No. 22-6070

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

LISA KAY GOINS,

Plaintiff-Appellee,

v.

SAINT ELIZABETH MEDICAL CENTER, INC.; KROGER CO.; JOHN DOES; JANE DOES; MODERNATX, INC.,

Defendants;

TRI-STATE GASTROENTEROLOGY ASSOCIATES; JOEL M. WARREN, M.D.,

Defendants-Appellants.

On Appeal from the United States District Court
for the Eastern District of Kentucky
Case No. 2:22-cv-0091
Hon. David L. Bunning, District Judge

BRIEF OF AMICUS CURIAE PUBLIC CITIZEN IN SUPPORT OF APPELLEE

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May 4, 2023

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UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Disclosure of Corporate Affiliations and Financial Interest

Sixth Circuit
Case Number: 22-6070 Case Name: Goins v. St. Elizabeth Medical Center

Name of counsel: Adam R. Pulver

Pursuant to 6th Cir. R. 26.1, Public Citizen
Name of Party
makes the following disclosure:

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

No

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

No

CERTIFICATE OF SERVICE

I certify that on May 4, 2023 the foregoing document was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by placing a true and correct copy in the United States mail, postage prepaid, to their address of record.

s/Adam R. Pulver

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

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INTEREST OF AMICUS CURIAE[1]

Amicus curiae Public Citizen is a nonprofit consumer advocacy organization with members in all fifty states. Public Citizen advocates for enactment and enforcement of laws to protect consumers, workers, and the public, as well as for policies that protect the health and safety of vulnerable populations. Public Citizen has a longstanding interest in patient safety and in holding health care providers accountable for protecting patients, including by supporting individuals' ability to access the civil justice system.[2] In that regard, it often appears as amicus curiae to address issues concerning the preemptive effect of various health care-related statutes. Since 2021, Public Citizen has filed briefs as amicus curiae addressing the scope of the immunity provisions of the Public Readiness and Emergency Preparedness (PREP) Act in the Third,

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[1] The parties have consented to the filing of this brief. No party's counsel authored this brief in whole or part, no party or party's counsel contributed money intended to fund the brief's preparation or submission, and no person other than amicus curiae, its members, or its counsel contributed money intended to fund the brief's preparation or submission.

[2] Some of Public Citizen's work in these areas is collected at https://www.citizen.org/topic/health-care and https://www.citizen.org/topic/justice-the-courts/health-safety.

Seventh, Ninth, and Eleventh Circuits. *See, e.g.*, *Martin v. Petersen Health Ops., LLC*, 37 F.4th 1210 (7th Cir. 2022); *Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393 (3d Cir. 2021); *Hampton v. California*, 9th Cir. No. 22-15481; *Polanco v. Diaz*, 9th Cir. No. 22-15496; *Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC*, 3d Cir. No. 20-3287; *Schleider v. GVDB Ops., LLC*, 11th Cir. No. 21-11765.

Public Citizen submits this brief to explain that, if accepted, Appellants' erroneous arguments regarding the scope of the PREP Act would wrongly deprive injured plaintiffs of access to meaningful remedies.

INTRODUCTION

The Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. §§ 247d-6d–6e, provides "[t]argeted liability protections for pandemic and epidemic products and security countermeasures." *Id.* § 247d-6d. Among these protections is an immunity from liability under both federal and state law for certain claims against "covered persons" relating to the administration to or use by an individual of "covered countermeasures" designated by the Secretary of Health and Human Services. To establish entitlement to this immunity, a defendant must

establish that it meets requirements specified both in the Act and in declarations of the Secretary.

Here, the district court correctly held that the allegations in the complaint, construed in the light most favorable to Plaintiff-Appellee Lisa Kay Goins, do not establish that Defendant-Appellants Tri-State Gastroenterology Associates and Joel M. Warren, M.D., were entitled to PREP Act immunity for claims based on Dr. Warren's allegedly negligent endoscopic procedures and a pancreatic biopsy. Under the plain language of the statute, the district court was correct to reject the only argument offered by Appellants below: that simply because Dr. Warren was qualified to administer a covered countermeasure, he is a "covered person" and thus eligible for PREP Act immunity. The statute is explicit that qualified persons are only covered persons where they have administered covered countermeasures. Here, the only covered countermeasure identified by Appellants in their motion to dismiss below was the COVID-19 vaccine, and the complaint does not allege that Appellants administered the vaccine to Ms. Goins or anyone else.

On appeal, Tri-State and Dr. Warren make a new argument: that Dr. Warren is a covered person for purposes of PREP Act immunity

because the devices that he used to perform the allegedly negligent medical procedures were covered countermeasures. Because this argument was never presented to the district court, this Court should decline to address it. In addition, the argument rests on misrepresentations of the allegations of the complaint—Appellants assert that Ms. Goins alleges that she was "diagnosed" with an adverse reaction to the COVID-19 vaccine when, in fact, the complaint alleges that Ms. Goins's symptoms were a mystery to doctors, including Dr. Warren. The complaint's allegation that, *after* Dr. Warren conducted the procedures at issue, unspecified doctors hypothesized that her symptoms *could* be a reaction to the COVID-19 vaccine is not sufficient to meet Appellants' burden to establish that Dr. Warren was treating side effects of the vaccine, and thus using covered COVID-19 countermeasures, when he allegedly nicked Ms. Goins's spleen and irritated her pancreas.

At the Rule 12 stage, the possibility that Appellants might be able to adduce evidence to show that Dr. Warren's treatment was intended to mitigate a reaction to the COVID-19 vaccine is not enough to entitle them

to dismissal. That issue is properly left to be resolved in the state court after further factual development on remand.[3]

BACKGROUND

I. The PREP Act and the 2020 Declaration

A. Initially enacted in 2005 "[t]o encourage the expeditious development and deployment of medical countermeasures during a public health emergency, the [PREP Act] authorizes the Secretary of Health and Human Services (HHS) to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines." Cong. Res. Serv., The PREP Act and COVID-19, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures 1 (updated Apr. 13, 2022).[4] The Secretary of HHS

[3] Tri-State and Dr. Warren do not argue that the district court erred in remanding the matter after denying their motion to dismiss. In light of this Court's decision in *Hudak v. Elmcroft of Sagamore Hills*, 58 F.4th 845, 854–55 (6th Cir. 2023), which rejected the same federal-question jurisdiction theories asserted in Tri-State and Dr. Warren's notice of removal, the only possible basis for jurisdiction was supplemental jurisdiction. The decision not to exercise supplemental jurisdiction over the remaining state-law claims after dismissing the defendants that had invoked federal-officer jurisdiction, RE 32, Page ID# 546–47, was not an abuse of discretion. *Cf. Burnett v. Griffith*, 33 F.4th 907, 915 (6th Cir. 2022) (noting that a district court should ordinarily remand state-law claims after dismissing all federal claims).

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

triggers the PREP Act by issuing a declaration that a public health emergency exists and "recommending" the "manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures," under certain conditions. 42 U.S.C. § 247d-6d(b)(1). The Secretary may designate only certain drugs, biological products, and devices authorized or approved for use by the Food and Drug Administration or the National Institute for Occupational Safety and Health as "covered countermeasures." *Id.* § 247d-6d(*i*)(1)(A)–(D).

Subsection (a)(1) of the PREP 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.'" *Hudak*, 58 F.4th at 849 (quoting 42 U.S.C. § 247d-6d(a)(1)) (alteration and omission in original). The PREP Act, however, "limits both the reach and effect of its immunity provision." *Id*.

As to reach, the statute provides immunity only to "covered person[s]," defined by the statute to mean six categories of persons and

entities, 42 U.S.C. § 247d-6d(*i*)(2), for claims for injuries that have "a causal relationship with the administration to or use by an individual of a covered countermeasure," *id.* § 247d-6d(a)(2)(B). Immunity is also available "with respect to a covered countermeasure" only if the countermeasure was used for the purposes specified in a Secretarial declaration, during the effective period of a declaration, and with respect to an individual in the population specified by a declaration. *Id.* § 247d-6d(a)(3). The statute also gives the Secretary authority to further limit the scope of immunity. *Id.* §§ 247d-6d(b)(1)–(2).

Even where all of these conditions are satisfied, the statute creates an exception to its grant of immunity for claims for "willful misconduct," as defined by the statute, which can be brought before a three-judge panel in the District Court for the District of Columbia and are subject to special procedural requirements. *Id.* §§ 247d-6d(d)–(e). Where an injury was not caused by willful misconduct, an injured party may obtain relief from a statutory administrative compensation scheme. *Id.* § 247d-6e.

B. On March 10, 2020, the HHS Secretary issued a "Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19." 85 Fed. Reg. 15,198

(published Mar. 17, 2020). The Declaration recommended the "manufacture, testing, development, distribution, administration, and use" of "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product." *Id.* at 15,201–02.

The Secretary has amended the Declaration several times.[5] As vaccines became available, several amendments "add[ed] additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID-19 vaccines that are covered countermeasures under the Declaration." HHS, Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 87 Fed. Reg. 982, 983 (Jan. 7, 2022) (summarizing prior amendments). The Fourth Amendment incorporated by reference four advisory opinions previously issued by

[5] All of these amendments, as well as the Office of General Counsel's advisory opinions, are available at https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx.

HHS's Office of General Counsel (OGC). 85 Fed. Reg. 79,190, 79,191 & n.5 (Dec. 9, 2020). In one of those opinions, citing preamble language in the Second Amendment to the Declaration, OGC opined that epinephrine qualified as a covered countermeasure under the Declaration when used "to address … severe acute vaccine reaction." OGC, Advisory Opinion 20-03, at 3–4 (Oct. 22, 2020, as modified on Oct. 23, 2020) (citing HHS, Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 35,100, 35,101 (June 8, 2020)).[6] "The PREP Act would not cover the administration of epinephrine to address unrelated respiratory or cardiovascular symptoms," it explained. *Id.* at 4.

II. Factual allegations

Ms. Goins's complaint alleges that Ms. Goins was administered two doses of a COVID-19 vaccine manufactured by Defendant ModernaTX at a pharmacy operated by Defendant Kroger in Florence, Kentucky, in July 2021. RE 9-3, PageID# 100, ¶¶ 12–13. After the second dose, the complaint alleges, Ms. Goins noticed that her blood glucose levels were

[6] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO3.1.2_Updated_FINAL_SIGNED_10.23.20_0.pdf.

fluctuating "from her standard controlled level."[7] *Id.* ¶ 14. When her blood glucose level became very low and did not improve, she went to the emergency room of St. Elizabeth Hospital. *Id.* ¶ 15. St. Elizabeth admitted her to the intensive care unit, where she was seen by a variety of doctors who were puzzled by her condition. *Id.*, Page ID# 101, ¶¶ 15, 18–22.

While at the hospital, Ms. Goins reported a new symptom of abdominal pain. *Id.* ¶ 22. Defendant Dr. Warren, of Defendant Tri-State Gastroenterology, was called for a consultation. *Id.* On August 7, 2021, Dr. Warren performed an upper endoscopic ultrasound with fine needle aspiration, an esophagogastroduodenoscopy, and a pancreatic biopsy. *Id.*, PageID# 102, ¶ 23. Finding nothing, Dr. Warren diagnosed Ms. Goins with "non-specific hyperechoic pancreatic parenchyma with no identifiable mass." *Id.* ¶ 25.

Other doctors performed other tests on Ms. Goins. *Id.*, PageID# 101–02, ¶¶ 18, 26. After no conclusive diagnosis was reached, "doctors stated [her symptoms] could have been a reaction to her July 31, 2021

[7] The complaint is not specific, but this allegation, along with other references to Ms. Goins's preexisting "medical condition," *see, e.g.*, RE 9-3, PageID# 108, ¶ 6, suggests Ms. Goins may suffer from type 2 diabetes.

second Moderna COVID-19 vaccine." *Id.*, PageID# 102, ¶ 26. After Ms. Goins's blood glucose levels stabilized, she was discharged from St. Elizabeth on August 22, 2021. *Id.* ¶ 27.

After she got home, Ms. Goins got sicker—getting weak, losing her appetite, and being unable to hold down any food. *Id.* ¶¶ 28–29. A CT scan conducted at a local emergency room revealed that she had pancreatitis and a pseudocyst on her pancreas—which was "more than likely caused from an[] irration like a biopsy." *Id.*, PageID# 103, ¶¶ 32–33. She was discharged from the local hospital after two days, but found herself back at St. Elizabeth's emergency room two days later, suffering from severe pain, nausea, and pancreatitis. *Id.* ¶¶ 36–38. A new CT scan revealed a large intraabdominal bleed, a subcapsular splenic hematoma, and evidence of subcapsular splenic parenchymal laceration/rupture. *Id.*, PageID# 104, ¶ 40. Ms. Goins was rushed to emergency surgery for an exploratory laparotomy, splenectomy, pancreatic debridement, repair of gastric perforation, and feeding tube placement. *Id.* ¶ 41. Afterwards, she "was informed her spleen may have ruptured from being nicked." *Id.* ¶ 43.

After this surgery, Ms. Goins experienced complications arising

from her feeding tube, which remained in place for nearly three months. *Id.,* PageID# 105–06, ¶¶ 55–63. She has experienced persistent pain, anxiety, and depression since the August 7 procedure performed by Dr. Warren, as well as an inability to work. *Id.,* PageID# 107, ¶¶ 65–67.

III. Procedural history

Ms. Goins commenced this action in the Boone County, Kentucky Circuit Court on June 22, 2022, bringing claims against Kroger, ModernaTX, St. Elizabeth (and related Does), Tri-State, and Dr. Warren. As to Kroger and Moderna, Ms. Goins alleged claims for negligence and battery, arguing that the COVID-19 vaccine "was contraindicated for [her] medical condition," and that she "would not have agreed to the vaccination if she knew the vaccine [was] contraindicated." RE 9-3, PageID# 111–13, ¶¶ 25–38.

As to Dr. Warren and the St. Elizabeth-affiliated Does, the complaint alleges that they were negligent in their provision of care. *Id.*, PageID# 107–08, ¶¶ 1–4. It also alleges that they committed battery "by performing a high risk surgical procedure that was contraindicated for [her] medical condition," and that she "would not have agreed to the

surgery if she knew the surgery [was] contraindicated." *Id.*, Page ID# 108, ¶¶ 5–8.

As to St. Elizabeth and Tri-State, the complaint alleges four claims: (1) for negligence in their treatment of her; (2) for vicarious liability for Dr. Warren and the Does' acts and omissions; (3) for negligent hiring, retention, and supervision of Dr. Warren; and (4) for "breach of fiduciary duty and negligence." *Id.*, PageID# 108–111, ¶¶ 9–24.

On July 18, 2022, Moderna removed the action to the United States District Court for the Eastern District of Kentucky, invoking the federal-officer removal statute, diversity jurisdiction, and federal-question jurisdiction, and noting the consent of all other named defendants. RE 1, PageID# 1. Moderna argued that St. Elizabeth, Tri-State, and Dr. Warren were improperly joined, noting that the claims against those defendants, unlike those against Moderna and Kroger, "do not even refer to the [COVID-19] Vaccine and instead allege that each Provider engaged in improper care and medical treatment of Plaintiff." *Id.*, PageID# 3; *see also id.*, PageID# 16–19. Two days later, Tri-State and Dr. Warren filed their own notice of removal, invoking only federal-question removal as a basis for jurisdiction. RE 9, PageID# 75.

In the district court, Moderna, Kroger, Tri-State, and Dr. Warren filed motions to dismiss.[8] RE 12, PageID# 396; RE 14, PageID# 429; RE 15, PageID# 438; RE 16, PageID# 473. Each defendant argued that the PREP Act barred Ms. Goins's state-law claims.

Contending that the court should dismiss the claims against them on the basis of PREP Act immunity, Dr. Warren and Tri-State argued that:

(1) "Dr. Warren is a 'qualified person' because he is licensed to practice medicine in Kentucky, the same state in which Ms. Goins received her Moderna vaccinations at the Kroger pharmacy located in Florence, Kentucky," RE 15-1, PageID# 447,

(2) "[t]he Moderna COVID-19 vaccines are covered countermeasures," *id.*, and

(3) "Ms. Goins's claims have a 'causal relationship' to the 'administration' or 'use' of covered countermeasures," because Dr. Warren was "treating medical conditions arising from the administration of a COVID-19 vaccine," *id.*, PageID# 446–47.

Tri-State and Dr. Warren also argued that the action should have been filed in the three-judge District of Columbia District Court pursuant to 42 U.S.C. § 247d-6d(e), and thus should be dismissed on the basis of improper venue, or, in the alternative, transferred to that court or

[8] Non-appealing defendant St. Elizabeth Medical Center filed an answer to the complaint in state court. *See* RE 10, PageID# 260.

dismissed for Ms. Goins's failure to exhaust the procedures provided for by 42 U.S.C. § 247d-6e(d)(1). RE 15-1, PageID# 451–54.

On November 11, 2022, the district court issued an order granting the motions to dismiss filed by Kroger and Moderna, but denying the motion filed by Tri-State and Dr. Warren. RE 32, PageID# 532. The court held that Moderna and Kroger were immune from Ms. Goins's battery and negligence claims, as they were, respectively, a manufacturer and a distributor of a covered countermeasure (the COVID-19 vaccine), and thus qualified as "covered persons" under the statute, 42 U.S.C. § 247d-6d(*i*)(2)(B)(i)–(ii), and because the claims against them arose out of the manufacture and administration of that covered countermeasure. RE 32, PageID# 541–543.

The district court denied Dr. Warren and Tri-State's motion because the complaint did not establish that they were "'covered persons' under the PREP Act." *Id.*, PageID# 543. In so doing, the court rejected the only argument that Dr. Warren or Tri-State raised below: that Dr. Warren was a covered person because he was authorized to prescribe and dispense COVID vaccines, and "because Ms. Goins' claims against Dr. Warren relate to the administration of her COVID vaccine." *Id.*, PageID#

544. Under the statute and the Secretary's Declaration, the court concluded, only someone who "prescribed, administered, or dispensed" a countermeasure was a "covered person," and there were no "allegations regarding Dr. Warren and Tri-State's prescription, administration, or dispensation of the vaccine." *Id.*, PageID# 545–46 (first quoting 42 U.S.C. § 247d-6d(*i*)(2)(B)(iv)).

The court noted that it had federal jurisdiction over the action based on Moderna's invocation of the federal-officer removal statute. *Id.*, PageID# 535 n.1. But after dismissing the claims against Moderna and Kroger, it declined to retain supplemental jurisdiction over the claims against St. Elizabeth, Tri-State and Dr. Warren, and remanded the case to state court. *Id.*, PageID# 547.

ARGUMENT

The PREP Act affords immunity only to "covered person[s]." 42 U.S.C. § 247d-6d(a)(1). As stated in the statutory provision on which Tri-State and Dr. Warren rely:

> The term "covered person", when used with respect to the administration or use of a covered countermeasure, means … a person or entity that is … a qualified person who prescribed, administered, or dispensed such countermeasure.

Id. § 247d-6d(*i*)(2)(B)(iv). The allegations of the complaint do not

establish that Dr. Warren fit this definition under either the theory raised below or the theory advanced for the first time in this Court.

I. Dr. Warren is not a covered person under the theory advanced in the district court.

In the district court, Tri-State and Dr. Warren argued that Dr. Warren is a covered person because (1) he is a "qualified person" and (2) "he provided [Ms. Goins] medical treatment on or about August 7, 2021 for medical issues that she alleges resulted from and related to her receipt of the Moderna COVID-19 vaccinations," which are covered countermeasures. RE 15-1, at PageID# 447.[9] As discussed further below, at 21–26, the second prong of this argument rests on assumptions and inferences against the Plaintiff that are inappropriate at the Rule 12(b)(6) stage. But even if both factual predicates of the argument were established by the complaint, they would not establish that Dr. Warren is a covered person.

Under the statutory text, a "qualified person" is a "covered person" only when the person "prescribed, administered, or dispensed" a covered

[9] Below, Appellants argued that "Dr. Warren is a covered person under the PREP Act" but did not argue that Tri-State was also a covered person. RE 15-1, PageID# 446.

countermeasure. 42 U.S.C. § 247d-6d(*i*)(2)(B)(iv). In the district court, the only covered countermeasures identified by Tri-State and Dr. Warren in their entire discussion of PREP Act immunity were "COVID-19 vaccinations." RE 15-1, PageID# 446; *see also id.*, PageID# 447 ("The Moderna COVID-19 vaccines are covered countermeasures."); *id.*, PageID# 448–49 ("Plaintiff's various claims thus plainly arise out of, relate to, and result from the administration of covered countermeasures, i.e., the Moderna COVID-19 vaccinations."). But, as the district court correctly concluded, the complaint does not suggest *Dr. Warren* prescribed, administered, or dispensed the COVID-19 vaccine to Ms. Goins—or anyone else. *See* RE 32, PageID# 544–46. Accordingly, although the vaccines are "covered countermeasures," they do not render Dr. Warren a "covered person." The district court's conclusion on this point should be affirmed.

II. Appellants' new argument is forfeited.

On appeal, Tri-State and Dr. Warren now argue that the district court committed a "fundamental error … in failing to acknowledge that 'countermeasures' expressly include the products and devices used to diagnose and treat adverse reactions to the vaccine." Appellants' Br. 14.

Any "error" though, was not committed by the district court, which properly ruled on the argument made by Tri-State and Dr. Warren below.

Tri-State and Dr. Warren had the burden to demonstrate that the facts alleged in the complaint established the elements of PREP Act immunity. *See Elec. Merchant Sys. LLC v. Gaal*, 58 F.4th 877, 882 (6th Cir. 2023) ("The burden of demonstrating that the complaint fails to adequately state a claim falls on the defendant."). Nowhere in their memorandum of law in support of their motion to dismiss, however, did they assert that the "products and devices" that Dr. Warren used in the August 7 procedures that he performed on Ms. Goins were covered countermeasures. *Cf.* RE 15-1, PageID# 446, 447, 448–49 (asserting that the COVID-19 vaccine was a covered countermeasure).

Because the question "whether the products and devices Warren and Tri-State are alleged to have utilized are covered countermeasures," Appellants' Br. 27, was not presented to the district court, Appellants have "forfeit[ed] the right to have the argument addressed on appeal." *Armstrong v. City of Melvindale*, 432 F.3d 695, 699–700 (6th Cir. 2006). This Court has "discretion to entertain issues not raised before the district court only in exceptional cases or when application of the rule

would produce a plain miscarriage of justice." *Ohio State Univ. v. Redbubble, Inc.*, 989 F.3d 435, 445 (6th Cir. 2021) (cleaned up). No exceptional circumstances exist here, particularly because Tri-State and Dr. Warren are free to make this argument on remand to the state court. *See Watkins v. Healy*, 986 F.3d 648, 667–68 (6th Cir. 2021) (holding that declining to address forfeited immunity argument would not cause "miscarriage of justice" given procedural posture of appeal from denial of motion to dismiss).

III. Appellants' new argument rests on impermissible inferences and speculation beyond the allegations of the complaint.

If the Court excuses Appellants' forfeiture of their new argument, it should reject the argument on its merits. The PREP Act defines "covered countermeasures" to include "qualified pandemic or epidemic product[s]." 42 U.S.C. § 247d-6d(*i*)(1)(A). On appeal, Tri-State and Dr. Warren assert that Dr. Warren administered covered countermeasures because the devices used in the August 7 procedure were "qualified pandemic (FDA-approved) products/devices." Appellants' Br. 7. The Court need not and, in this procedural posture, cannot accept this assertion as a basis to dismiss Ms. Goins's claims.

The definition of "qualified pandemic or epidemic product" has a number of elements. First, only a "drug," "biological product," or "device," as defined by various other provisions of federal law, can be a qualified pandemic or epidemic product. 42 U.S.C. § 247d-6d(*i*)(7). Second, the product must have been manufactured or used for a specified purpose, including "to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product" that itself was used "to diagnose, mitigate, prevent, treat or cure a pandemic or epidemic." *Id.* § 247d-6d(*i*)(7)(A)(i)–(ii). Third, the product must have been approved, cleared, or authorized for use under various sections of the Food, Drug, and Cosmetic Act, or be subject to a statutory exemption. *Id.* § 247d-6d(*i*)(7)(B). Even if the first and third requirements could be inferred from Ms. Goins's complaint, the second requirement—that Dr. Warren used the devices at issue to treat an adverse reaction to the COVID-19 vaccine, as Appellants suggest, *see, e.g.*, Appellants' Br. 7—cannot be.

PREP Act immunity is an affirmative defense. *See Nemeth v. Montefiore*, 2022 WL 4779035, at *6 (N.D. Ohio Oct. 3, 2022); *Copan Italia S.p.A. v. Puritan Med. Prods. Co.*, 2022 WL 1773450, at *2 (D. Me. June 1, 2022). In analyzing a motion to dismiss based on an immunity

defense, "[a]s with any other motion to dismiss," the court must "read[] the complaint in the light most favorable to the plaintiff," and "draw[] all reasonable inferences in [the plaintiff's] favor." *Hart v. Hillsdale Cnty.*, 973 F.3d 627, 635 (6th Cir. 2020) (citation omitted). Because "[a] complaint need not plead the absence of an affirmative defense," *Stein v. Regions Morgan Keegan Select High Income Fund, Inc.*, 821 F.3d 780, 786 (6th Cir. 2016), a motion to dismiss based on such a defense is only appropriate "where the undisputed facts conclusively establish [that] affirmative defense as a matter of law," *Estate of Barney v. PNC Bank, Nat'l Ass'n*, 714 F.3d 920, 926 (6th Cir. 2013) (quoting *Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603, 613 (6th Cir. 2009)).

Applying these standards, federal courts have recognized that, where a complaint does not on its face establish all of the elements of PREP Act immunity, a court is not free to fill in the gaps with inferences against the plaintiff, even if such inferences might be plausible at the motion to dismiss stage. *See, e.g.*, *Catholdi-Jankowski v. CVS Health Corp.*, __ F. Supp. 3d __, 2023 WL 2028926, at *7 (W.D.N.Y. Feb. 16, 2023); *Copan Italia*, 2022 WL 1773450, at *5. So long as it remains plausible that the elements of the PREP Act immunity are not satisfied,

dismissal on the basis of that defense is not justified. *Cf. Orton v. Johnny's Lunch Franchise, LLC*, 668 F.3d 843, 848 (6th Cir. 2012) (holding that, where a complaint "suggest[ed]" one possible explanation, but did not preclude other explanations, dismissal on the basis of an affirmative defense was inappropriate).

Here, accepting the allegations of the complaint as true, it remains plausible that Ms. Goins's gastrointestinal symptoms resulted from something *other* than the vaccine. The complaint alleges that, at the time of the procedures Dr. Warren performed, medical professionals "were confused by her case." RE 9-3, PageID# 101, ¶ 19. It alleges that one doctor thought that Ms. Goins was secretly injecting herself with insulin, and that Tri-State was consulted because "Ms. Goins complained of abdominal pain, unspecified abdominal location." *Id.*, ¶¶ 21–22. As to Dr. Warren, the complaint alleges that he performed procedures "to determine if an insulinoma was 'hiding' in her pancreas," and that, afterwards, he diagnosed her with "non-specific slightly hyperechoic pancreatic parenchyma with no identifiable mass." *Id.*, PageID# 102, ¶¶ 23, 25. The complaint does not suggest that Dr. Warren suspected, much less concluded, that Ms. Goins was suffering from an adverse

vaccine reaction.

Appellants are wrong that "[t]he Complaint avers that the vaccine was the determined root cause of Ms. Goins' original hypoglycemia and abdominal pain," Appellants' Br. 21, and that "Ms. Goins' physicians diagnosed the cause of her condition was a 'reaction to her … second Moderna COVID-19 vaccine,'" *id.* (quoting RE 1-2, PageID# 38–39)). The *only* allegation that Ms. Goins's ailments *may* have been related to her COVID-19 vaccine is a single allegation that, "*after* many tests were performed," including Dr. Warren's August 7 procedure, "and none resulted in a conclusive diagnosis, the doctors stated it *could* have been a reaction to [Ms. Goins's] July 31, 2021 second Moderna COVID-19 vaccine." RE 9-3, PageID# 102, ¶ 26 (emphases added). This allegation does not establish that Appellants were treating a vaccine reaction and does not bring the claims against them within the scope of the PREP Act.

Advisory Opinion 20-03 provides a helpful example, making clear that a provider's purpose for utilizing a particular drug or device may be dispositive in determining whether it is a "covered countermeasure." There, OGC opined that epinephrine would be a "covered countermeasure" when it is used "to address … acute vaccine reactions,"

but not when it is used "to address unrelated respiratory or cardiovascular symptoms." Advisory Opinion 20-03 at 4. Under this reasoning, which is consistent with the text of the statute, if a complaint alleged that epinephrine had been administered to address respiratory or cardiovascular symptoms of unknown origin, an allegation that, *after* the fact, a health care provider stated that those symptoms *could* have been an adverse reaction to a vaccination would not be enough to meet a defendant's burden on a motion to dismiss to establish that epinephrine *was* used to mitigate a vaccine reaction in the case before it. So too here, the possibility that Ms. Goins's symptoms were caused by a COVID-19 vaccine does not conclusively establish that all steps taken to diagnose and treat her mysterious symptoms were taken to mitigate a vaccine reaction. *Cf. Wilhelms v. ProMedica Health Sys.*, 205 N.E.3d 1159, 1167 (Ohio Ct. App. 2023) (citing the district court opinion in this case approvingly, and concluding that the allegation that the plaintiff was hospitalized with COVID was "[in]sufficient to establish that … all individuals treating appellant during the entire course of his treatment were 'covered persons'").

Because the complaint does not establish that Dr. Warren was a

"covered person" entitled to invoke the PREP Act's immunity defense, the motion to dismiss was properly denied.

CONCLUSION

The Court should affirm the district court's order.

Respectfully submitted,

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May 4, 2023

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 29(a)(4)(G) and 32(g)(1), I certify that the foregoing brief complies with the typeface and volume limitations set forth in Federal Rules of Appellate Procedure 29(a)(5), 32(a)(5), 32(a)(6), and 32(a)(7)(B) as follows: The proportionally spaced typeface is 14-point Century Schoolbook and, as calculated by my word processing software (Microsoft Word for Office 365), the brief contains 4,969 words, exclusive of those parts of the brief not required to be included in the calculation by Federal Rule of Appellate Procedure 32(f) and the rules of this Court.

/s/ Adam R. Pulver
Adam R. Pulver

CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2023, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Adam R. Pulver
Adam R. Pulver