 W. 9th Street
Suite 135
Cleveland, OH 44113

Adam R. Pulver
Allison M. Zieve
Scott L. Nelson
PUBLIC CITIZEN
LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
(202) 588-1000

Counsel for Plaintiff-Appellee

July 19, 2022

STATEMENT IN SUPPORT OF ORAL ARGUMENT

Appellee believes that oral argument would assist the Court in its consideration of the issues presented in this appeal. Appellants, relying on sweeping assertions unsupported by precedent, cited documents, or the record below, ask this Court to adopt theories of complete preemption, embedded federal question jurisdiction, and federal-officer jurisdiction expressly rejected by four circuit courts of appeals. They recast the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. §§ 247d-6d, 247d-6e, which creates limitations on liability and an administrative compensation scheme applicable in narrow scenarios, as both a congressional directive that all state-law claims relating to pandemics belong in federal court, and a mechanism by which the federal government took control of state and local public health authorities and the private entities they regulate. Appellants also ignore the facts alleged, the nature of the state-law claims actually brought, and the procedural history of the case. Oral argument would likely assist the Court in understanding the many legal issues and the factual background.

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Disclosure of Corporate Affiliations and Financial Interest

Sixth Circuit
Case Number: 21-2836 Case Name: Hudak v. Elmcroft of Sagamore Hills

Name of counsel: Adam R. Pulver

Pursuant to 6th Cir. R. 26.1, Laura Hudak, Executrix of the Estate of William P. Koballa
Name of Party
makes the following disclosure:

1. Is said party a subsidiary or affiliate of a publicly owned corporation? If Yes, list below the identity of the parent corporation or affiliate and the relationship between it and the named party:

No

2. Is there a publicly owned corporation, not a party to the appeal, that has a financial interest in the outcome? If yes, list the identity of such corporation and the nature of the financial interest:

No

CERTIFICATE OF SERVICE

I certify that on July 19, 2022 the foregoing document was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by placing a true and correct copy in the United States mail, postage prepaid, to their address of record.

s/Adam R. Pulver
Public Citizen Litigation Group

This statement is filed twice: when the appeal is initially opened and later, in the principal briefs, immediately preceding the table of contents. See 6th Cir. R. 26.1 on page 2 of this form.

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STATEMENT OF JURISDICTION

As explained below, at 21–23, this Court lacks appellate jurisdiction. Because this action was not "removed pursuant to [28 U.S.C.] section 1442 or 1443," the district court's remand order is not reviewable. 28 U.S.C. § 1447(d).

The district court correctly concluded that it lacked subject-matter jurisdiction.

STATEMENT OF ISSUES

1. Whether a passing reference to "original jurisdiction" "pursuant to 28 U.S.C. § 1442(a)(1)" in a removal notice is sufficient to render a remand order appealable under 28 U.S.C. § 1447(d).

2. Whether claims that an assisted living facility resident's death from COVID-19 resulted from the facility's failure to adopt adequate infection-control measures are claims based on an injury with a "causal relationship with the administration to or use by an individual of a covered countermeasure" and thus within the ambit of the PREP Act.

3. Whether the PREP Act completely preempts all claims concerning pandemic infection control.

4. Whether Appellants forfeited their embedded federal question jurisdiction argument by failing to raise it in opposing remand and, if not, whether assertion of a PREP Act immunity defense is sufficient to create such jurisdiction.

5. Whether Appellants forfeited their federal-officer removal jurisdiction argument by failing to raise it in opposing remand and/or inadequately pleading it in their notice of removal.

6. Whether non-binding recommendations from federal agencies, the PREP Act, or state agency regulatory supervision converted assisted living facilities into entities "acting under" federal officers for purposes of 28 U.S.C. § 1442(a)(1).

STATEMENT OF THE CASE

I. 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 Apr. 13, 2022).[1]

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," 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 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 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).

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

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). For claims within the carve-out, the statute creates an "exclusive Federal cause of action," *id.*, 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 compensation scheme, available only for injuries "directly caused by the administration or use of a covered countermeasure." 42 U.S.C. § 247d-6e(a). HHS regulations confirm that compensation is limited to "injured countermeasure recipients" and their survivors, 42 C.F.R. § 110.10(a), and excludes "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 "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 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 Office of General Counsel (OGC). *Id.* at 79,191 & n.5. In one of those opinions, OGC had 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. OGC, Advisory Opinion 20-04, at 4 (Oct. 22, 2020, as modified on Oct. 23, 2020).[2]

On January 6, 2021, OGC issued Advisory Opinion 21-01, which opined that "the PREP Act is a [c]omplete [p]reemption statute" and that it applies to situations where a covered person makes a decision regarding allocation of covered countermeasures that "results in non-use

[2] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO4.2_Updated_FINAL_SIGNED_10.23.20-2.pdf

by some individuals," but *not* where non-use was the result of "nonfeasance." RE 6-1, PageID #88–90. It also asserted that "substantial federal question" jurisdiction, recognized in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), applies to any case where a defendant invokes the PREP Act. *Id.* PageID #90–91. Like the previous advisory opinions, it stated that it "sets forth the current views" of OGC, is "not a final agency action or a final order," and "does not have the force or effect of law." *Id.* PageID #91.

II. The Federal-State Pandemic Response

Since January 2020, federal agencies have issued guidance on best practices to reduce COVID-19's spread and the applicability of existing regulations. Guidance by HHS's Centers for Disease Control and Prevention (CDC) and Centers for Medicare and Medicaid Services (CMS) about infection control in long-term care settings reflected the expectation that state and local governments would retain their roles as primary protectors of public health. *See, e.g.*, CDC & CMS, COVID-19 Long-Term Care Facility Guidance (LTC Guidance) (Apr. 2, 2020)[3]; CDC,

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

Coronavirus Disease 2019 (COVID-19) Preparedness Checklist for Nursing Homes and other Long-Term Care Settings (Preparedness Checklist) (Mar. 13, 2020).[4] 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 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*, March 2022 (Version 26) (compiling "many creative plans that state governments and other entities have put into operation").[5]

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

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

Consistent with HHS's expectations, Ohio took several actions to address COVID-19 in care facilities. In March 2020, Governor DeWine declared a state of emergency. Ohio Exec. Order 2020-01D.[6] The Directors of the Ohio Department of Health (ODH) and the Ohio Department of Veterans Services then issued a joint order limiting access to care facilities and mandating screening and other infection control measures. In Re: Order to Limit Access to Ohio's Nursing Homes and Similar Facilities (Mar. 11, 2020).[7] Four state agencies jointly issued guidance for care facilities, addressing personal protective equipment and COVID-19 screening and treatment practices. *See* Ohio Dep't of Aging, et al., Pre-Surge Planning Toolkit for Providers of Long Term Services and Supports (LTSS) (Apr. 3, 2020).[8] And ODH issued an order regarding notification of COVID-19 cases at residential care facilities.

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[6] https://governor.ohio.gov/media/executive-orders/executive-order-2020-01-d.

[7] https://content.govdelivery.com/attachments/OHOOD/2020/03/12/file_attachments/1398815/ODH%20Order%20on%20Nursing%20Homes.pdf.

[8] https://www.ohca.org/docs/documents/5963/COVID-19_LTSS_FINAL_Pre-surge_Planning_Toolkit_4-3-20_-_FINAL.pdf.

ODH, Director's Order to Facilities to Notify Residents, Guardians and Sponsor of Positive or Probable Cases of COVID-19 (Apr. 15, 2020).[9]

III. Elmcroft's Negligent Care and the Resulting Death of Mr. Koballa

Defendants-Appellants, collectively, "Elmcroft," operated a residential care facility in Northfield, Ohio. Compl., RE 1-1, PageID #25. William Koballa lived there with his wife Nancy from 2016 until his May 2020 death. *Id.* PageID #18, 19.

In response to the COVID-19 pandemic, in April 2020, Elmcroft adopted infection-control protocols, including limiting visits and group activities, and mandating mask and glove wearing by Elmcroft employees. *Id.* PageID #19–20. Elmcroft, however, did not follow its own protocols or those mandated by ODH. *Id.* PageID #22.

On May 4, 2020, Mrs. Koballa reported to Elmcroft staff that her husband had been coughing the previous night. *Id.* PageID #20. The following day, he began experiencing gastrointestinal issues. *Id.* At the time, Elmcroft told one of Mr. Koballa's daughters, plaintiff-appellee Laura Hudak that her father had seen a nurse practitioner and doctor

[9] https://www.ohca.org/docs/documents/5963/SignedNursingHomeOrder-041520.pdf.

and been thoroughly assessed. *Id.* Mr. Koballa had not actually seen either one. *Id.*

Mr. Koballa's health continued to deteriorate, and he displayed impaired mobility and speech—eventually becoming unable to walk or feed himself. *Id.* PageID #20–21. Yet Elmcroft continued to falsely inform Mr. Koballa's daughters that he was doing well. *Id.* PageID #21. Mr. Koballa's daughters came to the facility on May 10, 2020, were shocked by his condition, and demanded that he be transported to a hospital. *Id.* The emergency medical technicians who transported Mr. Koballa to the hospital noted that Elmcroft staff were not wearing masks. *Id.* PageID #20, 22.

At the hospital, Mr. Koballa tested positive for COVID-19 and was immediately placed in intensive care. *Id.* PageID #22. Nine days later, he died of hypoxia and COVID pneumonia. *Id.*

IV. Procedural History

A. Ms. Hudak's Complaint

As Executrix of her father's estate, Ms. Hudak commenced this action in the Court of Common Pleas, Summit County, Ohio, on December 11, 2020. *See* Notice of Removal (NOR), RE 1, PageID #2.

The first count of her complaint, labeled "Negligence," alleges that Elmcroft was "negligent in the care, services and treatment provided to" her father, citing Elmcroft's failure to properly assess its ability to provide him with suitable care and/or transfer him to a facility that could do so. *Id.* PageID #23.

The second count, labeled "Reckless, Intentional, Willful and Wanton Misconduct," alleges that Elmcroft acted with "reckless disregard for the consequences so as to affect the life or health of" Mr. Koballa and other Elmcroft residents, constituting "intentional misconduct or willful or wanton misconduct" under Ohio law. *Id.* PageID #23–24.

The third count, "Survivorship Claim," alleges that Mr. Koballa suffered injuries as a result of Elmcroft's wrongs, and the fourth (mistakenly labeled a second "Count Three"), "Wrongful Death," alleges injuries suffered by Mr. Koballa's next of kin. *Id.* PageID #24.

The next count alleges that Elmcroft violated multiple provisions of the Ohio Nursing Home Patient's Bill of Rights, and invokes the right of action provided by Revised Code § 3721.17(I). *Id.* PageID #25. The complaint alleges that Elmcroft violated its duties to provide Mr. Koballa

with necessary and appropriate care, Revised Code § 3721.13(A)(3), and to ensure that he would be free from physical, verbal, mental and emotional abuse, Revised Code § 3721.13(A)(2). *Id.*

The last count requests punitive damages. *Id.* PageID #26.

B. Elmcroft's Removal Notice

On January 8, 2021, Elmcroft removed the action to the District Court for the Northern District of Ohio, asserting that the action was "properly removed" because it "alleges a federal question pursuant to the December 3, 2020 amendment of the [PREP Act Declaration], 85 Fed. Reg. 79190." NOR, RE 1, PageID #1–2. The notice contained four numbered headings: "Statement of the Case," "Procedural Requirements," "COVID-19 and the PREP Act," and "Argument and Citation to Authority." NOR, RE 1. In the first section, Elmcroft asserted that the action arose "from alleged misconduct by a covered person in the administration of a covered countermeasure under the [PREP Act]." *Id.* PageID #2–3. In the second section, Elmcroft addressed procedural requirements of 28 U.S.C. § 1446. *Id.* PageID #3. In the third section, Elmcroft opined on the history and meaning of the PREP Act. *Id.* PageID

#4–5. In the fourth section, Elmcroft discussed its theory of complete preemption under the PREP Act. *Id.* PageID #6–12.

The notice's only reference to 28 U.S.C. § 1442 appears in that fourth section, stating:

> This case is removable under 28 U.S.C.A. § 1441(a) on the basis of "original jurisdiction" because Plaintiff's Complaint asserts a claim "arising under" federal law within the meaning of § 1331. Original jurisdiction is also through an action pursuant to 28 U.S.C. §1442(a)(1). The Court also has supplemental jurisdiction over state law claims under 28 U.S.C. § 1367.

Id. PageID #6. The remainder of the "Argument" section solely addresses federal-question jurisdiction under 28 U.S.C. § 1331. *Id.* PageID #6–12.

The Notice concludes with a request that the district court exercise jurisdiction because Elmcroft "has shown that this case is properly removable on the basis of federal question jurisdiction." *Id.* PageID #12.

C. Remand Proceedings

On February 3, 2021, Ms. Hudak moved to remand the action to state court. Remand Mot., RE 8. She argued that federal-question jurisdiction did not exist because her claims "do not fall under the purview of the PREP Act" and thus the PREP Act could not completely preempt her claims. *Id.* PageID #135–41.

Elmcroft opposed remand, arguing that complete preemption by the PREP Act created jurisdiction. Remand Opp'n, RE 24, PageID #327–51. Elmcroft made no reference to *Grable*, embedded federal-question jurisdiction, or federal-officer removal jurisdiction. *Id.*

The district court granted the remand motion on August 19, 2021. Order of Remand (Order), RE 31, PageID #453. "[J]oin[ing] it[s] sister district courts within the Sixth Circuit, and district courts around the country," the district court rejected Elmcroft's complete preemption argument. *Id.* PageID #464, 468.[10] The court noted that "the PREP Act does not provide a federal cause of action for covered claims," but rather immunity, and thus does not meet the complete preemption standard. *Id.* PageID #465. The court also rejected Elmcroft's argument that the administrative compensation scheme created complete preemption. *Id.* PageID #466–67. The court declined to defer to HHS's view expressed in AO 21-01, finding the statute's plain meaning unambiguous and the opinion's reasoning "neither reasonable nor persuasive." *Id.* PageID #472. It also noted that *Chevron* deference does not apply to advisory

[10] In light of this holding, the court found it unnecessary to address "whether plaintiff's claims fall under the purview of the PREP Act." Order, RE 31, PageID #463.

opinions and that "HHS lacks authority to interpret the jurisdiction of the federal courts." *Id.* PageID #473–74 (citations omitted).

Observing that Elmcroft had cited the "substantial federal question" doctrine in its removal notice, the court found it inapplicable because the complaint "d[id] not necessarily raise an issue of federal law," as "[n]one of plaintiff's claims are premised upon the PREP Act, nor is any component of the PREP Act an element of her claims." *Id.* PageID #475, 477.

Finally, the district court observed that, although the removal notice referenced 28 U.S.C. § 1442(a)(1), no party had addressed it in briefing on the remand motion. *Id.* PageID #480. "To the extent that the removing defendants have not abandoned this statute as a basis for this Court's jurisdiction," the court stated, "they have failed to show at a minimum that, as private parties, they are persons 'acting under' a federal officer for purposes of establishing this Court's jurisdiction under the statute." *Id.* (citing *Dupervil v. Alliance Health Ops., LLC*, 516 F. Supp. 3d 238, 259–61 (E.D.N.Y. 2021)).

D. Proceedings in this Court

Elmcroft appealed the remand. Ms. Hudak moved to dismiss for lack of appellate jurisdiction, asserting that Elmcroft's abandonment of any federal-officer removal argument in opposing remand deprived it of the right to appeal under 28 U.S.C. § 1447(d). Motion to Dismiss (Document 12) at 2. Without deciding whether Elmcroft had forfeited any arguments, a motions panel denied the motion to dismiss, holding that section 1447(d) did not "require affirmative argument or a judicial determination that removal is authorized under § 1442 or § 1443" for a remand order to be appealable. Mar. 25, 2022 Order (Document 17-1) at 2.

SUMMARY OF ARGUMENT

I. Pursuant to 28 U.S.C. § 1447(d), this Court lacks jurisdiction to review the district court's remand. Elmcroft's removal notice repeatedly asserted that, pursuant to 28 U.S.C. § 1441(a), the action was "removable" to federal court by virtue of federal-question jurisdiction. A passing reference in the "argument" section of the notice to "original jurisdiction" under 28 U.S.C. § 1442 is insufficient to trigger section 1447(d)'s exception for cases removed "pursuant to" section 1442.

II. Like the Third, Fifth, Seventh, and Ninth Circuits and district courts across the country have done in similar cases, this Court should reject Elmcroft's argument that its intent to raise a PREP Act defense to Ms. Hudak's state-law claims creates federal subject-matter jurisdiction.

A. Elmcroft argues that subsection (e)(1) of the PREP Act, which provides exclusive federal jurisdiction for claims brought pursuant to subsection (d)'s cause of action, *expressly* provides removal jurisdiction. That novel argument cannot help Elmcroft here. Ms. Hudak's complaint contains no subsection (d) cause of action.

B. For three reasons, the PREP Act does not completely preempt Ms. Hudak's claims.

First, PREP Act immunity and the subsection (d) exception to immunity extend only to claims based on injuries with a "causal relationship" to "the administration or use of a covered countermeasure by an individual." Neither has any application to Ms. Hudak's claims, which are not based on administration or use of covered countermeasures, but on allegations that Elmcroft failed to adopt and implement adequate infection-control policies and provided substandard care to Mr. Koballa after he contracted COVID-19.

Second, unlike statutes found to have complete preemptive effect, the PREP Act does not replace substantive state law with federal rights and duties. And, as four courts of appeals have held, Congress's creation of a federal cause of action for "willful misconduct" claims does not provide a basis to convert *other* kinds of covered countermeasure claims into federal claims, as is required for complete preemption.

C. By failing to raise the "embedded federal question" doctrine in the district court, Elmcroft has forfeited any such argument. The argument also fails on the merits given well-established precedent that a defendant's intent to assert a federal defense does not make a federal question an "essential element" of a state-law claim. Federal jurisdiction over all pandemic-related claims would massively disrupt the balance of responsibility between state and federal courts.

III. Like every federal court to have addressed the argument in similar cases, this Court should reject Elmcroft's argument that it was "acting under" federal officers and entitled to removal on that basis.

To begin with, the argument is not properly before this Court. First, Elmcroft did not raise section 1442(a)(1) in opposing the remand motion, and it has thus forfeited that argument. Second, the argument Elmcroft

seeks to make is beyond the scope of its removal notice, which failed to include the required short statement of facts supporting each element of jurisdiction. Elmcroft cannot remedy this failure by introducing new theories of federal-officer control, not fairly alleged in its removal notice, on appeal.

On the merits, Elmcroft fails to establish any of the elements of federal-officer removal jurisdiction recognized by this Court's precedent. Neither federal agency guidance, Elmcroft's potential qualification for PREP Act immunity as a "program planner," nor Elmcroft's regulation by ODH demonstrate that it was in a subservient role to a federal officer, as required to meet the "acting under" element of 28 U.S.C. § 1442(a)(1). Elmcroft is also not being sued for acts it took under purported federal officer direction. Finally, because the PREP Act defense does not even arguably apply, Elmcroft has not established the colorable federal defense required for federal-officer removal.

STANDARD OF REVIEW

"[T]he party requesting a federal forum…bears the burden of establishing federal jurisdiction." *Siding & Insulation Co. v. Acuity Mut. Ins. Co.*, 754 F.3d 367, 368 (6th Cir. 2014). This Court reviews *de novo* a

district court's ruling that the burden has not been met. *See Mays v. City of Flint, Mich.*, 871 F.3d 437, 442 (6th Cir. 2017).

ARGUMENT

I. The Court lacks jurisdiction over this appeal.

28 U.S.C. § 1447(d) allows review of an order rejecting an assertion of removal jurisdiction only where the order "remand[s] a case to the State court from which it was removed pursuant to [28 U.S.C.] section 1442 or 1443." To fall within this exception, "a defendant's notice of removal must assert the case is *removable* in accordance with or by reason of" either section 1442 or 1443. *BP P.L.C. v. Mayor & City Council of Balt.*, 141 S. Ct. 1532, 1538 (2021) (cleaned up; emphasis added). Here, the removal notice made no such assertion. Throughout, Elmcroft asserted federal-question jurisdiction pursuant to 28 U.S.C. § 1441(a) as the source of removability. *See, e.g.*, NOR, RE 1, PageID #1–2 (asserting action "alleges a federal question…and therefore is properly removed"); PageID #12 ("Wherefore, having shown that this case is properly removable on the basis of federal question jurisdiction…"). It never referenced removability pursuant to section 1442; its single oblique reference to the statute was in the "argument" section of the notice, where

it noted that "original jurisdiction" existed under that statute, alongside a reference to supplemental jurisdiction under 28 U.S.C. § 1367. This passing reference does not render the case "removed pursuant to" section 1442.[11]

As one district court noted in addressing the same language in another case, the reference to section 1442 "is nearly impossible to parse." *Estate of Spring v. Montefiore Home*, 2022 WL 1120381, at *6 n.2 (N.D. Ohio Apr. 14, 2022). To the extent it is intelligible, the sentence citing section 1442 refers to that provision (incorrectly) only as a basis for "original jurisdiction" under section 1441(a). But original jurisdiction is distinct from *removal* jurisdiction, which is all that section 1442(a)(1) provides.

Moreover, courts have repeatedly held that a defendant must do more than merely reference a statute or doctrine in its notice of removal to preserve a basis of jurisdiction. *See Cty. of San Mateo v. Chevron Corp.*,

[11] This Court previously denied Ms. Hudak's motion to dismiss based on Elmcroft's failure to invoke the federal-officer removal statute in opposing remand. *See* Mar. 25, 2022 Order. Her argument here, though, is based on Elmcroft's removal notice—not Elmcroft's subsequent litigation choices. Moreover, a motions panel's ruling "is not the law of the case [where] it involves a jurisdictional question." *In re Bli Farms*, 465 F.3d 654, 658 n.2 (6th Cir. 2006).

32 F.4th 733, 763 n.23 (9th Cir. 2022) (holding that a "reference to 'federal common law'" in removal notice was insufficient to invoke admiralty jurisdiction); *Sonoma Falls Developers, LLC v. Nev. Gold & Casinos, Inc.*, 272 F. Supp. 2d 919, 925 (N.D. Cal. 2003) (holding reference to federal statute in "background and facts" section of notice was not invocation of federal-question jurisdiction); *Thompson v. Gulf Stream Coach, Inc.*, 2007 WL 2413108, at *2–3 (W.D. Mich. Aug. 21, 2007) (holding notice did not invoke federal-question jurisdiction where it explicitly cited diversity as the basis for removal).

As *BP* indicates, the only relevant question in determining whether the remand order is appealable under 1447(d) is whether Elmcroft asserted that section 1442 made the action removable. Elmcroft made no such assertion, nor did it include any allegations of the elements of federal-officer removal (or any legal argument supporting it). Thus, the Court lacks appellate jurisdiction.

II. Ms. Hudak's claims do not arise under federal law.

Although Ms. Hudak brings claims only under Ohio law, Elmcroft argues that her claims arise under federal law for purposes of 28 U.S.C. § 1331 under three different theories tied to the PREP Act. First,

Elmcroft argues that the PREP Act *expressly* divested Ohio courts of jurisdiction over Ms. Hudak's claims. Second, Elmcroft asserts that the claims are completely preempted. Third, it argues that the claims fall within the narrow "embedded federal question" doctrine. All three arguments are wrong.

A. Elmcroft's new "express" jurisdiction argument lacks merit.

For the first time, Elmcroft argues that subsection (e)(1) "expressly provides for exclusive federal jurisdiction" over this action. Appellants' Br. 25. But that provision only provides for exclusive federal jurisdiction over "any action under subsection (d)" of the Act. 42 U.S.C. § 247d-6d(e)(1). It does not "expressly" provide for jurisdiction over any state-law causes of action—unlike the Price-Anderson Act, which expressly provides for removal of any "public liability action." *Matthews v. Centrus Energy Corp.*, 15 F.4th 714, 721 (6th Cir. 2021). Ms. Hudak's complaint does not include a subsection (d) claim, and thus subsection (e)(1) is only relevant if an exception to the well-pleaded complaint rule, like complete preemption, applies. *See Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987).

B. The PREP Act does not completely preempt Ms. Hudak's claims.

"[A]n exception to the well-pleaded complaint rule arises from the misleadingly named doctrine of complete preemption, which is more aptly described as a jurisdictional doctrine." *Hogan v. Jacobson*, 823 F.3d 872, 879 (6th Cir. 2016) (cleaned up). That doctrine applies "where the pre-emptive force of a statute is so 'extraordinary,' that it 'converts an ordinary state common-law complaint into one stating a federal claim for purposes of the well-pleaded complaint rule.'" *Matthews*, 15 F.4th at 720 (quoting *Caterpillar*, 482 U.S. at 393). Establishing complete preemption is "exceedingly difficult," requiring "clear congressional intent," *Miller v. Bruenger*, 949 F.3d 986, 995 (6th Cir. 2020), "not merely to preempt a certain amount of state law, but also to transfer jurisdiction to decide the preemption question from state to federal courts," *Musson Theatrical, Inc. v. Fed. Exp. Corp.*, 89 F.3d 1244, 1253 (6th Cir. 1996), *amended by* 1998 WL 117980 (6th Cir. Jan. 15, 1998). "Without evidence of Congress's intent to transfer jurisdiction to federal courts, there is no basis for invoking federal judicial power." *Id.* As dozens of courts have concluded, the PREP Act does not reflect Congress's intent to transfer claims like Ms. Hudak's to federal courts.

1. Ms. Hudak's claims are not within the ambit of the PREP Act.

Ms. Hudak's "claims do not fall under the PREP Act, thus making it irrelevant whether the PREP Act is a complete preemption statute." *Thomas v. Century Villa Inc.*, 2021 WL 2400970, at *4 (C.D. Cal. June 10, 2021). Subsection (a)(1)'s immunity and the exception to that immunity provided for in subsection (d) of the Act 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). And Ms. Hudak does *not* allege that her father died because of the "administration to or use by an individual of a covered countermeasure." She alleges that her father died because Elmcroft failed to "follow infection control procedures" and because it provided Mr. Koballa deficient medical and custodial care. Compl., RE 1-1, PageID #22–23; *see also Alongi v. Ford Motor Co.,* 386 F.3d 716, 727 (6th Cir. 2004) ("[T]he complete preemption doctrine does not abrogate the federal courts' traditional focus on the complaint, in deciding questions of removal jurisdiction."). As the Seventh Circuit recently held, claims like these "are not even arguably preempted" by the PREP Act. *Martin v. Petersen Health Ops., LLC*, 37 F.4th 1210, 1213 (7th Cir. 2022); *accord*

Manyweather v. Woodlawn Manor, Inc., 2022 WL 2525732, at *5 (5th Cir. July 7, 2022) (holding similar claims are outside PREP Act's scope). 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 Sq. Retirement & Assisted Living*, 537 F. Supp. 3d 1231, 1240 (D. Colo. 2021).[12] The only relationship that such claims conceivably have with covered countermeasures is with their *non*-use—contrary to, not consistent with, the Secretary's recommendations. As Judge Easterbrook explained in *Martin*, an allegation of *non*-use "is

[12] *Accord, e.g., Arbor Mgmt. Servs., LLC v. Hendrix*, 2022 WL 2234983, at *4 (Ga. Ct. App. June 22, 2022); *Whitehead v. Pine Haven Operating LLC*, 2022 WL 2071025, at *4 (N.Y. Sup. Ct. June 8, 2022); *Harris v. Allison*, 2022 WL 2232525, at *9–10 (N.D. Cal. May 18, 2022); *Spring*, 2022 WL 1120381, at *4–5; *Hampton v. California*, 2022 WL 838122, at *10–11 (N.D. Cal. Mar. 20, 2022); *Rosen v. Montefiore*, 2022 WL 278106, at *4 (N.D. Ohio Jan. 31, 2022); *Ruiz v. ConAgra Foods Packaged Foods, LLC*, 2021 WL 3056275, at *4 (E.D. Wisc. July 20, 2021); *Roderick v. Life Care Centers of Am.*, 2021 WL 6337496, at *2 (E.D. Tenn. Apr. 30, 2021); *Stone v. Long Beach Healthcare Ctr.*, 2021 WL 1163572, at *4–5 (C.D. Cal. Mar. 26, 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*, 516 F. Supp. 3d at 255–56; *Eaton v. Big Blue Healthcare*, 480 F. Supp. 3d 1184, 1192–95 (D. Kan. 2020).

the opposite of a contention that a covered countermeasure caused harm." 37 F.4th at 1214. And the statutory text and purpose make clear that the PREP Act applies only where a plaintiff claims that *use* of a covered countermeasure caused injury.

a. The statutory text limits its applicability to claims with a causal relationship to actual use of covered countermeasures.

"Statutory interpretation … begins with the text." *Ross v. Blake*, 578 U.S. 632, 638 (2016). This "approach 'calls on the judicial interpreter to consider the entire text, in view of its structure and of the physical and logical relation of its many parts.'" *Hueso v. Barnhart*, 948 F.3d 324, 333 (6th Cir. 2020) (quoting Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 167 (2012)). Here, the PREP Act's text makes plain that only claims with a causal relationship to actual use of covered countermeasures fall within the statute's scope. *See* 42 U.S.C. § 247d-6d(a)(2)(b).

Elmcroft's suggestion that the phrase "administration or use" expands the statute to all claims relating to COVID-19 infection-control policies ignores important words in the text. *See* Appellants' Br. 16 (citing 42 U.S.C. §§ 247d-6d(c)(1)(A), (c)(2)(A), (e)(3)(A)). Whereas Elmcroft cites

definitional and procedural sections, the substantive provisions state that liability protections apply to 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). These words show that Elmcroft relies on an incorrect meaning of the word "administration." 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.com Dictionary.[13] Elmcroft appears to invoke the former definition. But when the provision is read as a whole, 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 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. And, as the Fifth Circuit has held, although the term "relating to" is broad, it must be construed in accordance with the "scope of claims for loss" provision—which requires a "causal relationship with the administration to or use by an individual of a covered

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

countermeasure" for the statute to apply. 42 U.S.C. § 247d-6d(a)(2)(B). *Manyweather,* 2022 WL 2525732, at *5. A relationship with *non*-use of countermeasures is insufficient. *See id.*

While Elmcroft points to subsection (e)(3), which uses the phrase "act or omission," that section supports Ms. Hudak's reading. It sets out pleading standards for willful misconduct claims, requiring a plaintiff 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). The inclusion of "act or omission" does not change that the covered countermeasure must have been "administered to or used by" the victim. It simply reflects, for example, that the statute may apply to a claim that a facility failed to provide proper training to employees administering vaccines, resulting in an employee nicking a patient's artery while administering the vaccine. In that scenario, a covered countermeasure was used, and the complaint would allege an omission by the facility constituting willful misconduct in relation to its use.

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 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).

The statutory text also does not support Elmcroft's suggestion that the Act applies to all COVID-19 claims against it because, it asserts, it was administering a countermeasure "program." Appellants' Br. 16–18. "[T]hat a facility us[ed] covered countermeasures somewhere in the facility is [in]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." *Eaton*, 480 F. Supp. 3d at 1194; *see also Shapnik v. Hebrew Home for Aged at Riverdale*, 535 F. Supp. 3d 301, 321 (S.D.N.Y. 2021) (rejecting

argument that statute applies where the decedent "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"). Here, no such connection is alleged.

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

Where the text of a statute is unclear, this Court "may look at the broader context of the statute and statutory purpose together to resolve the ambiguity." *United States ex rel. Felten v. William Beaumont Hosp.*, 993 F.3d 428, 431 (6th Cir. 2021) (cleaned up). If the PREP Act's text left any ambiguity as to its scope, its purpose would leave no doubt that it applies only where an injury was caused by actual use—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 sub nom. Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393 (3d Cir. 2021). Supporters explained that the bill would ensure that a pandemic flu "vaccine gets developed and to make sure 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 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.

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

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 by* 37 F.4th 1210.

Throughout 2020, Congress debated—but did not enact—liability protections for claims like Ms. Hudak'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 "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.

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

c. The Secretary's Declaration does not suggest that the PREP Act applies.

Elmcroft asserts that the Secretary's PREP Act Declaration expanded the scope of PREP Act immunity to the claims here. Not only does the Declaration not purport to do so, but this Court is not bound by the Secretary's interpretations of the statute.

Elmcroft points to the Declaration's definition of the term "Administration of a Covered Countermeasure." Appellants' Br. 16, 17 (citing 85 Fed. Reg. at 15,200).[16] That definition, however, does not suggest that the statute applies to claims based on non-use of covered countermeasures or inadequate policies more generally. Rather, it states that "administration" extends to both the "physical provision of a

[16] Elmcroft seems to have abandoned its argument, raised below, that HHS Advisory Opinions 20-04 and 21-01, are relevant and "controlling." *See* Opp'n to Remand, RE 24, PageID #349–51. And with good reason, since, at most, these statements reflect HHS's opinion that the statute applies 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 circumstance is present here. Cases such as this one involving "general neglect" do not fall under the PREP Act, even under HHS's view. *Estate of McCalebb v. AG Lynwood, LLC*, 2021 WL 911951, at *5 (C.D. Cal. Mar. 1, 2021); *see Goldblatt v. HCP Prairie Village KS OpCo LLC*, 516 F. Supp. 3d 1251, 1264 (D. Kan. 2021).

countermeasure to a recipient" and "activities related to management and operation of programs and locations for providing countermeasures to recipients … only insofar as those activities directly relate to the countermeasure activities." 85 Fed. Reg. at 15,200. In both scenarios, countermeasures are "provided" "to recipients." And the emphasis on a "direct relationship" undercuts the notion that providing a covered countermeasure to someone somewhere triggers immunity for *all* COVID-19-related claims.

If the Secretary *had* suggested that the PREP Act applies to claims like Ms. Hudak's, that statutory interpretation would not bind this Court. Where a statute is unambiguous, a court owes no deference to an agency interpretation. *See, e.g.*, *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 175 (2016). Here, as explained above (at 28–34), the text and purpose of the PREP Act unambiguously demonstrate that only claims based on injuries caused by administration or use of a covered countermeasure fall under the statute.

Even where a statute is ambiguous, an agency's interpretation is controlling 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). The Secretary did not purport to exercise any delegated authority to make rules carrying the force of law about the meaning of "related to the administration to or use by an individual of a covered countermeasure." Nor could he, as Congress only delegated him 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 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]

[17] Elmcroft cites *Maglioli* for the proposition that "Congress empowered the HHS Secretary to tailor the scope of the Act, including the definition of countermeasure 'administration', to the applicable public health emergency in his/her declaration." Appellants' Br. 16–17.

Where an agency interpretation lacks the force of law, "the agency's interpretation of the statute is given weight in proportion to its power to persuade. Factors to be considered include '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.'" *Navistar, Inc. v. Forester*, 767 F.3d 638, 645 (6th Cir. 2014) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). Here, the Declaration does not address the relevant statutory language, including the requirement of a "causal relationship" with the administration "to" or "use by an individual," nor does it consider the statute's purpose of stimulating manufacture and use. Any conclusion the agency reached without doing so is not entitled to deference.

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.

2. The PREP Act does not completely preempt all state-law claims relating to covered countermeasures.

Because Ms. Hudak's claims do not relate to the administration to or use by an individual of a covered countermeasure, the Court need not determine whether the PREP Act completely preempts claims that *do*. Nonetheless, the district court, like the Third, Fifth, Seventh and Ninth Circuits, correctly concluded that the statute does not completely preempt such claims.

"Only state-court actions that originally could have been filed in federal court may be removed to federal court by the defendant." *Caterpillar*, 482 U.S. at 392. Complete preemption is not an exception to this rule; rather, it recognizes rare circumstances where Congress has converted state-law causes of actions into federal ones, so that a state-law claim is "wholly replaced by a claim for relief under federal law." *Martin*, 37 F.4th at 1214; *see Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8 (2003).

Here, Congress has not converted all claims relating to the administration or use of covered countermeasures into federal claims for relief. In enacting the PREP Act, Congress has not entirely displaced state law, as this Court has held is necessary for complete preemption.

Congress has created a federal cause of action for only *some* countermeasure-related claims—those that may be pursued under subsection (d). There is no federal cause of action that non-willful misconduct claims can be converted into. And because Ms. Hudak's claims could not have been brought under subsection (d), there is no need for the court to determine whether claims that could be pleaded as subsection (d) claims are completely preempted.

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

Unlike statutes courts have recognized as completely preemptive, the PREP Act "is, at its core, an immunity statute; it creates no rights, duties, or obligations." *Dupervil*, 516 F. Supp. 3d at 251. But "[c]omplete preemption that permits removal is reserved for statutes 'designed to occupy the regulatory field with respect to a particular subject.'" *Roddy v. Grand Trunk W. R.R. Inc.*, 395 F.3d 318, 323 (6th Cir. 2005) (quoting *Warner v. Ford Motor Co.*, 46 F.3d 531, 535 (6th Cir. 1995) (*en banc*)). As this Court recently explained, if a statute merely "incorporat[es] state law into the federal action, [it] does not entirely displace state law" and fails to meet the complete preemption standard. *Matthews*, 15 F.4th at 720.

As *Matthews* recognizes, federal causes of action that are completely preemptive depend on federal-law rights or duties. *Id.* For complete preemption to exist under section 502(a) of ERISA, for example, the plaintiff's claim must be "dependent on ERISA or on the ERISA plan's terms"; "no other independent legal duty may be implicated by a defendant's actions." *K.B. by & through Qassis v. Methodist Healthcare-Memphis Hosps.*, 929 F.3d 795, 800–01 (6th Cir. 2019) (quoting *Aetna Health Inc. v. Davila*, 542 U.S. 200, 210 (2004); cleaned up). Similarly, section 301(a) of the Labor Management Relations Act only completely preempts claims that require interpretation of collective bargaining agreements—which are governed by federal law. *See Adamo Demolition Co. v. Int'l Union of Operating Engineers Loc. 150, AFL-CIO*, 3 F.4th 866, 873 (6th Cir. 2021). "If the claim 'does not invoke contract interpretation' and 'is borne of state law,' then it is not preempted." *Id.* at 873. And a claim is only completely preempted by sections 85 and 86 of the National Bank Act where it addresses conduct covered by those provisions' federal "substantive limits on the rates of interest that national banks may charge." *Beneficial*, 539 U.S. at 9, 11.

The PREP Act, however, creates no federal rights or duties beyond its ordinary preemption defense. In this regard, the subsection (d) cause of action is indistinguishable from the cause of action created by the Price-Anderson Act, 42 U.S.C. § 2014(hh), which *Matthews* held does not create complete preemption. *Compare* 42 U.S.C. § 247d-6d(e)(2) (providing that, for subsection (d) claims, state law provides "the substantive law for decision," "unless such law is inconsistent with" federal law, including the liability protections of the PREP Act), *with* 42 U.S.C. § 2014(hh) (providing that the "substantive rules for decision in [a public liability] action shall be derived from the law of the State in which the nuclear incident involved occurs, unless such law is inconsistent with the provisions of such section").

By preserving a prominent role for state law, "Congress has not manifested a clear intent for the PREP Act to occupy the field so completely" as to trigger complete preemption. *Bolton v. Gallatin Ctr. for Rehab. & Healing, LLC*, 535 F. Supp. 3d 709, 729 (M.D. Tenn. 2021); *see also Martin*, 37 F.4th at 1213 (rejecting complete preemption argument because subsection (d) does not "occupy the field of health safety").

b. The subsection (d) cause of action does not evidence congressional intent to transfer jurisdiction over other claims.

Elmcroft argues that, by vesting federal courts with exclusive jurisdiction to hear subsection (d) claims, which are carved out from subsection (a)(1) immunity, Congress also vested federal courts with exclusive jurisdiction over any state-law claims as to which subsection (a)(1) may apply. Four courts of appeals have rejected this argument. *Martin*, 37 F.4th at 1213; *Mitchell v. Advanced HCS, L.L.C.*, 28 F.4th 580, 586–87 (5th Cir. 2022); *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679, 688 (9th Cir. 2022); *Maglioli*, 16 F.4th at 410–11. As the Ninth Circuit explained, "[t]he provision of one specifically defined, exclusive federal cause of action undermines [Elmcroft]'s argument that Congress intended the Act to completely preempt all state-law claims related to the pandemic." *Saldana*, 27 F.4th at 688; *accord Estate of Cowan v. LP Columbia KY, LLC*, 530 F. Supp. 3d 695, 702 (W.D. Ky. 2021) ("Congress' decision to provide an exclusive federal cause of action for willful misconduct under the PREP Act underscores its decision not to do so for the remaining claims.").

For a state-law claim to be completely preempted, it must "come[] within the scope of [a federal] cause of action." *Beneficial*, 539 U.S. at 8. But in enacting the PREP Act, Congress created 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, "the elements of the state cause of action need not 'precisely duplicate' the elements of the federal cause of action for complete preemption to apply." *Maglioli*, 16 F.4th at 411 (quoting *Davila*, 542 U.S. at 216)). "But complete preemption does not apply when federal law creates an entirely *different* cause of action from the state claims in the complaint." *Id.* "Congress could have created a cause of action for negligence or general tort liability. It did not. Just as intentional torts, strict liability, and negligence are independent causes of action, so too willful misconduct under the PREP Act is an independent cause of action." *Id.* (citations omitted).

Contending that *Maglioli* is contrary to *Davila*, Elmcroft asserts that if *any* claim that implicates the PREP Act's liability protections is completely preempted, *all* such claims must be. Not so. As *Davila* reaffirmed, for a claim to be completely preempted by ERISA, the key

question is whether a plaintiff "could have brought his claim under ERISA § 502(a)(1)(B)." *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, 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). As this Court noted post-*Davila*, the "case law does not set up an automatic triggering mechanism whereby the simple presence of an ERISA plan on the balance sheet brings down the hammer of complete federal preemption every time." *K.B.*, 929 F.3d at 803. Likewise, the existence of the subsection (d) cause of action does not convert other countermeasure claims into federal ones. [18]

[18] Below, Elmcroft argued that the administrative compensation scheme is a remedy with complete preemption effect. *See* Opp. to Remand, RE 24, PageID #341–42. The district court correctly rejected this argument because an administrative scheme is not "evidence of Congress's intent to transfer jurisdiction to federal courts." Order, RE 31, PageID #467; *see Maglioli*, 16 F.4th at 411–12; *see also Strong v. Telectronics Pacing Sys.*, 78 F.3d 256, 261 (6th Cir. 1996) (reaching the same conclusion with respect to the administrative scheme under Medical Device Amendments to the Food, Drug, and Cosmetics Act). In this Court, Elmcroft abandons this argument, asserting instead that the administrative process "in no way impact[s] the original jurisdiction vested by Congress in the" District Court for the District of Columbia

c. Ms. Hudak's claims are not subsection (d) claims.

Whether complete preemption would provide federal jurisdiction if a plaintiff attempted to plead a subsection (d) claim as a state-law claim is irrelevant here, as Ms. Hudak has not pleaded a claim that could be brought under the cause of action created by subsection (d)(1) of the PREP Act. *See Manyweather*, 2022 WL 2525732, at *4–5.

As discussed above, Ms. Hudak's claims are not within the scope of the PREP Act cause of action because they do not relate to the administration or use of a covered countermeasure. Additionally, a subsection (d) willful misconduct claim requires "(1) 'an act or omission,' that is taken (2) 'intentionally to achieve a wrongful purpose,' (3) 'knowingly without legal or factual justification,' and (4) '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.'" *Maglioli*, 16 F.4th at 310 (quoting 42 U.S.C. § 247d-6d(c)(1)(A)). "The PREP Act also provides a rule of construction: the willful-misconduct requirement 'shall be construed as establishing a standard for liability that is more stringent than a

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over subsection (d) claims. Appellant's Br. 34. The district court did not hold otherwise.

standard of negligence in any form or recklessness.'" *Id.* (quoting 42 U.S.C. § 247d-6d(c)(1)(B)).

Here, like the *Maglioli* plaintiffs, Ms. Hudak does not "allege or imply that [Elmcroft] acted 'intentionally to achieve a wrongful purpose,'" or that Elmcroft "acted 'knowingly without legal or factual justification.'" *Id.* at 411 (quoting 42 U.S.C. §§ 247d-6d(c)(1)(A)(i), 247d-6d(c)(1)(A)(ii)); *accord Manyweather*, 2022 WL 2525732, at *4; *Massamore v. RBRC, Inc.*, 2022 WL 989178, at *2 (W.D. Ky. Mar. 31, 2022). Although Ms. Hudak labeled one of her claims "reckless, intentional, willful and wanton misconduct," Compl., RE 23, PageID #24, that label is irrelevant—just as it would be if Ms. Hudak had alleged the elements of a subsection (d) claim but labeled it a claim for negligence. In substance, Ms. Hudak's claim is for reckless conduct under Ohio law. *Compare id.* PageID #24–25, ¶¶ 43–44 (alleging Elmcroft's conduct "constituted a reckless disregard for the consequences" to Mr. Koballa and that Elmcroft acted "with heedless indifference to the consequences [and] disregarded substantial and unjustifiable risks [its] conduct was likely to cause" injury), *with Anderson v. Massillon*, 135 Ohio St.3d 380, 388 (2012) ("Reckless conduct is characterized by the conscious disregard of or

indifference to a known or obvious risk of harm to another that is unreasonable under the circumstances.").

C. The narrow *Grable* doctrine does not apply.

1. Elmcroft forfeited its *Grable* argument.

The Court need not address the merits of Elmcroft's *Grable* theory. "[T]he failure to present an issue to the district court forfeits the right to have the argument addressed on appeal." *Armstrong v. City of Melvindale*, 432 F.3d 695, 699–700 (6th Cir. 2006). Elmcroft failed to raise *Grable* in opposing Ms. Hudak's motion to remand.

Although "[p]arties may not waive or forfeit jurisdictional *objections*," *Carter v. Hickory Healthcare Inc.*, 905 F.3d 963, 968 (6th Cir. 2018) (emphasis added), they can waive or forfeit arguments *supporting* subject matter jurisdiction, as recognized by decisions refusing to allow removing defendants to assert new theories of federal subject-matter jurisdiction on appeal.[19] *See, e.g.*, *Mays*, 871 F.3d at 446–47; *Cty. of San Mateo v. Chevron Corp.*, 32 F. 4th 733, 763 n. 23 (9th Cir. 2022); *Bd. of*

[19] Although "cases often use the terms [waiver and forfeiture] interchangeably," this Court has clarified that where a party has "passive[ly] fail[ed] to make" an argument, rather than affirmatively abandoning it, forfeiture is the correct term. *Berkshire v. Dahl*, 928 F.3d 520, 530 (6th Cir. 2019).

Cty. Comm'rs of Boulder Cty. v. Suncor Energy (U.S.A.) Inc., 25 F.4th 1238, 1262 n.6 (10th Cir. 2022); *Lopez-Munoz v. Triple-S Salud, Inc.*, 754 F.3d 1, 4 (1st Cir. 2014). Likewise, referring to a basis for jurisdiction in a removal notice, without raising it in opposition to a remand motion, forfeits the argument. *See Louque v. Allstate Ins. Co.*, 314 F.3d 776, 779 n.1 (5th Cir. 2002).

This Court "has discretion to entertain issues not raised before the district court only in exceptional cases or when application of the rule would produce a plain miscarriage of justice." *Ohio State Univ. v. Redbubble, Inc.*, 989 F.3d 435, 445 (6th Cir. 2021) (cleaned up). No exceptional circumstances exist here.

2. Elmcroft does not meet the *Grable* standard.

If the Court overlooks Elmcroft's forfeiture, it should adopt the judicial consensus that actions like this one fall outside the "special and small category of cases in which arising under jurisdiction still lies" despite the absence of a federal-law claim. *Gunn v. Minton*, 568 U.S. 251, 258 (2013). Under *Grable*'s "embedded federal question" doctrine, federal courts may exercise jurisdiction over state-law actions 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." *Id.* (citing *Grable*, 568 U.S. at 313–14). "This pathway is a 'slim category' ... that is to be read narrowly." *Cornell v. Bayview Loan Servicing, LLC*, 908 F.3d 1008, 1014 (6th Cir. 2018) (quoting *Empire Healthchoice Assur., Inc. v. McVeigh*, 547 U.S. 677, 701 (2006)).

Elmcroft's brief neither addresses *Grable*'s elements nor acknowledges that every federal court to consider whether *Grable* provides jurisdiction in similar cases has concluded that it does not. *See 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.[20] As in those cases, none of the elements of *Grable* jurisdiction is present here.

First, the complaint does not "necessarily raise" any issues of federal law and, therefore, raises no "substantial" or "actually disputed" issues of federal law. The well-pleaded complaint rule applies, and thus

[20] District courts are likewise unanimous on this point. *See*, *e.g.*, *Massamore*, 2022 WL 989175, at *4; *Bolton*, 535 F. Supp. 3d at 717–18; *Cowan*, 530 F. Supp. 3d at 704–05; *Dorsett v. Highlands Lake Ctr., LLC*, 557 F. Supp. 3d 1218, 1234–35 (M.D. Fla. 2021); *Gwilt*, 537 F. Supp. 3d at 1243; *Shapnik*, 535 F. Supp. 3d at 320; *Robertson*, 523 F. Supp. 3d at 1286; *Goldblatt*, 516 F. Supp. 3d at 1264 n.7; *Dupervil*, 516 F. Supp. 3d at 257.

potential federal defenses are irrelevant. *Miller*, 949 F.3d at 993. A potential PREP Act defense—the federal question suggested by Elmcroft—is not an essential element of any of Ms. Hudak's state-law claims, and thus it cannot provide the requisite substantial federal question for *Grable* jurisdiction.

That "pandemics raise matters of national public health, national critical infrastructure, and national security," Appellants' Br. 52, does not mean that all pandemic-related claims belong in federal court.[21] A federal substantive policy interest is alone insufficient to create a federal question. *See Caterpillar*, 482 U.S. at 399; *Miller*, 949 F.3d at 990. *Grable* requires "a serious federal interest in claiming the advantages thought to be inherent in a federal forum," 545 U.S. at 313, but the mere desire to have federal courts interpret federal law is not such an interest. "The state court in which the personal-injury suit was lodged is competent to

[21] In a footnote, Elmcroft asserts that the district court was wrong to "disregard[]" HHS's views of *Grable* jurisdiction, as expressed in AO 21-01 and the Fourth Amended Declaration. Appellants' Br. 48 n.21 (citing Order, RE 31, PageID #477–79). The district court correctly held that (1) courts owe no deference to agencies' views on federal-question jurisdiction, and (2) neither document has persuasive value because neither addressed the relevant legal standard. Order, RE 31, PageID #478–79; *see Maglioli*, 16 F.4th at 403 (declining to defer to HHS's thoughts on *Grable* jurisdiction).

apply federal law, to the extent it is relevant." *McVeigh*, 547 U.S. at 701. *Cf. Arbor Mgmt.*, 2022 WL 2234983, at *2–4 (state court application of PREP Act); *Whitehead*, 2022 WL 2071025, at *3–4 (same).

This case also fails to satisfy the fourth *Grable* factor, which asks whether assuming federal jurisdiction would disrupt the federal-state balance approved by Congress. In analyzing this factor, this Court looks "to federalism and comity concerns," including whether an issue is "traditionally the province of the state courts," and whether exercising jurisdiction would lead to "an influx of cases" in the federal system. *Miller*, 949 F.3d at 994. Enforcing health-care providers' duties of care is a traditional state-court function: States have "special responsibility for maintaining standards among members of the licensed professions," *Gunn*, 568 U.S. at 264. "[G]ranting federal jurisdiction here would risk swinging open the federal courtroom doors to any dispute" involving the failure to take adequate precautions to minimize transmission of COVID-19. *Id.* "[S]uch a dramatic shift would distort the division of judicial labor assumed by Congress under section 1331." *Eastman v. Marine Mech. Corp.*, 438 F.3d 544, 553 (6th Cir. 2006). Moreover, it would ignore Congress's specific judgment in the PREP Act that only a narrow

category of state-law cases belong in federal court: claims brought by plaintiffs alleging "willful misconduct" in 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.

III. Federal-officer removal jurisdiction is lacking.

"Persons like [Elmcroft], who are not federal officers, must satisfy three requirements in order to invoke the federal-officer removal statute: (1) the defendants must establish that they acted under a federal officer, (2) those actions must have been performed under color of federal office, and (3) the defendants must raise a colorable federal defense." *Mays*, 871 F.3d at 442–43. In its opening brief, for the first time in this litigation, Elmcroft offers a theory as to how it meets these elements. Elmcroft forfeited that argument by neither raising it in the district court nor adequately pleading it in its removal notice. Regardless, Elmcroft's theory lacks merit.

A. Elmcroft forfeited any federal-officer argument by failing to raise it in opposing remand.

Elmcroft forfeited its federal-officer argument by failing to raise it in response to Ms. Hudak's remand motion in the district court. *See* Order, RE 31, PageID #480 (noting federal-officer argument likely "abandoned"). As with Elmcroft's *Grable* argument, *see supra* section II.B.1, the Court should decline to consider that forfeited argument, particularly in light of its fact-intensive nature. Elmcroft asks this Court to conclude that it was acting under direction of federal officers based on documents that it did not even reference below, let alone provide to the court. *See, e.g.*, Appellants' Br. 47, 47 n. 22 (relying on CMS and ODH guidance documents that are outside the record); *Id.* at 47 (invoking HHS Advisory Opinion 20-01, which was not cited in Elmcroft's removal notice or opposition to remand). Given that this Court is "a court of review, not first view," *United States v. Houston*, 792 F.3d 663, 669 (6th Cir. 2015) (citing *Wood v. Milyard*, 566 U.S. 463, 474 (2012)), the Court should decline to consider Elmcroft's new theory of federal-officer removal.

B. Elmcroft cannot advance federal-officer theories outside the scope of its removal notice.

Elmcroft's argument as to federal-officer jurisdiction is also barred because it is beyond the scope of the removal notice. "Like plaintiffs

pleading subject-matter jurisdiction under Rule 8(a)(1), a defendant seeking to remove an action may not offer mere legal conclusions; it must allege the underlying facts supporting each of the requirements for removal jurisdiction." *Leite v. Crane Co.*, 749 F.3d 1117, 1122 (9th Cir. 2014); *see also Dart Cherokee Basin Operating Co. v. Owens*, 574 U.S. 81, 83–84 (2014). "[T]he removal notice must make the basis for federal jurisdiction clear, and contain enough information so that the district judge can determine whether jurisdiction exists." Wright & Miller, 14C Fed. Prac. & Proc. Juris. § 3733 (Rev. 4th ed.).

Elmcroft fell far short of this standard. The only reference to federal-officer removal in its notice was: "Original jurisdiction is also through an action pursuant to 28 U.S.C. §1442(a)(1)." NOR, RE 1, PageID #6. The notice addressed *none* of the elements of federal-officer removal jurisdiction. *Cf. Lopez-Munoz*, 754 F.3d at 4 (holding that mere citation to federal-officer removal statute in notice did not preserve jurisdictional argument).

Although a removing party may "set out more specifically the grounds for removal that already have been stated in the original notice," "defendants may not add completely new grounds for removal or furnish

missing allegations" in later briefing to remedy a failure to meet the pleading standard. Wright & Miller, 14C Fed. Prac. & Proc. Juris. § 3733. Doing so constitutes a substantive amendment of the notice of removal—which is barred outside the thirty-day removal period. *See Wood v. Crane Co.*, 764 F.3d 316, 322 (4th Cir. 2014); *Snell v. State Auto Prop. & Casualty Ins. Co.*, 2021 WL 1292509 (E.D. Ky. Apr. 7, 2021).

Applying these principles in *Mays*, this Court refused to consider a removing defendant's argument that certain communications with the federal government not referenced in the removal notice were the source of federal direction for section 1442 purposes. 871 F.3d at 446–47. The Court should likewise reject Elmcroft's belated argument. The Court's inquiry into whether federal officer jurisdiction is appropriate is "cabined by the notice of removal," *Lopez-Munoz*, 754 F.3d at 4, and Elmcroft's appellate arguments go far beyond that notice.

C. Elmcroft's new arguments do not establish federal-officer removal jurisdiction.

1. Elmcroft was not acting under a federal officer.

As used in the federal-officer removal statute, the term "under" refers to a relationship of subservience, and, therefore, the statute applies only where a private person undertakes "an effort to *assist*, or to

help *carry out*, the duties or tasks of the federal superior." *Watson v. Philip Morris Cos.*, 551 U.S. 142, 151–52 (2007). To invoke section 1442(a)(1), "the defendant seeking removal must be in a relationship with the federal government where the government is functioning as the defendant's superior." *Mays*, 871 F.3d at 444 (citing *Watson*, 551 U.S. at 151)). "[S]imply *complying* with the law" is insufficient, even if a private entity is subject to regulation that "is highly detailed and even if the private firm's activities are highly supervised and monitored." *Watson*, 551 U.S. at 153. Rather, to establish the "subservient" relationship required, a defendant must show a delegation of legal authority from the federal government. *Mays*, 871 F.3d at 444–45.

Elmcroft claims that it was a "federal surroga[te]" that was "marshal[ed]" by the federal government "to help it do the job of containment." Appellants' Br. 51. These vague assertions do not meet Elmcroft's "burden of providing 'candid, specific and positive' allegations, that [it] w[as] acting under federal officers" when it failed to comply with its state-law duties. *In re MTBE Prods. Liab. Litig.*, 488 F.3d 112, 130 (2d Cir. 2007) (quoting *Willingham v. Morgan*, 395 U.S. 402, 408 (1969)). Here, as in *Watson*, there is "no evidence of any delegation of legal

authority from" a federal officer, nor "of any contract, any payment, any employer/employee relationship, or any principal/agent arrangement." 551 U.S. at 156. And the few specific documents that Elmcroft identifies as evidence of federal delegation do not support its theory.

As the Seventh, Fifth, Ninth, and Third Circuits have held in rejecting arguments like Elmcroft's, nothing the federal government did in the early days of the pandemic with respect to long-term care or other health care facilities evidences the subservient relationship indicative of "acting under" federal officer direction. *See Martin*, 37 F.4th at 1212–13; *Mitchell*, 28 F.4th at 590–91; *Saldana*, 27 F.4th at 684–86; *Maglioli*, 16 F.4th at 405–06.[22]

a. Cited federal guidance does not show a subservient relationship.

The agency documents that Elmcroft cites as evidence of federal officer direction are materially indistinguishable from those that other circuits have found insufficient to demonstrate an "acting under"

[22] Every district court to reach the issue has agreed. *See, e.g.*, *Massamore*, 2022 WL 989178, at *4–5; *Rosen*, 2022 WL 278106, at *5; *Khalek v. S. Denver Rehab., LLC*, 543 F. Supp. 3d 1019, 1029–30 (D. Colo. 2021); *Dupervil*, 516 F. Supp. 3d at 259–61.

relationship.[23] *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. This Court should reach the same conclusion.

First, Elmcroft suggests that Ms. Hudak's allegations that "Elmcroft failed to follow infection control procedures mandated by CMS" are proof of a federal officer relationship. Appellants' Br. 47 (citing Compl., RE 1-1, PageID #22). But even if Elmcroft were subject to these requirements (which it *disputes*, *id.* at 40), they do not create the necessary subservient relationship.

Elmcroft also asserts that "HHS (through CMS), notes and directs long term care facilities through its state level AJHs [sic]." Appellants' Br. 47. But nothing Elmcroft cites transcends an ordinary regulatory relationship, assuming that the cited material even applies to Elmcroft. For example, the CMS and CDC long-term care guidance document cited by Elmcroft contains only "recommendations to State and local

[23] Elmcroft asserts that the Third, Fifth, Seventh, and Ninth Circuits' conclusions about these guidance documents are inapplicable because, "prior to the pandemic, Elmcroft was not overseen or directed by HHS." Appellants' Br. 40. That assertion relies on a *non sequitur*. If the guidance did not constitute federal officer direction to entities over which HHS *has* direct regulatory authority, it could not constitute such direction to entities over which HHS does *not* have regulatory authority.

governments and long-term care facilities (also known as nursing homes) to help mitigate the spread of the 2019 Novel Coronavirus (COVID-19)." LTC Guidance 1, *cited in* Appellants' Br. 47 n.22.[24] "Recommendations" do not create an "acting under" relationship. *See Saldana*, 27 F.4th at 685; *Massamore*, 2022 WL 989178, at *4. Elmcroft also cites a CMS document directed at "State Survey Agency Directors," which provides guidance as to how CMS will enforce its existing infection-control regulations with respect to 17 categories of health care providers, none of which Elmcroft falls into. *See* CMS, Guidance for Use of Certain Industrial Respirators by Health Care Personnel (Mar. 10, 2020), *cited in* Appellants' Br. 47 n.22. Elmcroft's concession that it "had not been previously regulated by the federal government," Appellants' Br. 6 n.7, confirms that this guidance interpreting pre-existing regulations did not apply to Elmcroft. Even if did, though, an agency's statement of how it

[24] It is unclear whether this document applies to Elmcroft, which is not a nursing home.

will interpret regulations cannot support federal-officer removal where the regulations themselves do not do so.

b. The PREP Act scheme does not create an "acting under" relationship.

In making a federal-officer removal argument, Elmcroft suggests that the terms "program planner" and "authority having jurisdiction" in the PREP Act's immunity provisions reflect a delegation of federal authority. *See, e.g.*, Appellants' Br. 40–42. Nothing in the statute or other HHS materials supports that suggestion.

First, "program planner" is one of the categories of entities included in the definition of the term "covered person." 42 U.S.C. § 247d-6d(i)(2). While "program planners" may qualify for PREP Act immunity. *Id.* § 247-d-6d(a)(1), no statutory provision, or anything else, delegates authority or otherwise places all "program planners" into a subservient relationship with the federal government.[25] Given the broad statutory definition of "program planner" to include virtually every state, local, and tribal government and public health employee thereof, such a delegation

[25] Elmcroft repeatedly states that it was "formally declared" a program planner, *see* Appellants' Br. 41, 45, 51, but cites no supporting evidence.

would be a massive disruption of our federal scheme. *Cf. Maglioli*, 16 F.4th at 400 ("There is no COVID-19 exception to federalism.").

Second, the term "authority having jurisdiction" does not reflect any delegation of federal authority. It has legal significance solely in the context of limitations on PREP Act immunity imposed by the Secretary. *See, e.g.*, Declaration, 85 Fed. Reg. at 15,202. In the initial Declaration, the Secretary extended PREP Act immunity to "covered persons" for claims relating to the administration or use of covered countermeasures for COVID-19 only where that administration or use was related to (a) agreements with the federal government, or (b) "activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction," a term defined as "the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, state, or federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority." *Id.*

The inclusion of this limitation on PREP Act immunity does not bestow any entity with federal power. To the contrary, AO 20-04 recognizes the *opposite*—that is, that the Declaration did not displace the

public health powers of those sovereigns. As an illustrative example of how the limitation on immunity applies, the opinion stated, "if there were a conflict between [] CDC guidance and 'any state, local, territorial, or tribal health and safety laws, rules, and regulations with which schools must comply,' a covered person must rely on guidance of the latter jurisdiction." AO 20-04 at 5. That statement is inconsistent with a relationship of subservience between covered persons (including state agencies and employees) and the federal government.

Elmcroft also invokes subsection (f) of the PREP Act as evidence that authorities having jurisdiction and "healthcare infrastructure participants" are federal "instrumentalities." Appellants' Br. 42. Nothing in that provision, entitled "Actions by and against the United States" and specifying that the statute's liability protections do not limit other rights, defenses, and immunities to suit the federal government and its instrumentalities may have, supports Elmcroft's view. *See* 42 U.S.C. § 247d-6d. Entities like Elmcroft are not "federal instrumentalities." *See Commodities Export Co. v. Detroit Int'l Bridge Co.*, 695 F.3d 518, 529–30 (6th Cir. 2012) (discussing doctrine).

c. Elmcroft's regulation by the Ohio Department of Health is irrelevant.

Finally, Elmcroft repeatedly suggests that regulation by the *Ohio* Department of Health brought it under the direction of a federal officer. *See, e.g.*, Appellants' Br. 40–42. This argument appears to rest on three propositions: (1) ODH had a contract with HHS to survey and enforce federal regulations as to *other* healthcare facilities; (2) because ODH is a federal contractor, it was "acting under" a federal officer; and (3) because Elmcroft was regulated by ODH as a residential care facility, it too was acting under a federal officer. Appellants' Br. 41. This entire chain of reasoning is flawed.

First, Elmcroft asserts that ODH has a contract with HHS relating to certain federal regulations. Appellants' Br. 6 n.7. ODH's authority over residential care facilities like Elmcroft, however, is a function of state law. *Cf. Mays*, 871 F.3d at 448 (stating that a state agency was not acting under a federal officer even where it "might have been guided" by federal law, because it was "ultimately enforcing Michigan law"). That ODH may have a federal contract to do something else is of no moment.

Moreover, this Court has held that not all federal contracts create an "acting under" relationship. Indeed, it has done so in the specific

context of "state officers working in a joint federal-state regulatory system." *Mays*, 871 F.3d at 445. In *Mays*, Michigan's Department of Environmental Quality contended that its role in enforcing the Safe Drinking Water Act, consistent with EPA regulations and pursuant to federal funding mechanisms, meant it was "acting under" EPA. *Id.* at 441–42. Rejecting this assertion, the Court held "that the receipt of federal funding alone" did not establish the delegation of authority required by *Watson*. *Id.* at 444. And while acknowledging that *Watson* suggested that "*certain* government contractors" could invoke the federal-officer removal statute, the Court explained that the point was limited to scenarios where the contractor did not "have any authority to take actions beyond those specified in the contract" because, in those scenarios, "the federal government can properly be viewed as acting in a superior relationship to the private entity." *Id.* at 445 (emphasis added). Here, there is no evidence that the cooperative federalism arrangement between ODH and HHS is meaningfully different from that at issue in *Mays*.

Finally, even if ODH had been acting as or under a federal officer, Elmcroft would not fall into that category simply because it is regulated

by ODH. If a regulatory relationship between a federal agency and private entity cannot create an "acting under" relationship for purposes of the federal-officer removal statute, such a relationship between a *state* agency and a private entity cannot either. Elmcroft cites no authority for the sort of pass-through federal-officer relationship it suggests.

2. Elmcroft was not acting under color of federal office.

To meet the statute's second requirement, "the removing party must show that it is being sued because of the acts it performed at the direction of the federal officer." *Bennett v. MIS Corp.*, 607 F.3d 1076, 1088 (6th Cir. 2010). Here, Elmcroft is not being sued for actions it undertook pursuant to federal-officer direction. At most, it is being sued for *not* following federal instructions. *See* Compl., RE 1-1, PageID #22.

3. Elmcroft lacks a colorable federal defense.

Finally, Elmcroft lacks a colorable federal defense. As explained above, at 26–38, the complaint does not allege that Mr. Koballa'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). Accordingly, Ms. Hudak's claims are "not even arguably preempted" by the PREP Act. *Martin*, 37 F.4th at 1213; s*ee also Bennett*, 607 F.3d at 1089–90 (noting that, in determining colorability of a novel defense, the

Court looks to plausibility in light of decisions of sister circuits and district courts).

CONCLUSION

The Court should affirm the district court's remand order.

Respectfully submitted,

s/ Adam R. Pulver
Adam R. Pulver
Allison M. Zieve
Scott L. Nelson
PUBLIC CITIZEN
LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
(202) 588-1000

Patrick T. Murphy
Christian D. Foisy
DWORKEN & BERNSTEIN CO., L.P.A.
1468 W. 9th Street
Suite 135
Cleveland, OH 44113

Counsel for Plaintiff-Appellee

July 19, 2022

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), I certify that the foregoing brief complies with the typeface and volume limitations set forth in Federal Rule of Appellate Procedure 32(a)(5), (a)(6), and (a)(7)(B) as follows: The proportionally spaced typeface is 14-point Century Schoolbook and, as calculated by my word processing software (Microsoft Word for Office 365), the brief contains 12,985 words, exclusive of those parts of the brief not required to be included in the calculation by Federal Rule of Appellate Procedure 32(f) and the rules of this Court.

/s/ Adam R. Pulver
Adam R. Pulver

CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Sixth 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.

July 19, 2022

/s/ Adam R. Pulver
Adam R. Pulver

ADDENDUM

(Pursuant to 6 Cir. R. 28(b)(1)(A)(i) and R. 30(g)(1))

DESIGNATION OF RELEVANT DISTRICT COURT DOCUMENTS

Pursuant to Sixth Circuit Rules 28(b)(1)(A)(i) and 30(g)(1), Plaintiff-Appellee designates as relevant the following docket entries from the U.S. District Court for the Northern District of Ohio, Case No. 5:21-CV-00060:

RE#	Description	Page ID # Range
1	Notice of Removal	1–14
1-1	Ex. A to Notice of Removal: Complaint	15-37
6	Defendants-Appellants' Notice of Supplemental Authority (Jan. 13, 2021)	81–86
6-1	Ex. A to Notice of Supplemental Authority: HHS OGC Advisory Opinion 21-01 (Jan. 8, 2021)	87–91
8	Plaintiff-Appellee's Motion to Remand (Feb. 3, 2021)	120–144
23	Defendants-Appellants' Reply in Further Support of Motion to Dismiss or Alternatively, to Transfer Venue	312–326
24	Defendants-Appellants' Response in Opposition to Motion to Remand (Mar. 5, 2021)	327–354
31	Order of Remand (Aug. 19, 2021)	453–481
34	Notice of Appeal (Sept. 17, 2021)	484–486
34-1	Ex. A to Notice of Appeal: Order of Remand	487–515