



replied that he could use the restroom and shop around the store while he waited for the fifteen minutes to expire. Compl. ¶ 23. Defendant Polovitch never instructed Mr. Roeder to lie down or remain seated within the pharmacy area as CDC guidelines recommend. Compl. ¶ 27.

Mr. Roeder went to the restroom. Shortly thereafter, he was found unconscious and seriously injured. Compl. ¶ 35. Mr. Roeder was taken to the emergency room where he was eventually put into a medically induced coma. Compl. ¶ 37. He passed away 7 months later. Compl. ¶ 39.

Plaintiff, Mr. Roeder's wife, and the administrator of Mr. Roeder's estate filed this lawsuit seeking compensation for Mr. Roeder's injuries and death. In her Complaint, Plaintiff alleges that Defendants acted negligently in administering Mr. Roeder's vaccination and in supervising him thereafter. Plaintiff draws her cause of action from state tort law. Defendants removed the case to this Court on the basis of federal question jurisdiction, arguing in the alternative that either the cause of action created by the Public Readiness and Emergency Preparedness Act (the "PREP Act") completely preempts the state law claims set forth in Plaintiff's complaint or Defendant's preemption defense under the PREP Act raises a substantial federal issue. Notice of Removal, ECF No. 1. Plaintiff has moved to remand. Mot. to Remand ECF No. 11. Plaintiff's motion is presently before the Court.

## **II. LEGAL STANDARD**

A defendant can remove a case to federal court only if the action could have originally been filed in federal court by the plaintiff. *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392, 107 S.Ct. 2425, 96 L.Ed.2d 318 (1987). A plaintiff may file a motion to remand a case back to state court after a defendant has removed it. 28 U.S.C. § 1447. When a motion to remand is filed, the burden to prove the case satisfies federal question jurisdiction falls on the removing party. *Boyer*

*v. Snap-On Tools Corp.*, 913 F.2d 108, 111 (3d Cir.1990). The removal statutes are “to be strictly construed against removal, and all doubts in favor of remand.” *Id.*

### **III. DISCUSSION**

Defendants argue the Court has subject matter jurisdiction for two reasons. First, Defendants argue the PREP Act completely preempts Plaintiff’s state law claims. Second, Defendants argue Plaintiff’s complaint raises important federal issues and therefore comes within the Court’s subject matter jurisdiction pursuant to the *Grable* test. The Court will address each argument in turn.

#### **A. Complete Preemption**

A federal statute is completely preemptive if it “provides the exclusive cause of action for the claim asserted and also sets forth procedures and remedies governing that cause of action.” *Beneficial Nat’l Bank v. Anderson*, 539 U.S. 1, 8 (2003). The Third Circuit applies this principle in two steps. First, the Court asks whether the statute creates an exclusive federal cause of action. *Maglioli v. All. HC Holdings LLC*, 16 F.4th 393, 407 (3d Cir. 2021). If the Court concludes that the statute does create an exclusive federal cause of action, then the Court asks whether any of the Plaintiff’s claims fall within the scope of that cause of action. *Id.* If both steps are satisfied, then the claims are completely preempted and removable to federal court.

##### **i. Does the statute create an exclusive federal cause of action?**

Defendants rest their theory of complete preemption entirely on the PREP Act. Congress enacted the PREP Act to protect certain individuals and entities, such as pharmacies and drug manufacturers, during public health emergencies. *Maglioli*, 16 F.4th at 400.

The statute empowers the Secretary of the Department of Health and Human Services (“HHS”) to declare a public health emergency by publishing a declaration. In this declaration,

the Secretary may identify countermeasures that are necessary to address the public health emergency. *Id.* The PREP Act provides legal protections for “covered person[s]” that administer these countermeasures. 42 U.S.C. § 247d-6d(a)(1). Covered persons that qualify under the Act include “manufacturers, distributors, program planners” and their “employees.” *Maglioli*, 16 F.4th at 401. These persons enjoy immunity from claims relating to “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 countermeasures. 42 U.S.C. § 247d-6d(a)(2)(B).

The parties disagree as to whether Defendants are covered persons. But the Court would reach the same result regardless of whether Defendants are covered persons, so the Court will presume they are covered persons for the purpose of this analysis.

When the Secretary declares a public health emergency, covered individuals and entities become immune from many of the legal claims that could ordinarily be brought against them. 42 U.S.C. § 247d-6d(a)(1). The statute also expressly preempts contrary state law so long as the emergency declaration is effective. 42 U.S.C. § 247d-6d(b)(8) (“[N]o State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure that relates to the administration by qualified persons of the covered countermeasure any provision of law or legal requirement that . . . is different from, or is in conflict with, any requirement applicable under this action.”). The one exception to immunity under the PREP Act is that the Act creates “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).

Because the PREP Act immunizes covered persons for their administration of countermeasures, preempts all contrary state law causes of action, and then creates an “exclusive Federal cause of action” that can pierce this immunity, the PREP Act clearly evidences congressional intent to create an exclusive cause of action. *Maglioli*, 16 F.4th at 409. Accordingly, the PREP Act satisfies step one of the complete preemption analysis.

**ii. Do any of the Plaintiff’s claims fall within the scope of that cause of action?**

Next, the Court must consider whether Plaintiff’s claims fall within the scope of the PREP Act’s exclusive cause of action as required under step two of the complete preemption analysis.

Plaintiff alleges only state law negligence claims in her Complaint. Compl. ¶ 40–70. These claims fall within the PREP Act’s scope insofar as they relate to the administration of countermeasures by covered persons during a public health emergency. Indeed, there is no question that the Secretary issued a declaration identifying the COVID-19 pandemic a public health emergency, that the declaration identified COVID-19 vaccines as a countermeasure, and that the declaration remained in effect when the conduct involved in this suit allegedly occurred. *See Declaration Under the PREP Act for Medical Countermeasures Against COVID-19*, 85 Fed. Reg. 15,201 (Mar. 17, 2020).

What is not clear, however, is that Plaintiff’s claims rely on a standard of care that falls within the PREP Act’s exclusive cause of action. The PREP Act’s cause of action permits suits only for “willful misconduct.” 42 U.S.C. § 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 further specifies that willful misconduct “shall be 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).

In her complaint, Plaintiff does not allege that Defendants took “risks so great to make it highly probable that the harm will outweigh the benefit.” 42 U.S.C. § 247d-6d(c)(1)(A)(iii). They only allege facts pertaining to the Defendant’s failures to implement and follow certain guidelines and procedures set forth by the CDC. Compl. ¶ 24. It is true that Plaintiff is alleging the Defendants ignored a risk, but there is nothing in the complaint that suggests this risk was so great that it would make it “highly probable that the harm will outweigh the benefit.” *Id.* The threshold set forth by the PREP Act is a high threshold to meet, and none of the allegations in Plaintiff’s complaint rise to threshold’s level.

Plaintiff’s allegations sound in negligence, not willful misconduct. Accordingly, Plaintiff’s claims do not fall within the PREP Act’s scope. *See Maglioli*, 16 F.4<sup>th</sup> at 411 (“Congress could have created a cause of action for negligence or general tort liability. It did not.”). Thus, the state law claims set forth in Plaintiff’s complaint are not completely preempted under the PREP Act, and as a result do not give this court jurisdiction.

## **B. The Grable Test**

Defendants’ second argument to resist remand is that Plaintiff’s complaint raises a substantial federal issue and therefore comes within the Court’s subject matter jurisdiction. State law claims that implicate federal issues come within a federal court’s subject matter jurisdiction only when the federal issue is “(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.” *Gunn v. Minton*, 568 U.S. 251, 257 (2013). This test for subject matter jurisdiction is

often referred to as the “*Grable* test,” named after the Supreme Court’s decision in *Grable & Sons Metal Products v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005).

Here, Plaintiff properly plead her state law negligence claims without mentioning the PREP Act in her complaint. The PREP Act would only become relevant to Plaintiff’s claims insofar as it provides Defendants a preemption defense. As the Third Circuit has already made clear, the PREP Act’s preemption defense is not “necessarily raised” by a state law claim of negligence. *Maglioli*, 16 F.4th at 413. Accordingly, Defendants’ second argument “fails at *Grable*’s first step.” *Id.*

#### IV. CONCLUSION

Plaintiff’s motion to remand to the Philadelphia Court of Common Pleas is granted. The PREP Act does not completely preempt Plaintiff’s state law negligence claims as Plaintiff has plead them. And the federal issue involved in a preemption defense based on the PREP Act is not “necessarily raised,” as required for federal jurisdiction under the *Grable* test, by a state law claim for negligence.

BY THE COURT:

/s/ John M. Gallagher  
JOHN M. GALLAGHER  
United States District Court Judge