

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

|                                |   |                     |
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| LAURA HUDAK,                   | ) | CASE NO. 5:21-cv-60 |
|                                | ) |                     |
|                                | ) |                     |
| PLAINTIFF,                     | ) | JUDGE SARA LIOI     |
|                                | ) |                     |
| vs.                            | ) | ORDER OF REMAND     |
|                                | ) |                     |
|                                | ) |                     |
| ELMCROFT OF SAGAMORE HILLS, et | ) |                     |
| al.,                           | ) |                     |
|                                | ) |                     |
| DEFENDANTS.                    | ) |                     |

This matter is before the Court on the motion of plaintiff Laura Hudak (“Hudak” or “plaintiff”) to remand this action to the Summit County Court of Common Pleas. (Doc. No. 8 [“Mot.”].) The removing defendants opposed the motion<sup>1</sup> (Doc. No. 24 [“Opp’n”]), to which plaintiff replied<sup>2</sup> (Doc. No. 25 [“Reply”]).

For the reasons that follow, plaintiff’s motion to remand is granted.<sup>3</sup>

**BACKGROUND**

**A. State Court Complaint**

Plaintiff is the executrix of the estate of her father, William Koballa, who was a resident at the assisted living facility defendant Elmcroft of Sagamore Hills (the “Elmcroft Facility”) from

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<sup>1</sup> Defendants filed a motion for oral argument on plaintiff’s motion to remand (Doc. No. 26), which plaintiff opposed (Doc. No. 27). Because oral argument will not assist the Court in ruling on plaintiff’s motion to remand, defendants’ motion for oral argument is denied.

<sup>2</sup> Plaintiff filed a supplement to her reply listing additional cases in support of her motion to remand (Doc. No. 29.), to which defendants responded (Doc. No. 30).

<sup>3</sup> Also before the Court is the removing defendants’ motion to dismiss this action for lack of subject matter jurisdiction or, in the alternative, to transfer venue. (Doc. No. 7.) Because plaintiff’s motion to remand is granted, the Court lacks jurisdiction to rule on defendants’ motion to dismiss or transfer.

July 1, 2016 until May 10, 2020. (Doc. No. 1-1 (Complaint [“Compl.”]) ¶¶ 1, 3, 4.) On December 11, 2020, Hudak filed this action in the Summit County Court of Common Pleas against eight defendants: (1) Elmcroft of Sagamore Hills; (2) AL Sagamore Hills Operations, LLC; (3) Elmcroft by Eclipse Senior Living; (4) Eclipse Senior Living, Inc.; (5) Eclipse Portfolio Operations, LLC; (6) Eclipse Portfolio Operations II, LLC; (7) Senior Care Operations Holdings, LLC; and (8) Jamie Ashley Cohen (defined by plaintiff collectively as “the Elmcroft Defendants”), who owned, operated, and/or managed the Elmcroft Facility. (*Id.* ¶ 6.)

According to the complaint, William Koballa and his wife, Nancy Koballa, were residing at the Elmcroft Facility at the onset of the COVID-19 pandemic on February 21, 2020, when the Centers for Disease Control (“CDC”) issued COVID-19 recommendations for healthcare professionals, including infection prevention and control policies, and on March 9, 2020, when the Governor of Ohio declared a state of emergency and authorized the Ohio Department of Health to implement procedures to alleviate the threat to public health posed by COVID-19. (*See id.* ¶¶ 7, 8, 11, 12.) Plaintiff alleges that the Elmcroft Facility implemented restrictive protocols as early as April 29, 2020, which included suspending family visitation and group activities, serving meals in residents’ rooms, daily monitoring for COVID-19 symptoms, requiring all Elmcroft Facility employees to wear masks and gloves while at the facility and follow strict hand-washing procedures, and requiring employees to have their temperatures taken and be screened for symptoms prior to each shift. (*Id.* ¶ 13.)

On May 4, 2020, Nancy Koballa reported to the Elmcroft Facility staff that her husband was ill. (*Id.* ¶¶ 15, 16.) Plaintiff claims that on May 5, 2020, Elmcroft’s director of nurses and residential services, Jeffery Timms, falsely told plaintiff that her father had been seen by a nurse

practitioner on May 4 and a doctor on May 5, 2020. (*Id.* ¶¶ 17, 18.) William Koballa’s symptoms worsened to the point that he was unable to walk or feed himself, but the staff at the Elmcroft Facility told his daughters that he was doing well. (*Id.* ¶¶ 20–26.) On May 10, 2020, plaintiff entered the Elmcroft Facility to see her father and, upon seeing his condition, insisted that he be taken to the hospital, where he tested positive for COVID-19 and was placed in intensive care. (*Id.* ¶¶ 27, 28, 33.) William Koballa died on May 19, 2020 of hypoxia and COVID pneumonia. (*Id.* ¶ 34.) Plaintiff alleges that his only exposure to other persons at the Elmcroft Facility was facility staff and that they failed to follow infection control procedures required by Medicare and the Ohio Department of Health as well as the infection control procedures required by Eclipse Senior Living. (*Id.* ¶¶ 35–37.) Based upon these facts, plaintiff asserts five state law causes of action against the Elmcroft Defendants, including negligence, wrongful death, and intentional and willful misconduct. (*See id.* ¶¶ 38–61.)

## **B. Notice of Removal**

On January 8, 2021, defendants, 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 (collectively, the “removing defendants”), removed this action from the Summit County Court of Common Pleas to the United States District Court for the Northern District of Ohio.<sup>4</sup> (Doc. 1 (Notice of Removal [“Notice”]) ¶ 1.)

The complaint was removed under 28 U.S.C. § 1441(a) pursuant to the Court’s original federal jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1442(a)(1). (*Id.* ¶ 16.) First the

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<sup>4</sup> According to the Notice, defendants AL Sagamore Hills Operations, LLC and Senior Care Operations Holdings, LLC are not related to the removing defendants, but were served with the state-court complaint and consented to removal of this action to federal court. (Notice ¶¶ 1, 2.)

removing defendants state that, on its face, plaintiff's action arises under the federal Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d ("PREP Act" or "Act"), and claim the Act completely preempts plaintiff's state law claims. (*See id.* ¶¶ 4, 17–35.)<sup>5</sup> Second, the removing defendants claim federal jurisdiction under 28 U.S.C. § 1442(a)(1), which provides that a civil action commenced in state court against the United States or any agency of the United States or any of its officials, whether sued in their official or individual capacities, for or relating to any act under color of such office, may be removed to federal court. (*Id.* ¶ 16.) Last, the removing defendants contend that this Court has jurisdiction over this action because the case involves a substantial question of federal law. (*Id.* ¶¶ 36–38.)

### C. Motion to Remand

In the motion, plaintiff contends that her claims are not covered by the PREP Act but, even if they are, the Act constitutes no more than a federal defense and, therefore, is insufficient to confer federal question jurisdiction over the complaint. (*See Mot.* at 125–39.)<sup>6</sup> Plaintiff further argues that the PREP Act is not a statute Congress intended to completely preempt state law and does not confer federal subject matter jurisdiction over plaintiff's claims. (*Id.* at 140–143.)

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<sup>5</sup> On January 13, 2021, the removing defendants supplemented the Notice with an advisory opinion issued on January 8, 2021 by the Department of Health and Human Services' ("HHS") General Counsel. (Doc. No. 6-1 (Advisory Opinion 21-01 ["Adv. Op."].) (*See* Doc. No. 6 (Notice of Supplemental Authority to Notice of Removal ["Notice Suppl."].) The Advisory Opinion was issued as a result of inquiries flowing from "a spate of recent lawsuits, most involving nursing homes and other healthcare facilities, where patients or their estates allege that patients contracted COVID-19 because the facility, among other things, failed to provide its staff with personal protective equipment ('PPE'), failed to teach the staff how to properly use that equipment, or failed to ensure that its staff used the PPE that it had been given. This Advisory Opinion addresses these questions in the context of our administration of the PREP Act and the Secretary's PREP Act Declaration, as amended." (*Id.* at 87.) The Advisory Opinion concludes that the PREP Act is a "complete preemption" statute but the author acknowledges that "[i]t does not have the force or effect of law." (*Id.* at 88–91.)

<sup>6</sup> Page number references are to page identification numbers generated by the Court's electronic filing system.

## THE PREP ACT

The PREP Act is central to defendants’ removal and plaintiff’s motion to remand. As noted by a sister district court within the Sixth Circuit addressing a motion to remand a state court case asserting negligence and wrongful death claims related to COVID-19 against a long-term care facility, there are numerous cases “currently percolating through the federal judiciary [regarding the issue of] to what extent state law claims implicating the COVID-19 pandemic are subject to federal jurisdiction via the [PREP Act], 42 U.S.C. § 247d-6d.” *Estate of Winfred Cowan v. LP Columbia KY, LLC*, No. 1:20-cv-00118, 2021 WL 1225965, at \*1 (W.D. Ky. Mar. 31, 2021). Numerous district court decisions across the country have extensively detailed the PREP Act in the context of motions to remand plaintiffs’ state court claims concerning COVID-19 against nursing homes, senior care, and assisted living facilities. *See e.g., Dupervil v. All. Health Operations, LCC*, No. 20-cv-4042, —F. Supp. 3d—, 2021 WL 355137, at \*2–7 (E.D.N.Y. Feb. 2, 2021); *Maltbia, ex rel. Dockery, v. Big Blue Healthcare, Inc.*, No. 20-cv-2607, 2021 WL 1196445, at \*4–12 (D. Kan. Mar. 30, 2021).

The PREP Act empowers the Secretary of the Department of Health and Human Services (“Secretary”) to “to deem an event a ‘public health emergency’ and then take action to utilize funds established by the Treasury to manage the emergency.” *Bolton v. Gallatin Ctr. for Rehab. & Healing, LLC*, No. 3:20-cv-00683, —F. Supp. 3d—, 2021 WL 1561306, at \*3 (M.D. Tenn. Apr. 21, 2021) (citing *Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC*, No. 20-cv-1198, 2020 WL 6140474, at \*6 (W.D. Pa. Oct. 16, 2020) (citing 42 U.S.C. § 247d(a)); *see also* 42 U.S.C. § 247d(b)(1)). “If the Secretary determines that a public health emergency exists, ‘the Secretary may make a declaration . . . recommending . . . the manufacture, testing, development, distribution,

administration, or use of one or more covered countermeasures’ to combat the emergency.” *Id.* (citing 42 U.S.C. § 247-6d(b)(1)) (alterations in original). In March 2020, the Secretary used his power under the PREP Act to declare “‘the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease, COVID-19’ [to be] a ‘public health emergency’ under the PREP Act.”<sup>7</sup> *Id.* (citing 85 Fed. Reg. 15198 (Mar. 17, 2020)).

“Covered countermeasures” are defined as qualified pandemic or epidemic products, drugs and biological products authorized for emergency use, security countermeasures, and respiratory protective devices. *See* 42 U.S.C. § 247d-6d(i)(1). Under the PREP Act, a “covered person,”<sup>8</sup> which includes individuals as well as private and public entities,

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

42 U.S.C. § 247d-6d(a)(1).

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<sup>7</sup> To date, the Secretary’s original declaration has been amended five times. *See* Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 21,012-02, 2020 WL 1864985 (Apr. 15, 2020) (“First Amended Declaration”); Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 35,100-01, 2020 WL 3050467 (June 8, 2020) (“Second Amended Declaration”); Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 52,136-01, 2020 WL 4922421 (Aug. 24, 2020) (“Third Amended Declaration”); Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79,190-01, 2020 WL 7227356 (Dec. 9, 2020) (“Fourth Amended Declaration”); Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 7,872-02, 2021 WL 325438 (Feb. 2, 2021) (“Fifth Amended Declaration”).

<sup>8</sup> *See* 42 U.S.C. §§ 247d-6d(i)(2) and (i)(5).

This immunity provision is at the core of the PREP Act.<sup>9</sup> When the PREP Act applies to covered losses (including death and injury) sustained as a result of a covered person’s use of “covered countermeasures,” the “Covered Countermeasure Process Fund” (“Fund”) provides the exclusive remedy available to the injured individual through an administrative process administered by the Secretary; “[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary” with respect to the Fund. *See* 42 U.S.C. §§ 247d-6e(a), (b)(1), (b)(5)(C). Compensation for injuries sustained as a result of actions that come within the purview of the PREP Act are exclusive of any other civil action or proceeding for any such claims and the PREP Act includes a provision expressly preempting state laws that conflict with its terms. 42 U.S.C. §§ 247d-6e(d)(4) and 247d-6d(b)(8).<sup>10</sup> *See also Dupervil*, 2021 WL 355137, at \*6.

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<sup>9</sup> The only exception to the immunity afforded covered persons by the PREP Act is a claim for death or serious injury caused by willful misconduct, which will be separately addressed herein.

<sup>10</sup> “During the effective period of a declaration [by the Secretary], or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the [FDCA].”

## **REMOVAL UNDER 28 U.S.C. § 1441(a)**

### **A. Standard of Review**

Under 28 U.S.C. § 1441(a), defendants may remove a civil action from a state court only when the federal court has original jurisdiction over the claims alleged in the state court complaint. That is, any civil case filed in state court may be removed to federal court if the case could have been brought originally in federal court. 28 U.S.C. § 1441(a); *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392, 107 S. Ct. 2425, 96 L. Ed. 2d 318 (1987). Absent jurisdiction based upon diversity of citizenship (28 U.S.C. § 1332), federal question jurisdiction under 28 U.S.C. § 1331 is required. *Caterpillar*, 482 U.S. at 392.

“The party seeking removal bears the burden of demonstrating that the district court has original jurisdiction.” *Eastman v. Marine Mech. Corp.*, 438 F.3d 544, 549 (6th Cir. 2006). Federal courts are courts of limited jurisdiction and possess only the power authorized by the United States Constitution or by statutes. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377, 114 S. Ct. 1673, 128 L. Ed. 2d 391 (1994). “[B]ecause lack of jurisdiction would make any decree in the case void and the continuation of the litigation in federal court futile, the removal statute should be strictly construed and all doubts resolved in favor of remand.” *Eastman*, 438 F.3d at 549–50 (quoting *Brown v. Francis*, 75 F.3d 860, 864–65 (3d Cir. 1996) (further citation omitted)).

#### **1. Federal Question Jurisdiction**

Here, the removing defendants do not contend that the Court has original jurisdiction under 28 U.S.C. § 1332, so the Court’s jurisdiction over this matter must be based upon 28 U.S.C. § 1331. Federal question jurisdiction exists in “all civil actions arising under the Constitution, laws, or treaties of the United States.” 28 U.S.C. § 1331. An action “arises under” federal law if: (1)



“federal law creates the cause of action[.]” or (2) “the vindication of a right under state law necessarily turn[s] on some construction of federal law.” *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808–09, 106 S. Ct. 3229, 92 L. Ed. 2d 650 (1986) (quoting *Franchise Tax Bd. v. Constr. Laborers Vacation Tr.*, 463 U.S. 1, 9, 103 S. Ct. 2841, 77 L. Ed. 2d 420 (1983)).

The presence or absence of federal-question jurisdiction is generally governed by the “well-pleaded complaint rule,” which provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff’s properly pleaded complaint. The rule makes the plaintiff the master of her claims, and she may avoid federal jurisdiction by exclusive reliance on state law. *Caterpillar*, 482 U.S. at 392 (internal citation omitted). “Accordingly, if the plaintiff chooses to bring a state law claim, that claim cannot generally be ‘recharacterized’ as a federal claim for the purposes of removal.” *Roddy v. Grand Trunk W. R.R. Inc.*, 395 F.3d 318, 322 (6th Cir. 2005) (quoting *Loftis v. United Parcel Serv., Inc.*, 342 F.3d 509, 515 (6th Cir. 2003)).

The “mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction.” *Merrell Dow*, 478 U.S. at 813. Further, “the existence of a federal defense normally does not create statutory ‘arising under’ jurisdiction, and a defendant may not [generally] remove a cause to federal court unless the *plaintiff’s* complaint establishes that the case ‘arises under’ federal law[.]” *Aetna Health Inc. v. Davila*, 542 U.S. 200, 207, 124 S. Ct. 2488, 159 L. Ed. 2d 312 (2004) (internal citations and quotation marks omitted) (alteration and emphasis in original); *see also Tisdale v. United Ass’n of Journeymen & Apprentices of Plumbing & Pipefitting Indus. of U.S. & Canada, Local 704*, 25 F.3d 1308, 1313 (6th Cir. 1994) (defensive assertion of federal statute “does not raise a federal question for removal purposes”).

Plaintiff's complaint alleges only state law causes of action and, on its face, does not raise a federal question upon which to base removal pursuant to 28 U.S.C. § 1331. But there are two exceptions to the well-pleaded complaint rule that defendants argue apply to plaintiff's state law claims and confer federal question jurisdiction upon this Court.

## **2. Exceptions to the Well-pleaded Complaint Rule**

The first exception to the well pleaded complaint rule is complete preemption. The Supreme Court has recognized this exception when the complaint, on its face, alleges only state law claims but those claims also state a cause of action under a federal statute that “completely preempts” an area of state law. *See Peters v. Lincoln Elec. Co.*, 285 F.3d 456, 468 n.11 (6th Cir. 2002) (citing *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63–64, 107 S. Ct. 1542, 95 L. Ed. 2d 55 (1987)). “[W]hen a federal statute wholly displaces the state-law cause of action through complete pre-emption, the state claim can be removed.” *Gardner v. Heartland Indus. Partners, LP*, 715 F.3d 609, 612 (6th Cir. 2013) (quoting *Aetna Health*, 542 U.S. at 207 (brackets and internal quotation marks omitted)).

The second exception is the substantial-federal-question doctrine. In *Mikulski v. Centerior Energy Corp.*, 501 F.3d 555 (6th Cir. 2007), the Sixth Circuit identified the applicability of this doctrine as an exception to the well-pleaded complaint rule, “where the vindication of a right under state law necessarily turn[s] on some construction of federal law.” *Id.* at 560 (quoting *Franchise Tax Bd.*, 463 U.S. at 9). “[U]nder the substantial-federal-question doctrine, federal question jurisdiction exists when ‘the state-law claim necessarily state[s] a federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing a congressionally approved balance of federal and state judicial responsibilities.’” *H.R. ex rel. Reuter v. Medtronic*,

*Inc.*, 996 F. Supp. 2d 671, 677 (S.D. Ohio 2014) (quoting *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314, 125 S. Ct. 2363, 162 L. Ed. 2d 257 (2005)).

There are two government publications that address these exceptions in the context of the PREP Act and plaintiff's claims. With respect to complete preemption, the general counsel of HHS issued an Advisory Opinion concluding that the PREP Act is a complete preemption statute. (*See Adv. Op.*) With respect to the substantial-federal-question doctrine, the Secretary's Fourth Amended Declaration (incorporated into the Advisory Opinion) states that there are "substantial federal legal and policy issues" and interests within the meaning of *Grable* in having a uniform response to the COVID-19 pandemic, and that Congress delegated to the Secretary the authority to strike that federal-state balance through PREP Act declarations. *See* 85 Fed. Reg. 79,190-01 (Dec. 9, 2020). The Court will consider each in its analysis of the two exceptions to the well-pleaded complaint rule as they apply to plaintiff's motion to remand.<sup>11</sup>

## **B. Analysis**

The parties extensively briefed the issue of whether plaintiff's claims fall under the purview of the PREP Act. But because the Court concludes that the PREP Act is not a complete preemption statute, and plaintiff's claims do not present a substantial federal question, there is no need for the Court to address that issue in order to rule on plaintiff's motion to remand. Nothing herein is intended by this Court to express any opinion as to whether plaintiff's claims do or do not come under the purview of the PREP Act.

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<sup>11</sup> The Court may take judicial notice of public records and government documents generally considered not to be subject to reasonable dispute and whose accuracy cannot reasonably be questioned. *See Total Benefits Planning Agency Inc. v. Anthem Blue Cross & Blue Shield*, 630 F. Supp. 2d 842, 849 (S.D. Ohio 2007), *aff'd*, 552 F.3d 430 (6th Cir. 2008).

### **1. The PREP Act does not completely preempt state law**

Complete preemption “applies only in the extraordinary circumstances when Congress intends, not merely to preempt a certain amount of state law, but also to transfer jurisdiction . . . from state to federal court.” *Peters*, 285 F.3d at 469 n.11 (citing *Metro. Life Ins. Co.*, 481 U.S. at 65–66). “[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.” *Strong v. Telectronics Pacing Sys., Inc.*, 78 F.3d 256, 260 (6th Cir. 1996) (citing *Warner v. Ford Motor Co.*, 46 F.3d 531, 534–35 (6th Cir. 1995) (en banc)). Complete preemption is rare and both the Supreme Court and the Sixth Circuit have limited expansion of complete preemption, recognizing that its force “is so powerful as to displace entirely any state cause of action” and that “[a]ny such suit is purely a creature of federal law, notwithstanding the fact that state law would provide a cause of action” in the absence of the doctrine.<sup>12</sup> See *Caterpillar*, 482 U.S. at 394 (quoting *Franchise Tax Bd.*, 463 U.S. at 23); *Tisdale*, 25 F.3d at 1310. The PREP Act is not one of those rare cases where Congress has decided not only to preempt state law, but also to transfer jurisdiction from state to federal court.

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<sup>12</sup> Both the Supreme Court and the Sixth Circuit have recognized complete preemption with respect to three federal statutes: Section 301 of the LMRA, Section 502(a) of ERISA, and the National Bank Act, 12 U.S.C. §§ 85–86. *Ohio ex rel. Skaggs v. Brunner*, 629 F.3d 527, 531 (6th Cir. 2010) (“[T]he doctrine of ‘complete preemption’ applies only to Employee Retirement Income Security Act claims, *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 107 S. Ct. 1542, 95 L. Ed. 2d 55 (1987), Labor Management Relations Act claims, *Avco Corp. v. Aero Lodge No. 735, Int’l Ass’n of Machinists*, 390 U.S. 557, 88 S. Ct. 1235, 20 L. Ed. 2d 126 (1968), and National Bank Act claims, *Beneficial Nat’l Bank v. Anderson*, 539 U.S. 1, 123 S. Ct. 2058, 156 L. Ed. 2d 1 (2003).”).

First, the PREP Act does not provide a federal cause of action for covered claims; indeed, it provides no cause of action at all. With the exception of willful misconduct, rather than providing a cause of action for covered claims, the PREP Act provides immunity to covered persons protected from liability by the Act. 42 U.S.C. § 247d-6d(a)(1). *See Schuster v. Percheron Healthcare, Inc.*, 493 F. Supp. 3d 533, 537 (N.D. Tex. 2021) (“The PREP Act does not provide the exclusive cause of action for claims that fall within its scope; in fact, for the most part, the Act provides no causes of action whatsoever. The PREP Act is, at its core, an *immunity* statute[.]”) (emphasis in original); *Dupervil*, 2021 WL 355137, at \*9 (“As an initial matter, it is important to note that the PREP Act is, at its core, an immunity statute; it does not create rights, duties, or obligations. *See* 42 U.S.C. § 247d-6d(a)(1)”). “Without creating a parallel federal cause of action for PREP Act claims, Congress has not manifested a clear intent for the PREP Act to occupy the field so completely that any ‘ostensibly state law claim’ touching on a response (or lack thereof) to COVID-19 ‘is in fact a federal claim’ for purposes of removal jurisdiction.” *Bolton*, 2021 WL 1561306, at \*7 (quoting *Roddy*, 395 F.3d at 323, 325 (quoting *AmSouth Bank v. Dale*, 386 F.3d 763, 776 (6th Cir. 2004))). “Complete preemption requires a finding that ‘the federal statutes at issue provided the exclusive cause of action for the claim asserted and also set forth procedures and remedies governing that cause of action[.]’ . . . [and] Congress knows how to enact exclusive private rights of action when it chooses to do so[.]” *Mikulski*, 501 F.3d at 564 (quoting *Beneficial Nat’l Bank v. Anderson*, 539 U.S. 1, 7–8, 123 S. Ct. 2058, 156 L. Ed. 2d 1 (2003) and citing *Cent. Bank v. First Interstate Bank*, 511 U.S. 164, 176–77, 114 S. Ct. 1439, 128 L. Ed. 2d 119 (1994)).

The PREP Act provides for no such exclusive federal cause of action for covered claims to which the immunity provision applies. *See Bolton*, 2021 WL 1561306, at \*7 (finding that the PREP Act does not provide an exclusive cause of action for covered claims and distinguishing the PREP Act from the Air Transportation Safety and System Stability Act (“ATSSSA”) where “the crucial difference between the ATSSSA and the PREP Act, at least with respect to complete preemption, is that the ATSSSA also created ‘a Federal cause of action for damages arising out of the hijacking and subsequent crashes’ that could only be filed in the United States District Court for the Southern District of New York and provided that ‘this *cause of action* shall be the *exclusive* remedy for [those] damages[.]’”) (quoting *In re WTC Disaster Site*, 414 F.3d 352, 373 (2d Cir. 2005) (emphases added in original)); *see also Jeffrey Leroy, as Co-Guardian of Silvia Leroy, Incapacitated Pers., et al. v. Heather Hume, M.D., et al.*, No. 20-cv-5325ARRCLP, 2021 WL 3560876, at \*5–6 (E.D.N.Y. Aug. 12, 2021) (rejecting the conclusion of *Rachal v. Natchitoches Nursing & Rehab. Ctr. LLC*, No. 12-cv-334, 2021 U.S. Dist. LEXIS 105847, \*3 n.3 (W.D. La. Apr. 30, 2021)—the only case to find the PREP Act to be a complete preemption statute by comparing it to the ATSSSA) (citing *In re WTC Disaster Site*, 414 F.3d at 373; *Bolton*, 2021 WL 1561306, at \*7; and *Dupervil*, 2021 WL 355137, at \*10–11).

Second, the PREP Act does not confer primary jurisdiction over covered claims in the federal courts, but upon the Secretary, who has sole authority to administer and provide compensation for covered claims from the Fund. 42 U.S.C. §§ 247d-6e(a), 247d-6e(b). *See Schuster*, 493 F. Supp. 3d at 537 (“In providing immunity to certain covered persons for certain types of claims, the PREP Act confers primary jurisdiction over most claims not to the federal courts but to the Secretary, who has the sole authority to administer and provide compensation

from a ‘Covered Countermeasure Process Fund.’”) (citing 42 U.S.C. §§ 247d-6e(a), 247d-6e(b)); *Dupervil*, 2021 WL 355137, at \*9 (same). Moreover, the PREP Act prohibits judicial review of the Secretary’s authority and the administrative remedy provided by the Act. 42 U.S.C. § 247d-(b)(5)(C). *See also Bolton*, 2021 WL 1561306, at \*3 (“The Secretary’s administration of the Process Fund is not subject to judicial review.”) (citing 42 U.S.C. § 247d-(b)(5)(C)). “Without evidence of Congress’s intent to transfer jurisdiction to federal courts, there is no basis for invoking federal judicial power.” *Peters*, 285 F.3d at 468 n.11 (citing *Strong*, 78 F.3d at 259); *Musson Theatrical, Inc. v. Fed. Exp. Corp.*, 89 F.3d 1244, 1253 (6th Cir. 1998)). So not only does the PREP Act fail to provide a federal cause of action for covered claims subject to its immunity provision, it provides only an administrative remedy and prohibits judicial review. The Sixth Circuit has specifically rejected the mere existence of a federal administrative remedy as a basis for complete preemption. *Strong*, 78 F.3d at 261 (“The federal administrative remedies under the [Medical Device Amendments to Federal Food, Drug, and Cosmetic Act] are insufficient to evince the clear manifestation of congressional intent necessary to create removal jurisdiction.”) (citation omitted).

Because the PREP Act does not provide an exclusive federal cause of action or vest jurisdiction in the federal court for covered claims subject to the Act’s immunity provision, these claims are not completely preempted by the PREP Act and, therefore, cannot be removed to federal court. Accordingly, after conducting its own review, the Court joins its sister district courts within

the Sixth Circuit,<sup>13</sup> and district courts around the country<sup>14</sup> in concluding that the PREP Act is not a complete preemption statute with respect to covered claims subject to immunity, notwithstanding the Advisory Opinion to the contrary.<sup>15</sup>

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<sup>13</sup> See *Estate of Cowan*, 2021 WL 1225965, at \*4 (“It is evident here that the PREP Act does not provide a cause of action for Plaintiffs’ [COVID-19] related negligence and wrongful death claims. The PREP Act simply extends immunity, i.e., a federal defense, and directs a federal agency, not a federal court, to provide the remedies. Apart from willful conduct claims, a plaintiff cannot bring a claim under the PREP Act in *any* court. . . . [And] the Secretary has primary jurisdiction for most claims under the Act, potentially including Plaintiffs’. Consider the logical inconsistency, for example, of allowing an action to be removed to federal court because it may have been originally brought there, yet also requiring the same court to dismiss it because an administrative agency has primary jurisdiction.”); *Bolton*, 2021 WL 1561306, at \*6 (the PREP Act does not completely preempt plaintiff’s state law negligence claims as it “does not provide the exclusive cause of action for claims that fall within its scope; in fact, for the most part, the Act provides no causes of action at all.”) (quoting *Dupervil*, 2021 WL 355137, at \*9).

<sup>14</sup> See e.g. *Schuster*, 493 F. Supp. 3d at 537–39 (finding that the PREP Act does not completely preempt state law negligence and wrongful death COVID-19 claims and granting plaintiff’s motion to remand); *Dupervil*, 2021 WL 355137, at \*9 (“[T]he PREP Act does not provide the exclusive cause of action for claims that fall within its scope; in fact, for the most part, the Act provides no causes of action at all.” Even if plaintiff’s negligence claims fall within the scope of the PREP Act, it “confers primary jurisdiction over most claims within its scope not to the federal courts, but to the Secretary, who has the sole authority to administer and provide compensation from a ‘Covered Countermeasure Process Fund.’ With the exception of willful misconduct, “PREP Act claims cannot be brought in federal Court.”); *Stone*, 2021 WL 1163572, at \*6 (To the extent plaintiff’s negligence claims fall within the ambit of the PREP Act, they are not completely preempted because the PREP Act provides an administrative remedy vested exclusively in the Secretary of HHS which is insufficient to transform a state claim into a federal cause of action.); *Winn v. California Post Acute LLC*, No. CV2102854, —F. Supp. 3d—, 2021 WL 1292507, at \*4 (C.D. Cal. Apr. 6, 2021) (even assuming that plaintiff’s claims fall within the PREP Act and may provide defendant with immunity to some of plaintiff’s claims, the PREP Act does not provide a substitute federal cause of action for plaintiff’s negligence claims but immunity for defendant); *Perez ex rel. Lozano, v. Southeast SNF LLC*, No. 21-cv-00088-JKP, 2021 WL 1381232, at \*3 (W.D. Tex. Apr. 12, 2021) (“[I]t is well established among the Federal district courts that the PREP Act does not completely preempt state court claims.”); *Evans v. Melbourne Terrace RCC, LLC*, No. 6:21-cv-381, 2021 WL 1687173, at \*2 (M.D. Fla. Apr. 29, 2021) (granting motion to remand finding persuasive *Dupervil*’s analysis and conclusion that the PREP Act is not a complete preemption statute).

<sup>15</sup> The only case this Court is aware of that gave deference to the Advisory Opinion is *Garcia v. Welltower OpCo Grp. LLC*, No. 20-cv-02250, 2021 WL 492581, at \*6–7 (C.D. Cal. Feb. 10, 2021), where the court found that, given the guidance of the Advisory Opinion, the PREP Act provides for complete preemption. The court in *Garcia* noted that earlier decisions to the contrary were issued before the Advisory Opinion or it was unclear whether those courts had considered the Advisory Opinion. See *id.* at \*6. But courts specifically considering the Advisory Opinion and *Garcia* have found the *Garcia* decision to be unpersuasive and an outlier in concluding that the PREP Act is a complete preemption statute. See e.g. *Bolton*, 2021 WL 1561306, at \*7; *Schuster*, 493 F. Supp. 3d at 537 (“*Garcia* is an outlier [in its conclusion that the PREP Act completely preempts state law COVID-19 claims] and not persuasive.”) (collecting cases); *Dupervil*, 2021 WL 355137, at \*10 n.2 (disagreeing with and finding unpersuasive the reliance of the court in *Garcia* on the Advisory Opinion to conclude that the PREP Act is a complete preemption statute); *Estate of Cowan*, 2021 WL 1225965, at \*6 (the court in *Garcia* did not explain the reason for agreeing with the Advisory Opinion’s complete preemption analysis). For the reasons contained herein, the Court also finds *Garcia* unpersuasive,



The only exception to the PREP Act’s immunity provision and prohibition on judicial review are covered claims where “death or serious physical injury” is caused by “willful misconduct.” 42 U.S.C. § 247d-6d(d)(1). But even in the case of willful misconduct claims, the plaintiff must first exhaust administrative remedies and then may file her action only in the United States District Court for the District of Columbia where she must prove her claim by clear and convincing evidence. See 42 U.S.C. §§ 247d-6d(c)(3), 247d-6d(e)(1), 247d-6e(d)(1) and (5). *Bolton*, 2021 WL 1561306, at \*6 (“Even with PREP Act claims involving ‘willful misconduct,’ which may be brought exclusively in the United States District Court for the District of Columbia, the plaintiff must first exhaust administrative remedies, and may elect to accept compensation from the Process Fund instead of filing suit in federal court. 42 U.S.C. §§ 247d-6e(d)(1), 247d-6e(d)(5); see also 42 U.S.C. §§ 247d-6d(d)(1), 247d-6d(e)(1).”) (quoting *Dupervil*, 2021 WL 355137, at \*9).

Because any covered claim involving willful misconduct first requires administrative exhaustion and then “shall be filed and maintained only in the United States District Court for the District of Columbia[.]” the PREP Act does not afford federal courts original and exclusive jurisdiction over such claims and, therefore, is not a complete preemption statute even with respect to willful misconduct claims. See *Estate of Cowan*, 2021 WL 1225965, at \*4 (“The only exclusive federal cause of action afforded by the PREP Act involves claims for willful misconduct, and even those claims require administrative exhaustion. See 42 U.S.C. §§ 247d-6d(d)(1), 247d-6d(e). Simply put, there is no federal cause of action conferring the federal courts with original exclusive jurisdiction over these claims.”); *Stone v. Long Beach Healthcare Ctr., LLC*, No. 21-cv-326, 2021 WL 1163572, at \*6 n.4 (C.D. Cal. Mar. 26, 2021) (“[T]o the extent Plaintiff’s claims are based on

willful misconduct (and assuming any of those claims actually fall within the scope of the PREP Act), the Court would, in any event, be barred from exercising jurisdiction over those claims because such an action shall be filed and maintained only in the United States District Court for the District of Columbia. *See* 42 U.S.C. § 247d-6d(e)(1).”).

Accordingly, the Court concludes that the PREP Act is not a complete preemption statute and the Court lacks federal question jurisdiction over plaintiff’s state law claims even if they fall within its purview.<sup>16</sup> Neither the PREP Act’s preemption provision nor the Advisory Opinion alter the Court’s conclusion that the PREP Act is not a complete preemption statute.

***PREP Act’s preemption provision***

The PREP Act includes a provision expressly preempting state laws that conflict with the terms of the Act. *See* 42 U.S.C. § 247d-6d(b)(8). But in the context of plaintiff’s motion to remand, it is critical to distinguish between complete preemption and ordinary preemption. “Complete preemption that permits removal is reserved for statutes ‘designed to occupy the regulatory field with respect to a particular subject and to create a superseding cause of action’ while ordinary preemption applies to statutory sections that arguably supersede conflicting state laws without creating the right of removal.” *Roddy*, 395 F.3d at 323 (quoting *Warner*, 46 F.3d at 535). Having

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<sup>16</sup> Moreover, it would be logically inconsistent to allow “an action to be removed to federal court because it may have been originally brought there, yet also requiring the same court to dismiss it because an administrative agency has primary jurisdiction.” *Estate of Cowan*, 2021 WL 1225965, at \*4; *see also Dupervil*, 2021 WL 355137, at \*10 (citing *Isufi v. Prometal Constr., Inc.*, 927 F. Supp. 2d 50, 58 (E.D.N.Y. 2013) (“It would be ‘internally inconsistent’ to assert that a district court has jurisdiction for the purpose of removal but that the court must then dismiss the action because the statute confers primary jurisdiction on another adjudicative body.”)); *Stone*, 2021 WL 1163572, at \*6 (“[A]llowing removal to federal court on complete-preemption grounds is internally inconsistent: the district court must have jurisdiction for removal to be proper, but the court must then dismiss the removed case because only the administrative agency, not federal courts, have primary jurisdiction.”)) (citing and quoting *Estate of McCaleb v. AG Lynwood, LLC*, 2021 WL 911951 (C.D. Cal. Mar. 1, 2021)). Indeed, though this Court will not rule on defendants’ motion to dismiss and transfer venue because it lacks jurisdiction over this matter, that is exactly what defendants ask this Court to do. (*See* Doc. No. 7.)

concluded that the PREP Act is not a complete preemption statute, the Act’s preemption provision constitutes only ordinary preemption which may provide a federal defense to state law claims covered by the PREP Act, but a federal defense insufficient to confer removal jurisdiction. “[A] case may not be removed on the basis of a federal defense, including the defense of [ordinary] preemption, even if the defense is anticipated in the complaint, and even if both parties concede that the federal defense is the only question truly at issue.” *Caterpillar*, 482 U.S. at 386. At best, the preemption provision of the PREP Act may provide defendants with a federal defense to plaintiff’s claims but does not confer federal subject matter jurisdiction upon this Court. *Estate of Cowan*, 2021 WL 1225965, at \*6; *Bolton*, 2021 WL 1561306, at \*6 (the PREP Act’s preemption provision provides only ordinary preemption—a federal defense—and for the purpose of ruling on plaintiff’s motion to remand, “the Court need not decide whether [plaintiff’s] state-law claims are subject to ordinary preemption under the PREP Act.”).

### ***The Advisory Opinion***

Among their arguments for complete preemption, defendants contend that the Court should defer to the conclusion of the Advisory Opinion that the PREP Act provides for complete preemption of covered claims. (Opp’n at 343–44.)

“In *Chevron U.S.A., Inc. v. Nat. Res. Def. Council*, 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984), the Supreme Court adopted a two-step approach for the interpretation of regulations and statutes. In step one, if the meaning of the statute in question is clear, then a court should look to the statute itself for guidance. Under step two, if the statute is unclear, the court should defer to a *reasonable* agency interpretation.” *Owner-Operator Indep. Drivers Ass’n, Inc.*

*v. Arctic Exp., Inc.*, 87 F. Supp. 2d 820, 827 (S.D. Ohio 2000) (emphasis in original) (citing *Chevron*, 467 U.S. at 842–43).

As an initial matter, the PREP Act’s provisions relevant to the issue of complete preemption are not unclear, and this Court (and every other district court in the country to consider the issue with the exception of the district court in *Garcia*) analyzed those unambiguous provisions and concluded that the PREP Act is not a complete preemption statute. On this basis alone, the Advisory Opinion is not entitled to *Chevron* deference. *See Wright v. Encompass Health Rehab. Hosp. of Columbia, Inc.*, No. 3:20-cv-02636, 2021 WL 1177440, at \*4 (D.S.C. Mar. 29, 2021) (“[T]he PREP Act is unambiguous. Thus, *Chevron* deference is inapplicable for HHS Advisory Opinion 21-01.”).

Second, the Advisory Opinion’s conclusion to the contrary is neither reasonable nor persuasive.<sup>17</sup> The Advisory Opinion states that “[t]he *sine qua non* of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both.” (Adv. Op. at 88.) But the opinion’s conclusion is not persuasive because it “cites no cases for its proposition that an exclusive federal administrative remedy is sufficient for complete preemption.” *Dupervil*, 2021 WL 355137, at \*10. And the Sixth Circuit has specifically rejected the mere existence of a federal administrative remedy as a basis for complete preemption. *Strong*, 78 F.3d

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<sup>17</sup> *Skidmore v. Swift & Co.*, 323 U.S. 134, 140, 65 S. Ct. 161, 164, 89 L. Ed. 124 (1944) (Agency interpretations and opinions, “while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”).

at 261 (“The federal administrative remedies under the [Medical Device Amendments to Federal Food, Drug, and Cosmetic Act] are insufficient to evince the clear manifestation of congressional intent necessary to create removal jurisdiction.”) (citation omitted); *Estate of Cowan*, 2021 WL 1225965, at \*5 (the PREP Act’s administrative remedy is insufficient to support complete preemption) (citing *Strong*, 78 F.3d at 261); *see also Dillon v. Medtronic, Inc.*, 992 F. Supp. 2d 751, 760 (E.D. Ky. 2014) (“The essential federal cause of action [necessary for complete preemption] is missing from the MDA. . . . Whatever federal administrative remedies might be available does not change that result.”) (citing *Strong*, 78 F.3d at 261).

Further, *Chevron* deference does not apply to non-binding advisory opinions. *Mid-Am. Care Found. v. NLRB*, 148 F.3d 638, 642 (6th Cir. 1998) (citations omitted). The author of the Advisory Opinion (HHS’ general counsel) concludes his opinion by stating that it “is not a final agency action or a final order” and “does not have the force or effect of law.” (Adv. Op. at 91.) For this additional reason, the Advisory Opinion’s conclusion on the issue of complete preemption is not entitled to deference. *See Bolton*, 2021 WL 1561306, at \*8 (citing *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 642 (6th Cir. 2004) (“only those administrative interpretations that Congress and the agency intend to have the ‘force of law,’ as opposed to those merely characterized as ‘authoritative,’ qualify for *Chevron* deference”)); *Estate of Cowan*, 2021 WL 1225965, at \*5 (The Advisory Opinion on its face states that it is not a final agency action or order and does not have

the force or effect of law and, therefore, is not entitled to *Chevron* deference.) (citing *Dupervil*, 2021 WL 355137, at \*10).<sup>18</sup>

Moreover, HHS lacks authority to interpret the jurisdiction of the federal courts. *Bolton*, 2021 WL 1561306, at \*8 (citing *Estate of Jones through Brown v. St. Jude Operating Co., LLC*, No. 3:20-cv-01088-SB, 2021 WL 900672, at \*6 (citing among authority *B&H Med., LLC v. United States*, 116 Fed. Cl. 671, 682 (2014) (“Although HHS possesses the expertise to administer the Medicare program generally, it is without the expertise to determine a federal court’s subject matter jurisdiction. Rather, it is the federal courts that ‘are [the] experts when it comes to determining the scope of federal-court subject-matter jurisdiction.’”)); *Wright*, 2021 WL 1177440, at \*4 (“[A]n ‘Agency’s position on jurisdiction is not entitled to deference under *Chevron*[.]’”) (quoting *Our Children’s Earth Found. v. U.S. Evtl. Prot. Agency*, 527 F.3d 842, 846 n.3 (9th Cir. 2008) (rejecting the agency’s argument that the district court lacked jurisdiction

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<sup>18</sup> Defendants’ argument that the Advisory Opinion is entitled to deference because it was incorporated into Fourth Amended Declaration does not change this analysis:

Although the Secretary’s Declaration under the PREP Act “must be construed in accordance with the Advisory Opinions of the Office of the General Counsel,” Fourth Amended Declaration, 85 Fed. Reg. 79,194–95, the Advisory Opinion here expressly states that it “does not have the force or effect of law” (Advisory Opinion 21-01[]). Thus, even assuming that Congress intended to delegate authority to the Secretary and HHS’s Office of the General Counsel “generally to make rules carrying the force of law,” the Office of the General Counsel interpretation relied upon by Defendants here explicitly was not “promulgated in the exercise of that authority” and is not entitled to *Chevron* deference.

*Dupervil*, 2021 WL 355137, at \*10 (internal citation to the record omitted).

*See also e.g. Estate of Cowan*, 2021 WL 1225965, at \*5 (finding that the Advisory Opinion stating on its face that it does not have the force or effect of law and is not a final agency action or final order is not entitled to deference simply because it is incorporated into the Fourth Amended Declaration); *Stone*, 2021 WL 1163572, at \*6 (“Finally, to the extent that Defendant relies on the Office of General Counsel’s January 8, 2021 Advisory Opinion and the HHS Secretary’s Fourth Amendment to the March 10, 2020 Declaration in support of its complete preemption argument . . . the Court concludes that HHS Secretary’s and the OGC’s interpretations of this Court’s jurisdiction under the PREP Act are not entitled to deference and lack the ‘power to persuade.’”) (collecting cases).

to evaluate statutory requirements)); *see also Shapnik v. The Hebrew Home for the Aged at Riverdale*, No. 20-cv-6774, 2021 WL 1614818, at \*13 (S.D.N.Y. Apr. 26, 2021) (Congress, not a federal agency, determines the existence of a federal cause of action and the jurisdiction of the federal courts) (citations omitted).

For all of these reasons, this Court concludes, as have numerous courts across the country, the Advisory Opinion is not entitled to deference.

## **2. Substantial federal-question doctrine**

Removing defendants also argue that this Court has jurisdiction over plaintiff’s claims because they present a substantial federal question—the second exception to the well-pleaded complaint rule. (*See* Notice ¶¶ 36–38.) The Supreme Court has found that, notwithstanding plaintiff’s characterization of her claims as arising under state law, a substantial federal question is present where claims “necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.” *Grable*, 545 U.S. at 314.<sup>19</sup> This doctrine “captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law[.]” *Id.* at 312. Under the substantial federal question doctrine, “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 resolution

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<sup>19</sup> In *Grable*, the Supreme Court found that a substantial federal-question doctrine supported removal jurisdiction. In that case, the Internal Revenue Service (“IRS”) seized the plaintiff’s property to satisfy the plaintiff’s federal-tax delinquency. *Grable*, 545 U.S. at 310–11. Plaintiff later filed a state law quiet title action against a third-party buyer, claiming that the sale was invalid because the IRS failed to comply with certain federally imposed notice requirements. *Id.* In determining that removal was proper because of the substantial federal question, the Supreme Court emphasized the federal government’s “strong interest” in being able to recover delinquent taxes through property seizures and ensuring they act properly in the process. *Id.* at 315.

in federal court without disrupting the federal-state balance approved by Congress.” *Gunn v. Minton*, 568 U.S. 251, 258, 133 S. Ct. 1059, 1065, 185 L. Ed. 2d 72 (2013) (citing *Grable*, 545 U.S. at 313-14). “Where all four of these requirements are met, . . . jurisdiction is proper[.]” *Id.* If any of the four requirements are not satisfied, the exception does not apply. *Bolton*, 2021 WL 1561306, at \*4 (citing *Dupervil*, 2021 WL 355137, at \*14 (citations omitted)). In conducting this analysis, the Court is mindful that the substantial federal question doctrine is narrowly applied— “‘*Grable* emphasized that it takes more than a federal element to open the ‘arising under’ door.’” *Mikulski*, 501 F.3d at 568 (quoting *Empire HealthChoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 701, 126 S. Ct. 2121, 165 L. Ed. 2d 131 (2006)).

With respect to the first factor, “[a] state-law claim ‘necessarily’ raises federal questions where the claim is affirmatively ‘premiered’ on a violation of federal law.” *Bolton*, 2021 WL 1561306, at \*4 (quoting *New York ex rel. Jacobson v. Wells Fargo Nat’l Bank, N.A.*, 824 F.3d 308, 315 (6th Cir. 2016) (citing *Grable*, 545 U.S. at 314)); *Dupervil*, 2021 WL 355137, at \*14 (“‘A state-law claim ‘necessarily’ raises federal questions when the claim is affirmatively ‘premiered’ on a violation of federal law.’”) (quoting *Jacobson*, 824 F.3d at 315 (quoting *Grable*, 545 U.S. at 314)). Applying these standards, the Court finds that plaintiff’s claims do not “necessarily” raise a federal issue and do not present a substantial federal question.

“The paradigmatic example of a state claim with an embedded (though not necessarily significant) federal issue is a common-law claim for negligence per se based on the violation of a federal duty.” *Bolton*, 2021 WL 1561306, at \*4 (quoting *Dillon*, 992 F. Supp. 2d at 756 (citing *Merrell Dow*, 478 U.S. at 814)). Here, plaintiff’s complaint alleges claims of negligence (Count One), reckless, intentional, willful and wanton misconduct (Count Two), survivorship and



wrongful death (Count Three<sup>20</sup>), violation of Ohio's nursing home bill of rights Ohio Rev. Code 3721.17(I) (Count Four), and malicious and conscious disregard for the rights and safety of plaintiff's decedent justifying punitive damages (Count Five).

None of plaintiff's claims are premised upon the PREP Act, nor is any component of the PREP Act an element of her claims. The state court can determine whether plaintiff's state law claims fall within the purview of the PREP Act and the impact of any affirmative defense defendants may have under the Act. That determination has no bearing on the PREP Act itself. *See Lecce v. Medtronic, Inc.*, No. 1:18-cv-2720, 2019 WL 2925102, at \*2 (N.D. Ohio July 8, 2019) (finding plaintiff's state law claims regarding an FDA regulated product did not present a substantial federal question because "the state court will not have to determine whether any government actions was proper or constitutional. Instead, the [state] court will determine only how federal law affects the parties in this case.").

Plaintiff's claims do not necessarily raise an issue of federal law. *Bolton*, 2021 WL 1561306, at \*4 (plaintiff's complaint does not necessarily raise an issue under the PREP Act because the Court could ignore entirely the PREP Act in determining whether Bolton established state-law COVID-19 claims for gross negligence and recklessness); *Dupervil*, 2021 WL 355137, at \*14 ("[N]one of Plaintiff's [COVID-19 state law] claims 'necessarily' raise a federal issue."). Accordingly, this Court concludes that plaintiff's complaint does not present a substantial federal question and an exception to the well-pleaded complaint rule under *Grable*. *See Dupervil*, 2021 WL 355137, at \*14 ("[T]he Court follows every district court to have considered the *Grable*

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<sup>20</sup> The complaint lists survivorship and wrongful death as separate counts but identifies both as Count Three. (*See* Compl. at 24.)

exception in this context, and concludes that federal-question jurisdiction does not ‘lie over’ Plaintiff’s state-law claims.”) (collecting cases); *Bolton*, 2021 WL 1561306, at \*5 (“[T]he Court does not find that this case falls within the “special and small category of cases” where the embedded-federal-question doctrine applies, and it would therefore be improper to remove Bolton’s case on that basis.”).

In addition to opining that the PREP Act is a complete preemption statute, the Advisory Opinion incorporates the Fourth Amended Declaration<sup>21</sup> and states that the Secretary’s determination that the Act implicates “substantial” federal legal and policy issues and interests “provides the underlying basis for invoking the *Grable* doctrine with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure.” (Adv. Op. at 91.) But the Secretary’s Fourth Amended Declaration and the Advisory Opinion concerning the application of the *Grable* exception to PREP Act claims do not change the Court’s conclusion as neither addresses the issue whether a disputed question of

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<sup>21</sup> The Fourth Amended Declaration states in relevant part:

COVID-19 is a global challenge that requires a whole-of-nation response. There are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng’g. & Mfg.*, 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities. The world is facing an unprecedented pandemic. To effectively respond, there must be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world. Thus, there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng’g. & Mfg.*, 545 U.S. 308 (2005), in having a uniform interpretation of the PREP Act. Under the PREP Act, the sole exception to the immunity from suit and liability of covered persons under 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. In all other cases, an injured party’s exclusive remedy is an administrative \*79198 remedy under section 319F-4 of the PHS Act. Through the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declarations.

Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 FR 79,197–98.

federal law is a necessary element of plaintiff's well pleaded claims. *Bolton*, 2021 WL 1561306, at \*5 (“[a]lthough the Secretary’s view on the federal interests underlying the PREP Act are compelling, neither the Fourth Amended Declaration nor the Advisory Opinion address[es] whether [plaintiff’s] claims necessarily state a federal issue, such that a disputed question of federal law is a *necessary element of one of the well-pleaded state claims*”) (emphasis in original) (internal quotation marks omitted) (quoting *Estate of Cowan*, 2021 WL 1225965, at \*6 (quoting *Mikulski*, 501 F.3d at 565)). Moreover, the general counsel’s conclusions, on their face, do not have the force or effect of law. *See Dupervil*, 2021 WL 355137, at \*10 (“Although the Secretary’s Declaration under the PREP Act ‘must be construed in accordance with the Advisory Opinions of the Office of the General Counsel,’ Fourth Amended Declaration, 85 Fed. Reg. 79,194–95, the Advisory Opinion here expressly states that it ‘does not have the force or effect of law’” and is not entitled to deference.).

For all of these reasons, the Court concludes that the Court lacks jurisdiction over plaintiff’s well-pleaded complaint and none of the exceptions to the well-pleaded complaint rule confers federal subject matter jurisdiction on this Court. To the extent that the Prep Act may provide an affirmative defense to plaintiff’s claims, a federal defense does not support removal jurisdiction. *Caterpillar*, 482 U.S. at 399 (emphasis in original) (“[A] *defendant* cannot, merely by injecting a federal question into an action that asserts what is plainly a state-law claim, transform the action into one arising under federal law, thereby selecting the forum in which the claim shall be litigated. If a defendant could do so, the plaintiff would be master of nothing. Congress has long since decided that federal defenses do not provide a basis for removal.”) (internal footnote and citation

omitted). Accordingly, the removing defendants have not carried their burden to establish the Court's original subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1441(a).

**REMOVAL UNDER 28 U.S.C. 1442(a)(1)**

28 U.S.C. § 1442(a)(1) provides that:

(a) A civil action or criminal prosecution that is commenced in a State court and that is against or directed to any of the following may be removed by them to the district court of the United States for the district and division embracing the place wherein it is pending:

(1) The 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.

While defendants identified this statute as a basis for removal, neither side addresses it in their briefing on plaintiff's motion to remand. To the extent that the removing defendants have not abandoned this statute as a basis for this Court's jurisdiction, 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. *See Dupervil*, 2021 WL 355137, at \*15–16.

It is removing defendants' burden to establish this Court's jurisdiction over this matter pursuant to § 1442(a)(1) and they have failed to do so.

**CONCLUSION**

For all of the foregoing reasons, plaintiff's motion to remand (Doc. No. 8) is granted. Defendant's motion for oral argument (Doc. No. 26) is denied. This case is remanded to the Summit County Court of Common Pleas.

**IT IS SO ORDERED.**

Dated: August 19, 2021

  
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**HONORABLE SARA LIOI**  
**UNITED STATES DISTRICT JUDGE**