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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

LAURA HUDAK, Executrix of the Estate of William P.
Koballa, deceased,

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; JAMIE ASHLEY
COHEN,

Defendants-Appellants.

No. 21-3836

Appeal from the United States District Court for the Northern District of Ohio at Akron.
No. 5:21-cv-00060—Sara E. Lioi, District Judge.

Argued: December 7, 2022

Decided and Filed: January 23, 2023

Before: MOORE, GIBBONS, and LARSEN, Circuit Judges.

COUNSEL

ARGUED: Teresa Pike Tomlinson, HALL BOOTH SMITH, P.C., Columbus, Georgia, for Appellants. Adam R. Pulver, PUBLIC CITIZEN LITIGATION GROUP, Washington, D.C., for Appellee. **ON BRIEF:** Teresa Pike Tomlinson, T. Andrew Graham, HALL BOOTH SMITH, P.C., Columbus, Georgia, Keith K. Hansbrough, MARSHALL DENNEHEY WARNER COLEMAN & GOGGIN, Cleveland, Ohio, for Appellants. Adam R. Pulver, Allison M. Zieve, PUBLIC CITIZEN LITIGATION GROUP, Washington, D.C., Patrick T. Murphy, Christian D. Foisy, DWORKEN & BERNSTEIN CO., L.P.A., Cleveland, Ohio, for Appellee. Jeffrey S. Bucholtz, Alexander Kazam, KING & SPALDING LLP, Washington, D.C., Kyle A. Palazzolo, AMERICAN MEDICAL ASSOCIATION, Chicago, Illinois, for Amici Curiae.

OPINION

KAREN NELSON MOORE, Circuit Judge. In May 2020, Laura Hudak’s father, William P. Koballa, died of COVID-19. Hudak, acting as executrix of Koballa’s estate, sued in state court, asserting negligence and related state-law claims against Elmcroft of Sagamore Hills, an assisted-living facility in Ohio, and several entities that own or operate the facility (collectively, “Elmcroft”), for their alleged failure to take care of her father. Elmcroft removed the case from state court to federal court pursuant to the general removal statute, 28 U.S.C. § 1441(a), and the federal-officer removal statute, 28 U.S.C. § 1442(a)(1), based on arguments it made under the Public Readiness and Emergency Preparedness Act (“PREP Act” or “Act”), 42 U.S.C. § 247d-6d. The district court found that the PREP Act did not provide grounds for removal under either removal statute and remanded the case to state court for lack of subject-matter jurisdiction. We **AFFIRM**.

I. BACKGROUND**A. Statutory Background**

The PREP Act lies at the center of this appeal. “Congress enacted the PREP Act in 2005 ‘[t]o encourage the expeditious development and deployment of medical countermeasures during a public health emergency’ by allowing the [Health and Human Services, or HHS] Secretary ‘to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines.’” *Cannon v. Watermark Ret. Cmty., Inc.*, 45 F.4th 137, 139 (D.C. Cir. 2022) (quoting KEVIN J. HICKEY, CONG. RSCH. SERV., LSB10443, THE PREP ACT AND COVID-19, PART 1: STATUTORY AUTHORITY TO LIMIT LIABILITY FOR MEDICAL COUNTERMEASURES 1 (Apr. 13, 2022)). The Act grants immunity from federal and state liability to “covered person[s] . . . with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure” if the HHS Secretary has issued a declaration under the Act “with respect to such

countermeasure.” 42 U.S.C. § 247d-6d(a)(1).¹ The Secretary’s declaration must identify, among other things, the threat to public health and the period during which the immunity is in effect. *Id.* § 247d-6d(b)(2).

The PREP Act limits both the reach and effect of its immunity provision. The Act provides immunity only from “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)(2)(B). This includes “a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.” *Id.* The Act also ensures that its grant of immunity does not foreclose all possible relief for harms caused by the administration or use of covered countermeasures by creating a “Covered Countermeasure Process Fund” and a corresponding administrative compensation scheme. *Id.* § 247d-6e(a).

The PREP Act creates one exception to its grant of immunity. The Act provides for “an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct . . . by such covered person.” *Id.* § 247d-6d(d)(1). The Act defines willful misconduct as “an act or omission that is taken—(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.” *Id.* § 247d-6d(c)(1)(A). The Act dictates that this standard “shall be

¹The PREP Act provides that “[t]he term ‘covered person’, when used with respect to the administration or use of a covered countermeasure, means—”

(A) the United States; or

(B) a person or entity that is--

(i) a manufacturer of such countermeasure;

(ii) a distributor of such countermeasure;

(iii) a program planner of such countermeasure;

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

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

42 U.S.C. § 247d-6d(i)(2). Elmcroft asserts that it is a “covered person” under the Act because it was designated a “program planner.” Appellant Br. at 7. Hudak does not challenge that assertion on appeal.

construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.” *Id.* § 247d-6d(c)(1)(B). Beyond creating the cause of action and defining the applicable standard of liability, the Act provides that “[t]he substantive law for decision” for claims brought pursuant to the statute “shall be derived from the law . . . of the State in which the alleged willful misconduct occurred.” *Id.* § 247d-6d(e)(2). Lastly, the Act requires all claims asserted under it to be brought before a three-judge panel in the District Court for the District of Columbia and to meet certain special pleading standards. *Id.* § 247d-6d(e)(1)–(9).

In March 2020, the HHS Secretary declared COVID-19 a public-health emergency under the PREP Act. *See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 Fed. Reg. 15,198 (Mar. 17, 2020). The Secretary recommended “the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures[.]” which included “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[.]” *Id.* at 15,201–202. The Secretary stated that immunity under the Act would extend through October 1, 2024. *Id.* at 15,202. Since issuing that initial declaration, the Secretary has amended the declaration several times, including most recently in January 2022. *See Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 87 Fed. Reg. 982 (Jan. 7, 2022).

B. Factual and Procedural Background

As alleged in the complaint, Koballa resided with his wife in Elmcroft’s assisted-care facility in Northfield, Ohio, prior to his death in May 2020. *See* R. 1-1 (Compl. ¶¶ 3, 12, 34) (Page ID #18–19, 22). In late April 2020, Elmcroft suspended family visitation, required its staff to wear masks and gloves, and instituted other policies in response to the developing COVID-19 pandemic. *Id.* ¶ 13 (Page ID #19–20). A few days later, on May 4, Koballa started to show signs of sickness. *Id.* ¶ 15 (Page ID #20). An Elmcroft employee sent an email to Hudak the following day stating that a nurse and a doctor had examined her father and that the doctor believed Koballa was suffering from allergies. *Id.* ¶¶ 17–18 (Page ID #20). Contrary to that email, however, Koballa had not been seen by either practitioner. *Id.* Koballa’s condition

continued to deteriorate, and by May 9 he was unable to walk or feed himself. *Id.* ¶¶ 19–24 (Page ID #20–21). Hudak and her sister, dissatisfied with Elmcroft’s communications, went to see Koballa in person and “were shocked to observe the physical condition of their father and insisted that he be taken to the hospital.” *Id.* ¶¶ 27–28 (Page ID #21). When medics arrived at the facility, they observed that Elmcroft employees were not wearing masks. *Id.* ¶ 29 (Page ID #22). The medics transported Koballa to a hospital, where he tested positive for COVID-19 and died several days later “from hypoxia and COVID Pneumonia.” *Id.* ¶ 34 (Page ID #22).

Hudak filed a lawsuit in Ohio state court in December 2020, asserting claims under state law for (1) negligence; (2) reckless, intentional, willful, and wanton misconduct; (3) survivorship; (4) wrongful death; and (5) violation of Ohio’s nursing home patient’s bill of rights. *Id.* ¶¶ 38–60 (Page ID #23–26). Beyond incorporating by reference the factual allegations discussed above, Hudak makes few additional allegations in connection with each claim. Hudak asserts with respect to her negligence claim, for example, that Elmcroft was negligent in caring for Koballa, assessing its ability to care for him, and in not transferring him to a hospital earlier. *Id.* ¶ 40 (Page ID #23). As to her claim of reckless, intentional, willful, and wanton misconduct, Hudak asserts that Elmcroft engaged in conduct “with heedless indifference to the consequences” and “disregarded substantial and unjustifiable risks” that its “conduct was likely to cause[] an unreasonable risk of injury, death, or loss to person or property to others, including . . . Koballa.” *Id.* ¶ 44 (Page ID #23–24). Hudak’s other claims include similar recitations of the elements of her causes of action.

Shortly after Hudak filed her complaint in state court, Elmcroft removed the case to the District Court for the Northern District of Ohio pursuant to § 1441(a) and § 1442(a)(1). *See* R. 1 (Notice of Removal ¶ 16) (Page ID #6). Elmcroft argued in its notice of removal that removal was appropriate under § 1441(a) for two reasons: Hudak’s claims were completely preempted by the PREP Act and the claims necessarily raised substantial federal issues. *Id.* ¶¶ 16–38 (Page ID #6–12). Elmcroft did not address § 1442(a)(1) in depth, but instead merely asserted that the case was removable under the statute. *Id.* ¶ 16 (Page ID #6). Hudak moved to remand the case back to state court for lack of subject-matter jurisdiction, R. 8 (Mot. to Remand at 1) (Page ID #125), and the district court granted the motion, *Hudak v. Elmcroft of Sagamore Hills*, 566 F.

Supp. 3d 771, 775 (N.D. Ohio 2021). Elmcroft appeals. R. 34 (Notice of Appeal) (Page ID #484).

II. APPELLATE JURISDICTION

At the outset, Hudak challenges our appellate jurisdiction to hear Elmcroft’s challenge to the district court’s remand order. Federal law provides as a general rule that “[a]n order remanding a case to the State court from which it was removed is not reviewable on appeal or otherwise[.]” 28 U.S.C. § 1447(d). But one exception to that rule is relevant here: “an order remanding a case to the State court from which it was removed pursuant to section 1442 . . . of this title shall be reviewable by appeal or otherwise.” *Id.*; see also *BP P.L.C. v. Mayor & City Council of Baltimore*, 141 S. Ct. 1532, 1537–43 (2021) (holding that appellate jurisdiction under § 1447(d) extends to all issues decided in the remand order). Here, Elmcroft asserted in its notice of removal that the case was removable under § 1442(a)(1), R. 1 (Notice of Removal ¶ 16) (Page ID #6), so we have appellate jurisdiction to review the district court’s order under § 1447(d). See *Hudak v. Elmcroft of Sagamore Hills*, No. 21-3836 (6th Cir. Mar. 25, 2022) (order) (reaching the same conclusion).

III. SUBJECT-MATTER JURISDICTION

Turning to Elmcroft’s challenge, Elmcroft argues that the district court erred in finding that the case could not be removed from state court to federal court under either § 1441(a) or § 1442(a)(1). We address Elmcroft’s arguments under the two statutes in turn.

A. Standard of Review

“We review de novo the district court’s determination that it lacked subject-matter jurisdiction and its consequent decision to issue a remand order.” *Mays v. City of Flint*, 871 F.3d 437, 442 (6th Cir. 2017) (citing *Smith v. Nationwide Prop. & Cas. Ins. Co.*, 505 F.3d 401, 404 (6th Cir. 2007)). “As the party requesting a federal forum,” Elmcroft “bears the burden of establishing federal jurisdiction.” *Siding & Insulation Co. v. Acuity Mut. Ins. Co.*, 754 F.3d 367, 369 (6th Cir. 2014) (citing *McNutt v. Gen. Motors Acceptance Corp. of Ind.*, 298 U.S. 178, 189 (1936)).

B. General Removal Under § 1441(a)

Elmcroft first invokes the general removal statute. Pursuant to § 1441(a), “[a] civil action filed in a state court may be removed to federal court if the claim is one ‘arising under’ federal law.” *Beneficial Nat’l Bank v. Anderson*, 539 U.S. 1, 6 (2003). We determine whether a claim “arises under” federal law using the well-pleaded complaint rule. *Aetna Health Inc. v. Davila*, 542 U.S. 200, 207 (2004). “Under this rule, a federal question must appear on the face of the complaint rather than as part of a defense, even if a federal-law defense is anticipated.” *Chase Bank USA, N.A. v. City of Cleveland*, 695 F.3d 548, 554 (6th Cir. 2012).

1. Complete Preemption

Elmcroft’s primary argument in support of removal under § 1441(a) is that Hudak’s state-law claims arise under federal law because they are completely preempted by the PREP Act.

Generally, preemption provides a defense, not a basis for removal. *See Caterpillar Inc. v. Williams*, 482 U.S. 386, 392–93 (1987). Ordinary preemption, for instance, flows from the Supremacy Clause of the United States Constitution and provides only a defense that can be invoked in state or federal court. *See Matthews v. Centrus Energy Corp.*, 15 F.4th 714, 720 (6th Cir. 2021). The “misleadingly named doctrine” of complete preemption, by contrast, refers to a jurisdictional doctrine that is distinct from ordinary preemption. *Hogan v. Jacobson*, 823 F.3d 872, 879 (6th Cir. 2016) (quoting *Hughes v. United Air Lines, Inc.*, 634 F.3d 391, 393 (7th Cir. 2011)); *see also Matthews*, 15 F.4th at 720–21 (distinguishing between forms of preemption).

Complete preemption occurs where “the pre-emptive force of a [federal] 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.’” *Caterpillar Inc.*, 482 U.S. at 393 (quoting *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 65 (1987)). “Once an area of state law has been completely pre-empted, any claim purportedly based on that pre-empted state law is considered, from its inception, a federal claim, and therefore arises under federal law.” *Id.* (citing *Franchise Tax Bd. v. Constr. Laborers Vacation Tr.*, 463 U.S. 1, 24 (1983)). Thus, a state-law claim that is completely preempted may be removed from state court to federal court pursuant to § 1441(a).

The Supreme Court has found only three provisions of federal law to be completely preemptive: § 301 of the Labor Management Relations Act (“LMRA”), § 502(a)(1)(B) of the Employee Retirement Income Security Act (“ERISA”), and §§ 85 and 86 of the National Bank Act. *See AmSouth Bank v. Dale*, 386 F.3d 763, 776 (6th Cir. 2004) (collecting authorities). In each instance, the federal statute “provided the exclusive cause of action for the claim asserted and also set forth procedures and remedies governing that cause of action.” *Roddy v. Grand Trunk W. R.R. Inc.*, 395 F.3d 318, 323 (6th Cir. 2005) (quoting *Beneficial Nat’l Bank*, 539 U.S. at 8). Consistent with the Court’s precedent, we have observed that “[t]he congressional intent necessary to confer removal jurisdiction upon the federal district courts through complete preemption is expressed through the creation of a parallel federal cause of action that would ‘convert’ a state cause of action into the federal action for purposes of the well-pleaded complaint rule.” *Id.* (quoting *Strong v. Telectronics Pacing Sys., Inc.*, 78 F.3d 256, 260 (6th Cir. 1996)).

Importantly, a federal statute will completely preempt only those state-law claims that fall within the scope of the federal cause of action. *See Davila*, 542 U.S. at 210 (holding that § 502(a)(1)(B) of ERISA completely preempts a state-law claim only if the state claim “could have [been] brought” under § 502(a)(1)(B) and “there is no other independent legal duty that is implicated by [the] defendant’s actions”); *Beneficial Nat’l Bank*, 539 U.S. at 8 (explaining that the Supreme Court has found complete preemption only where “the federal statutes at issue provided the exclusive cause of action for the claim asserted”); *see also Roddy*, 395 F.3d at 323 (explaining that complete preemption arises where a federal cause of action converts the state-law claim into a federal one for the purposes of the well-pleaded complaint rule).

Although our court has not previously considered whether the PREP Act completely preempts state-law claims within its ambit, several federal courts of appeals have addressed the issue in similar cases involving claims against assisted-living facilities and nursing homes during the COVID-19 pandemic. *See Maglioli v. All. HC Holdings LLC*, 16 F.4th 393, 406–13 (3d Cir. 2021); *Mitchell v. Advanced HCS, L.L.C.*, 28 F.4th 580, 584–88 (5th Cir. 2022); *Manyweather v. Woodlawn Manor, Inc.*, 40 F.4th 237, 242–46 (5th Cir. 2022); *Martin v. Petersen Health Operations, LLC*, 37 F.4th 1210, 1213–14 (7th Cir. 2022); *Saldana v. Glenhaven Healthcare*

LLC, 27 F.4th 679, 687–88 (9th Cir. 2022). These courts have taken different views as to whether the PREP Act completely preempts *any* state-law claims, but the courts have all held that the Act does not completely preempt claims, like Hudak’s, that do not allege willful misconduct related to the administration or use of covered COVID-19 countermeasures. We agree.

At the outset, there is no question that the PREP Act has significant “pre-emptive force.” *Caterpillar Inc.*, 482 U.S. at 393. The Act’s general immunity provision, for instance, provides immunity to “covered person[s]” from “suit and liability under Federal and State law with respect to all claims for loss caused by” the use of a “covered countermeasure.” 42 U.S.C. § 247d-6d(a)(1). But this immunity provision reflects “an ordinary rule of preemption, a defense to liability under state law.” *Martin*, 37 F.4th at 1213. It does not create a federal cause of action that completely preempts covered state-law claims. Thus, the immunity provision might or might not provide Elmcroft with a viable defense in state court, but it does not transform Hudak’s state-law claims into federal ones for purposes of “arising under” jurisdiction. *Id.*; *see also Beneficial Nat’l Bank*, 539 U.S. at 9 (explaining that a provision of the National Banking Act would completely preempt state-law claims “[o]nly if Congress intended [the provision] to provide the exclusive cause of action” for the claims); *Gardner*, 715 F.3d at 612 (observing that ERISA’s express-preemption clause, in contrast with § 502(a)(1)(B), “is no basis to remove [a] case from state court to federal”).

The sole cause of action created by the PREP Act is “an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct . . . by such covered person.” 42 U.S.C. § 247d-6d(d)(1). Unlike the general immunity provision, it is debatable whether § 247d-6d(d)(1) completely preempts certain state-law claims. The PREP Act defines certain (but not all) elements of the claim that may be asserted under the federal cause of action, *see id.* § 247d-6d(c)(1)(A), and dictates that such claims “shall be filed and maintained only in the United States District Court for the District of Columbia,” *id.* § 247d-6d(e)(1). Yet the Act also incorporates substantive state law into actions brought under its federal cause of action, *see id.* § 247d-6d(e)(2), making it “unlike other instances of complete preemption[.]” *Matthews*, 15 F.4th at 721. Other federal courts of appeals

have not reached a consensus as to whether the PREP Act completely preempts state-law claims that fall within the scope of § 247d-6d(d)(1)'s federal cause of action. *Compare Maglioli*, 16 F.4th at 409–10 (suggesting it does), *with Saldana*, 27 F.4th at 688 (suggesting it does not), *with Mitchell*, 28 F.4th at 586 (assuming but not deciding it does), and *Manyweather*, 40 F.4th at 245 n.6 (same).

We decline to decide whether § 247d-6d(e)(1) is completely preemptive because we hold that Hudak's claims do not fall within the scope of the federal cause of action for two reasons. First, Hudak does not allege that Elmcroft engaged in *willful* misconduct within the meaning of the PREP Act. The gravamen of Hudak's terse complaint appears to be that Elmcroft failed to ensure that its employees wore masks, to assess whether it could care for Koballa after he became sick, or to transfer him to another facility that could provide the appropriate care. *See* R. 1-1 (Compl. ¶¶ 29, 36–37, 40) (Page ID #22–23). To be sure, Hudak labels one of her claims as one for “reckless, intentional, willful and wanton misconduct.” R. 1-1 (Compl. ¶¶ 42–45) (Page ID #23–24). But “distinguishing between pre-empted and non-pre-empted claims based on the particular label affixed to them would ‘elevate form over substance[.]’” *Davila*, 542 U.S. at 214 (quoting *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202, 211 (1985)). Aside from its labels, Hudak's complaint is devoid of allegations that Elmcroft took actions “(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.” 42 U.S.C. § 247d-6d(c)(1)(A). Accordingly, Hudak could not bring her claims under the PREP Act's federal cause of action.

Elmcroft challenges this initial basis for our decision on the ground that it is error to focus on the PREP Act's standard of liability when determining whether Hudak's claims fall within the scope of the Act's federal cause of action. In Elmcroft's view, “the PREP Act creates a civil cause of action—regardless of the liability standard—for a ‘person who suffered an injury’ relating to a COVID-19 countermeasure,” and the Act thereby completely preempts *all* claims that relate to covered countermeasures irrespective of whether the claims allege negligence or willful misconduct. Appellant Br. at 30 (citing 42 U.S.C. § 247d-6d(d)(1), (d)(2), (e)(1)). Elmcroft draws its argument from *Davila*, in which the Supreme Court stated that it

would be inconsistent with the Court’s precedent “to conclude that only strictly duplicative state causes of action are pre-empted.” 542 U.S. at 216. We find Elmcroft’s view to be unpersuasive.

To begin, Elmcroft’s argument cannot be reconciled with the PREP Act’s plain text. Contrary to Elmcroft’s assertion, the PREP Act does not create a federal cause of action for all claims arising under the Act. Rather, as discussed, the Act begins by creating a rule of ordinary preemption, providing immunity to covered persons from *all* federal and state claims for loss caused by the administration or use of covered countermeasures. *See* 42 U.S.C. § 247d-6d(a)(1). The Act then provides that “the *sole* exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury *proximately caused by willful misconduct*[.]” *Id.* § 247d-6d(d)(1) (emphases added). Congress could have created an exclusive federal cause of action for any claim implicating the PREP Act, or it could have provided for the removal of any claim arising under the Act, but it chose not to do so. *Cf. Miller v. Bruenger*, 949 F.3d 986, 995 (6th Cir. 2020). Elmcroft asks us to override Congress’s choice. We cannot do so.

Further, Elmcroft’s reliance on *Davila* is misplaced. Elmcroft suggests that *Davila* requires us to ignore the elements of Hudak’s claims when determining whether her claims fall within the scope of the PREP Act’s federal cause of action. But *Davila* makes clear that a state claim will be completely preempted only if it falls within the scope of an exclusive federal cause of action. 542 U.S. at 210. *If* a plaintiff could have brought a claim under the federal cause of action (and the claim does not rest on an independent legal duty), *then* the fact that state law imposes additional pleading requirements will not save their claim from complete preemption. *Id.* at 216. Far from directing us to ignore the elements of Hudak’s state claims, *Davila* instead makes clear that we must begin our analysis by “examin[ing] [Hudak’s] complaint[.]” and the basis for her claims to determine whether federal law provides a substitute cause of action for the claims. *Id.* at 211. Because Hudak does not allege willful misconduct within the meaning of the PREP Act, the Act does not provide her with a federal cause of action and her claims are not completely preempted.

Even if we were to agree that Hudak asserts a willful misconduct claim, we would hold that Hudak’s claims fall outside the scope of the PREP Act’s federal cause of action for a second,

independent reason. As noted, a willful misconduct claim brought under the PREP Act must be for a loss that has a “causal relationship with the administration to or use by an individual of a covered countermeasure[.]” 42 U.S.C. § 247d-6d(a)(2)(B). Examples of the “administration to or use of” a covered countermeasure under the Act include: “the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.” *Id.* To state a willful misconduct claim under the Act, a plaintiff must “plead with particularity . . . 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[.]” *Id.* § 247d-6d(e)(3)(A) (emphasis added).

Nowhere in the complaint does Hudak allege that “the administration to or use by [Koballa] of a” COVID-19 countermeasure caused his illness or death. *Id.* § 247d-6d(a)(2)(B). The closest Hudak comes to making such a claim is her allegation that Elmcroft’s staff failed to wear masks or follow infection-control procedures. R. 1-1 (Compl. ¶¶ 29, 36–37) (Page ID #22). But an allegation that Elmcroft *failed* to use a COVID-19 countermeasure (facemasks) or to administer another (an infection protocol) differs in kind from an allegation that Elmcroft’s *administration* or Koballa’s *use* of those countermeasures caused Koballa’s death. *See Manyweather*, 40 F.4th at 245–46 (making a similar point); *Martin*, 37 F.4th at 1213–14 (same). Put differently, Hudak alleges that Elmcroft was wrong not to use medical countermeasures, not that it engaged in wrongful actions that had a causal relationship with the administration to or use by Koballa of a countermeasure. The PREP Act’s federal cause of action does not provide an avenue for asserting Hudak’s theory of liability and therefore cannot completely preempt her claims.² *See Martin*, 37 F.4th at 1213–14 (drawing a similar distinction and holding that comparable claims were “not even arguably preempted”).

²We express no opinion as to whether allegations relating to the non-use of a covered medical countermeasure could ever fall within the scope of the PREP Act’s federal cause of action. *Cf. Manyweather*, 40 F.4th at 246 (reserving decision on this issue). We hold only that Hudak’s particular claims fall outside the federal cause of action’s scope.

Elmcroft disputes this straightforward reading of the PREP Act by pointing to a portion of the HHS Secretary’s March 2020 declaration that addressed the “administration” of covered countermeasures. Appellant Reply Br. at 12–15 (citing Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (Mar. 17, 2020)). Under the PREP Act, the Secretary has the authority under certain circumstances to issue a declaration recommending “the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that [the Act’s immunity provision] is in effect with respect to the activities so recommended.” 42 U.S.C. § 247d-6d(b)(1). Pursuant to that provision, the Secretary’s declaration recommends the administration of covered countermeasures, Declaration Under the Public Readiness and Emergency Preparedness Act, 85 Fed. Reg. at 15,201, which the declaration defines as the

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

Id. at 15,202. Seizing on the final clause of this paragraph, Elmcroft argues that Hudak’s claims allege a causal connection between Koballa’s death and Elmcroft’s management and operation.

The Secretary’s declaration, though broad, does not rescue Elmcroft from the fundamental flaw in its argument. Setting aside the issue of what, if any, deference we owe to the Secretary’s reading of the PREP Act, the declaration does not suggest that the term “administration” extends to all activities associated with the management or operation of a facility. *Cf.* Appellant Reply Br. at 14. Rather, the declaration states that the term encompasses management and operation activities that are taken *for the purpose of distributing and dispensing countermeasures*. The declaration suggests that an entity that dispenses an antiviral medication (a covered countermeasure) might be immune from a claim for loss sustained while waiting in line for the medication that alleges that the facility failed to design and implement an appropriate waiting procedure (the administration of the countermeasure). *Cf.* Declaration Under the Public Readiness and Emergency Preparedness Act, 85 Fed. Reg. at 15,200 (discussing a similar example). But that same entity would not receive immunity under the PREP Act for injuries

unrelated to its provision of the covered countermeasure solely because it provides countermeasures. That distinction demonstrates why Hudak's claims do not fall within the PREP Act's exception to that immunity. Hudak does not allege that Koballa's illness or death was caused by Elmcroft's distribution or dispersal of countermeasures, but rather by its failure to use countermeasures or to take appropriate care of him. Thus, even on the Secretary's expansive reading of the PREP Act, Hudak does not assert a willful-misconduct claim related to the "administration" of covered countermeasures.

In sum, because Hudak does not allege that Elmcroft engaged in willful misconduct in the administration or use of a covered COVID-19 countermeasure, the PREP Act does not "provide[] the exclusive cause of action for the claim asserted" and does not completely preempt Hudak's state-law claims. *Beneficial Nat'l Bank*, 539 U.S. at 8. Accordingly, the district court did not err in finding that Elmcroft could not remove the case on that basis under § 1441(a).³

2. Substantial Federal Question

Elmcroft next argues that removal to federal court was appropriate under § 1441(a) because Hudak's state claims "turn on substantial questions of federal law[.]" *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005).⁴ We are unpersuaded.

The Supreme Court has "identified a 'special and small category' of cases in which arising under jurisdiction" lies over claims originating in state rather than federal law. *Gunn v. Minton*, 568 U.S. 251, 258 (2013) (quoting *Empire Healthchoice Assur., Inc. v. McVeigh*, 547 U.S. 677, 699 (2006)). Under *Grable*, "federal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of

³We express no view as to whether § 247d-6d(d)(1) completely preempts state-law claims that fall within its scope.

⁴Hudak argues that Elmcroft forfeited its *Grable* argument by failing to raise it in the district court in opposition to Hudak's motion to remand. Notwithstanding Elmcroft's failure to raise the issue at that time, the district court resolved the issue on the merits and both parties have briefed it on appeal. Under these circumstances, we decline to address forfeiture or waiver and will instead proceed to the merits of Elmcroft's argument. *See Bledsoe v. Tenn. Valley Auth. Bd. of Dirs.*, 42 F.4th 568, 588 n.4 (6th Cir. 2022) (considering argument that may have been forfeited where the district court resolved it on the merits and the parties fully briefed it on appeal); *United States v. Clariot*, 655 F.3d 550, 556 (6th Cir. 2011) ("When a district court resolves an issue, the losing party can challenge it. Otherwise, the more surprising a district court decision in terms of resolving unbriefed and unargued points, the more insulated from review that decision would be.").

resolution in federal court without disrupting the federal-state balance approved by Congress.”
Id.

Elmcroft’s argument fails at *Grable*’s first prong. Hudak’s claims are grounded in state common law and will turn on such issues as whether Elmcroft failed to comply with its COVID-19 policies, to provide adequate medical and other care to Koballa, and to take appropriate action once it became clear that Koballa was sick. *See* R. 1-1 (Compl. ¶¶ 36–37, 40) (Page ID #22–23). None of Hudak’s claims necessarily raises a federal issue or requires a court to address or resolve one. Although Elmcroft suggests that it will raise a federal-preemption defense under the PREP Act to Hudak’s claims, the assertion of a federal defense does not transform a state claim into one that “arises under” federal law. *See Metro. Life Ins. Co.*, 481 U.S. at 63. Accordingly, in line with the courts of appeals that have addressed similar claims, we hold that Hudak’s state-law claims do not arise under federal law and could not be removed under § 1441(a). *See Maglioli*, 16 F.4th at 413; *Mitchell*, 28 F.4th at 588–89; *Martin*, 37 F.4th at 1214–15; *Saldana*, 27 F.4th at 688–89.

C. Federal-Officer Removal Under § 1442(a)(1)

Turning to the second removal statute at issue, Elmcroft argues that the case is removable under the federal-officer removal statute.⁵ Section 1442(a)(1) permits a defendant to remove to federal court a state-court action brought against:

[t]he United States or any agency thereof or any officer (or any person acting under that officer) of the United States or of any agency thereof, in an official or individual capacity, for or relating to any act under color of such office or on account of any right, title or authority claimed under any Act of Congress for the apprehension or punishment of criminals or the collection of the revenue.

28 U.S.C. § 1442(a)(1). Federal courts have subject-matter jurisdiction over claims that are properly removed under § 1442(a)(1). *See Mesa v. California*, 489 U.S. 121, 136 (1989).

⁵As above, Hudak argues that Elmcroft forfeited this argument by failing to raise it in opposition to Hudak’s motion to remand. *See supra* n.4. Because the district court addressed the issue on the merits and the parties have fully briefed it on appeal, we again address Elmcroft’s argument on the merits.

Where, as here, “the removing party is not a federal officer, we apply a three-part test to determine whether removal is proper.” *Nappier v. Snyder*, 728 F. App’x 571, 574 (6th Cir. 2018). “The removing party must demonstrate that: (1) it is a ‘person’ within the meaning of the statute who ‘acted under a federal officer’; (2) ‘it performed the actions for which it is being sued under color of federal office’; and (3) ‘it raised a colorable federal defense.’” *Id.* (quoting *Bennett v. MIS Corp.*, 607 F.3d 1076, 1085 (6th Cir. 2010)). We limit our discussion to the first prong.

To demonstrate that it was acting under a federal officer, the removing party must show that it was “in a relationship with the federal government where the government [was] functioning as the defendant’s superior.” *Mays*, 871 F.3d at 444. This relationship “typically involves ‘subjection, guidance, or control’” exercised by the government over the removing party. *Watson v. Philip Morris Cos.*, 551 U.S. 142, 151 (2007) (quoting Webster’s New International Dictionary 2765 (2d ed. 1953)). “In addition, precedent and statutory purpose make clear that the private person’s ‘acting under’ must involve an effort to *assist*, or to help *carry out*, the duties or tasks of the federal superior.” *Id.* at 152 (emphasis in original).

Here, Elmcroft has not met its burden of establishing that it was “acting under” a federal officer within the meaning of § 1442(a)(1). Elmcroft argues that it was acting under a federal officer because it was subject to a series of regulations and other federal guidance. There is no question, however, that “the help or assistance necessary to bring a private person within the scope of the statute does *not* include simply *complying* with the law.” *Watson*, 551 U.S. at 152 (emphasis in original); *see also Martin*, 37 F.4th at 1212–13. Elmcroft also argues that it performed a governmental function by helping to contain the spread of the COVID-19 virus. But this argument merely repackages Elmcroft’s earlier one. Elmcroft has not shown that it was hired or enlisted by the federal government to perform a containment function. Rather, Elmcroft asserts that it came under a duty to take certain preventative measures while carrying out its preexisting duties to its residents, including “quarantining and isolating seniors through restricting visitation, canceling communal dining, and implementing active screening of staff for fever and respiratory symptoms.” Appellant Br. at 50. Elmcroft’s compliance with these mandates, as discussed above, does not demonstrate that it was “acting under” a federal officer.

See Maglioli, 16 F.4th at 404–06; *Mitchell*, 28 F.4th at 589–91; *Martin*, 37 F.4th at 1212–13; *Saldana*, 27 F.4th at 684–86.

Elmcroft’s reliance on *Bennett*, 607 F.3d 1076, and *Caver v. Central Alabama Electric Cooperative*, 845 F.3d 1135 (11th Cir. 2017), is misplaced. In both cases, private entities had agreements with the federal government under which the entities provided a service subject to the government’s extensive direction and control. In *Bennett*, for instance, we held that a mold remediation firm hired by the Federal Aviation Administration (“FAA”) was “acting under” the FAA for purposes of removal under § 1442(a)(1). 507 F.3d at 1082, 1086–88. We observed that the remediation firm had submitted evidence demonstrating that FAA officers had the authority to dismiss the remediation firm’s employees for cause, controlled the working hours of the firm’s employees, and were required to escort the employees on and off the worksite. *Id.* at 1087–88.

Similarly, the Eleventh Circuit held in *Caver* that a rural electric cooperative was “acting under” a federal officer within the meaning of § 1442(a)(1). 845 F.3d at 1138. Although the court observed that the electric cooperative received loans from and was heavily regulated by the federal government, it concluded that the “federal regulations alone [were] not enough to satisfy the federal removal statute[.]” *Id.* at 1143. The court therefore looked beyond the applicable federal regulations to historical evidence showing that “rural electric cooperatives are something more than public utilities; they are instrumentalities of the United States.” *Id.* The court found, consistent with that historical tradition, that the electric cooperative “helps assist or carry out the duties” of the federal government and “works closely with [the federal government] to fulfill the congressional objective of bringing electricity to rural areas that would otherwise go unserved.” *Id.* at 1144. Based on that evidence, the court concluded that the electric cooperative was “acting under” the federal government within the meaning of § 1442(a)(1). *Id.*

Here, by contrast, Elmcroft asserts only that it operated a facility that came under significant federal regulation as part of the federal government’s response to the COVID-19 pandemic. Elmcroft did not have an agreement with the federal government, did not produce a good or perform a service on behalf of the government, and has not shown that the federal government exercised control over its operations to such a degree that the government acted as

Elmcroft's superior. The district court did not err in finding that the case could not be removed under §1442(a)(1) and thus that it lacked subject-matter jurisdiction over Hudak's claims.

IV. CONCLUSION

Elmcroft may invoke the PREP Act as a potential defense to Hudak's claims in state court, but it has not met its burden of showing that the Act supports removal of her claims to federal court under either § 1441(a) or § 1442(a)(1). We therefore **AFFIRM** the judgment of the district court.