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Case No. 22-6070

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

FILED
Jan 22, 2024
KELLY L. STEPHENS, Clerk

LISA KAY GOINS

Plaintiff-Appellee,

v.

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

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

OPINION

Before: BATCHELDER, GRIFFIN, and BLOOMEKATZ, Circuit Judges.

BLOOMEKATZ, Circuit Judge. When Dr. Joel Warren performed an endoscopy and biopsy on Lisa Goins, he was looking for an insulinoma—a tumor in her pancreas. He and his provider group, Tri-State Gastroenterology, claim on appeal that these procedures addressed a side effect of Ms. Goins's COVID-19 vaccine. If that were so, the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d-6d, would bar Ms. Goins's medical malpractice suit against Dr. Warren and Tri-State. But the complaint did not plausibly contain those allegations, so it cannot now provide a basis for the PREP Act defense. Accordingly, we AFFIRM the district court's order denying Dr. Warren and Tri-State's motion to dismiss and remanding the case to the Boone County, Kentucky, Circuit Court.

BACKGROUND

I. Factual Background

This case comes to us at the motion to dismiss stage, so we recite the facts as they appear in the complaint. *Kaminski v. Coulter*, 865 F.3d 339, 344 (6th Cir. 2017). Plaintiff-Appellee Lisa Goins received her second dose of the Moderna COVID-19 vaccine at a Kroger pharmacy on July 31, 2021. On August 3, she visited the emergency room of Saint Elizabeth Medical Center due to unusual swings in her blood sugar. She was admitted, and her inconclusive blood work and imaging flummoxed her care team, who said they had "never seen anything like it." Compl., R. 1-2, PageID 38. Ms. Goins remained admitted as an overnight patient in the hospital between August 3 and August 22, 2021.

Dr. Joel M. Warren, a doctor associated with Tri-State Gastroenterology, examined Ms. Goins during her stay at Saint Elizabeth. After his examination, Dr. Warren performed "an upper endoscopic ultrasound with fine needle aspiration and an esophagogastroduodenoscopy" at the hospital "to determine if an insulinoma was 'hiding' in her pancreas." Compl., R. 1-2, PageID 39. Based on the ultrasound, Dr. Warren then "perform[ed] a pancreatic biopsy." *Id*. In layperson's terms, Dr. Warren examined Ms. Goins's upper gastrointestinal tract with a camera, then used a needle to take a sample from her pancreas (located right next to the stomach) to check for a tumor.[1] Dr. Warren did not find a tumor and diagnosed Ms. Goins with "non-specific slightly hyperechoic pancreatic parenchyma with no identifiable mass." *Id*. In other words, a noncancerous pancreatic abnormality. Ms. Goins further alleges "the doctors stated that" her symptoms "could have been a

[1] *See Endoscopic Ultrasound*, Mayo Clinic (July 6, 2022), https://perma.cc/WK9G-NTT9; Consandre P. Romain et al., *Masters Program Flexible Endoscopy Pathway: Diagnostic Esophagogastroduodenoscopy*, *in The SAGES Manual of Flexible Endoscopy* 15, 16 (Peter Nau et al. eds., 2020); *Insulinoma*, Johns Hopkins Medicine, https://perma.cc/VD8G-BBSS.

reaction to her July 31, 2021 second Moderna COVID-19 vaccine." *Id*. This is the only allegation connecting the endoscopy and biopsy with the vaccine. Ms. Goins does not allege that Dr. Warren believed her symptoms were in any way related to the vaccine, that such symptoms were possibly a reaction to the vaccine, or even that he knew she had received the vaccine.

Sadly, the early August hospitalization was not Ms. Goins's last. After she was discharged, Ms. Goins experienced abdominal pain; it became severe enough that she again went to the emergency room on September 18, 2021. This time, Ms. Goins had "pancreatitis and a pseudocyst on her pancreas," which a doctor "indicated was more than likely caused [by] any irritation like a biopsy." Compl., R. 1-2, PageID 40. After Ms. Goins spent two more nights in the hospital, the doctors sent her home. She continued to experience abdominal pain and, on the advice of a tele-doctor, returned to the emergency room on September 22. Ms. Goins had an abdominal bleed, which required emergency surgery. Apparently, Ms. Goins's "spleen may have been ruptured from being nicked." Compl., R. 1-2, PageID 41. Following the surgery to address the bleed, Ms. Goins underwent a procedure to drain fluid from her pancreas. Ms. Goins endured a lengthy recovery process, during which she experienced further complications, such as an infected feeding tube.

II. Procedural History

In June 2022, Ms. Goins filed this action in Boone County, Kentucky, Circuit Court, asserting claims of negligence, battery, and negligent hiring against Moderna, Kroger, Dr. Warren, Tri-State, and Saint Elizabeth.[2] Moderna, Saint Elizabeth, and the providers filed notices of removal. The district court concluded that Moderna was a person acting under a federal officer entitled to removal under 28 U.S.C. § 1442(a), allowing the entire action to be removed.

[2] Dr. Warren and Tri-State have been jointly represented throughout this action, so we sometimes refer to them as "the providers."

Moderna, the providers, and Kroger each filed motions to dismiss arguing they were immune from Ms. Goins's lawsuit under the Public Readiness and Emergency Preparedness (PREP) Act. Congress passed the PREP Act in 2005 to facilitate the national response to public health emergencies. PREP Act, Pub L. No. 109-148, Div. C § 2, 119 Stat. 2680, 2818–29 (2005) (codified at 42 U.S.C. § 247d-6d). The Act provides that, upon a declaration by the Secretary of Health and Human Services, "a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss" that involve "the administration to or the use by an individual of a covered countermeasure." *Id*. § 247d-6d(a)(1). All parties to this appeal agree that the Secretary has properly issued such a declaration for the COVID-19 pandemic and that, under it, the COVID-19 vaccine is a "covered countermeasure." *See id.* § 247d-6d(a)–(b).

The district court granted Moderna and Kroger's motions to dismiss.[3] Because Moderna's COVID-19 vaccine is a "covered countermeasure" under the Act, the court concluded that Moderna was immune as the manufacturer, and Kroger was immune because it administered the vaccine to Ms. Goins. Order, R. 32, PageID 541–43. Neither Moderna nor Kroger is involved in this appeal.

The court denied Dr. Warren and Tri-State's motion to dismiss, rejecting the contention that Dr. Warren was a "covered person" who administered a countermeasure to Ms. Goins. *Id*. at PageID 543–46. Having dismissed the claims against Moderna (the defendant over which it had original jurisdiction), the district court exercised its discretion under 28 U.S.C. § 1367(c) to

[3] While Ms. Goins's counsel filed an appearance in the district court, Ms. Goins did not otherwise respond to any of the motions to dismiss or litigate the action. The district court noted that this failure to prosecute would have been grounds for dismissal under Federal Rule of Civil Procedure 41(b). But the defendants instead moved to dismiss on PREP Act immunity grounds, triggering the district court's obligation to analyze the merits of those pleadings. *See Carver v. Bunch*, 946 F.2d 451, 452, 454 (6th Cir. 1991).

remand the case to state court, explaining that "in the absence of the vaccine defendants, this case is an ordinary malpractice suit brought under Kentucky law, by a Kentucky plaintiff, against Kentucky defendants." *Id*. at PageID 547. The court stayed its remand order, and the providers timely appealed the court's denial of their motion to dismiss.

JURISDICTION

Neither party challenges our jurisdiction, but the parties cannot confer it on themselves. We have an independent obligation to confirm our authority to adjudicate each appeal. *See Days Inns Worldwide, Inc. v. Patel*, 445 F.3d 899, 904 (6th Cir. 2006). This case raises questions regarding subject-matter and appellate jurisdiction, as we have not found (and the parties have not identified) binding caselaw addressing whether COVID-19 vaccine manufacturers are removable federal officers, nor whether we may review a denial of PREP Act immunity under the collateral order doctrine. Our analysis demonstrates that we have jurisdiction to resolve this appeal.

I. Subject-Matter Jurisdiction

First, we evaluate the basis for subject-matter jurisdiction. The district court concluded that it had subject-matter jurisdiction over Moderna under the federal officer removal statute, 28 U.S.C. § 1442(a)(1).[4] Under that statute, "any officer (or any person acting under that officer) of the United States or any agency thereof" may remove to federal court an action brought against them "for or relating to any act under color of such office." *Id*. Proper removal under § 1442 grants the district court a form of "arising under" subject-matter jurisdiction because "the raising of a federal question in the officer's removal petition . . . constitutes the federal law under which the action against the federal officer arises." *Mesa v. California*, 489 U.S. 121, 136 (1989). Proper removal

[4] The complaint did not raise a federal question under § 1441, *see Hudak v. Elmcroft of Sagamore Hills*, 58 F.4th 845, 852–58 (6th Cir. 2023), and the presence of the providers defeated complete diversity.

by the federal-officer defendant removes the entire case, including the non-officer defendants. *Bennett v. MIS Corp.*, 607 F.3d 1076, 1084 n.7 (6th Cir. 2010). Since § 1442 removal gives the district court original jurisdiction over the case against the federal officer, the court has supplemental jurisdiction under 28 U.S.C. § 1367(a) over the non-officer defendants.

A private entity like Moderna is a federal officer for the purposes of § 1442 when it can show that its challenged actions were performed under the federal government's direction, control, or close supervision, and that the entity asserted a plausible federal law defense to the suit. *See Bennett*, 607 F.3d at 1085; *Nappier v. Snyder*, 728 F. App'x 571, 574 (6th Cir. 2018). One situation commonly warranting federal removal is when the entity is "helping the Government to produce an item that it needs." *Watson v. Philip Morris Cos., Inc.*, 551 U.S. 142, 153 (2007); *cf. Bennett*, 607 F.3d at 1085–91 (holding that a cleaning company was a removable federal officer because, under close government supervision, it helped the FAA with "ridding a federal employee occupied building of an allegedly hazardous contaminant").

We agree with the district court that Moderna counts as a federal officer under § 1442 because of its participation in the Operation Warp Speed vaccine development program. This type of coordination with the government is paradigmatic of the close involvement and supervision necessary to make Moderna a removable federal officer. Moderna "co-developed" its COVID-19 vaccine with the federal government: one agency set the clinical trial protocols, another agency led the trials, and a third agency purchased hundreds of millions of doses of the vaccine and (with two more agencies) coordinated its distribution to retailers. Moderna Notice of Removal, R. 1, PageID 5–7. Unlike the nursing home defendant in *Hudak v. Elmcroft of Sagamore Hills*, which unsuccessfully asserted removability because it operated under strict federal COVID-19 regulations, here Moderna was not just following the law. 58 F.4th 845, 859 (6th Cir. 2023). At

each step of the way, Moderna worked under the "direction and control" of the federal government so that its vaccine would be available quickly. *Id.*

Ms. Goins's action against Moderna related to the vaccine that resulted from Operation Warp Speed. And because Moderna asserted a federal defense—PREP Act immunity—it satisfied the requirements to be a removable federal officer under § 1442. *See Bennett*, 607 F.3d at 1089 (explaining that for § 1442 removability, an asserted federal defense need only be plausible). The district court then had supplemental jurisdiction over Moderna's co-defendants, including Dr. Warren and Tri-State. *See* 28 U.S.C. § 1367(a); *Mesa*, 489 U.S. at 136. Therefore, the district court had subject-matter jurisdiction to issue the order denying the providers' motion to dismiss, which the providers timely appealed.

II. Appellate Jurisdiction

Next, we examine our appellate jurisdiction over the district court's order denying the PREP Act immunity defense. The providers' scattershot approach to appellate jurisdiction is unhelpful, but we do have authority to review this appeal under the collateral order doctrine.[5]

In most cases, "the denial of a Rule 12(b)(6) motion to dismiss is not a final order" of the type that 28 U.S.C. § 1291 grants us appellate jurisdiction to review. *Kaminski*, 865 F.3d at 344. That's because a denial of a motion to dismiss does not "terminate [the] action." *Cohen v. Beneficial Indus. Loan Corp.*, 337 U.S. 541, 545 (1949). The collateral order doctrine exception

[5] In addition to alluding to the collateral order doctrine, the providers argue that we have appellate jurisdiction because we can review orders remanding cases under 28 U.S.C. § 1367(c). We do not understand the providers to challenge the remand, so that line of cases does not apply here. The providers' citation to *BP P.L.C. v. Mayor & City Council of Baltimore* is also inapposite; that case is about appeal under 28 U.S.C. § 1447(d) of an order remanding a case for want of bases for removal. 593 U.S. 230, ---, 141 S. Ct. 1532, 1538 (2021). It is not relevant where, as here, the district court found removal proper, dismissed the claims over which it had original jurisdiction, and remanded under § 1367(c).

nonetheless permits appellate review of a non-final order if that order (1) is conclusive; (2) on an "important issue separate from the merits of the action; and (3) is effectively unreviewable on appeal from a final judgment." *Kaminski*, 865 F.3d at 344 (quoting *Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100, 105 (2009)). Oftentimes "the decisive consideration is whether delaying review until the entry of final judgment 'would imperil a substantial public interest' or 'some particular value of a high order.'" *Mohawk*, 588 U.S. at 107 (quoting *Will v. Hallock*, 546 U.S. 345, 352–53 (2006)).

It is well established in our circuit that a private entity may immediately appeal an order denying an affirmative defense of statutory immunity when the statute "provides immunity from suit, as opposed to immunity simply from liability." *Chesher v. Neyer*, 477 F.3d 784, 793 (6th Cir. 2007); *see also Black v. Dixie Consumer Prods. LLC*, 835 F.3d 579, 583–84 (6th Cir. 2016); *Osborn v. Halley*, 549 U.S. 225, 238–39 (2007). Like an order denying qualified immunity, an order denying statutory immunity conclusively resolves an issue separate from the merits of the action. That's so at least when our resolution of that issue turns on a question of law, such as the sufficiency of the allegations in a complaint. *Mitchell v. Forsyth*, 472 U.S. 511, 530 (1985); *Ctr. for Bio-Ethical Reform, Inc. v. Napolitano*, 648 F.3d 365, 369 (6th Cir. 2011). An order denying an immunity defense that turns on an issue of fact is not immediately appealable because factual disputes are too intertwined with the merits to be considered "separate" under the doctrine. *Johnson v. Jones*, 515 U.S. 304, 309–15 (1995).

Further, a statutory grant to a private entity of "immunity from suit is imbued with a significant public interest that is not always present with regard to a defense against liability." *Black*, 835 F.3d at 584 (internal quotation marks omitted) (quoting *DC Comics v. Pac. Pictures Corp.*, 706 F.3d 1009, 1015 (9th Cir. 2013)). That is because legislatures grant private entities

statutory immunity in exchange for an agreement from the entity to provide a good or service it otherwise would not. *See Black*, 835 F.3d at 583. Immediate review of a decision denying immunity from suit helps to make good on the deal between the government and the immunized entity, "because the core point of 'immunity is its possessor's entitlement not to have to answer for his conduct in a civil damages action.'" *Id*. at 582 (quoting *Mitchell*, 472 U.S. at 525).

Here, the PREP Act grants immunity "from suit and liability under Federal and State law with respect to all claims for loss" stemming from the administration or use of a "covered countermeasure." 42 U.S.C. § 247d-6d(a)(1). Ms. Goins's suit is a "claim[] for loss," so the plain text of the Act provides immunity "from suit." *Id.* Accordingly, the district court's denial of the providers' motion to dismiss on PREP Act immunity grounds is an immediately appealable collateral order. *See Hampton v. California*, 83 F.4th 754, 761–62 (9th Cir. 2023).

We have jurisdiction to hear this appeal.

PREP ACT IMMUNITY

The providers' claim is that Dr. Warren's care for Ms. Goins addressed "a serious or life-threatening condition caused by" her COVID-19 vaccine, and that, based on the complaint's bare allegations, the PREP Act thus immunizes him and Tri-State from her action.[6] They therefore seek Rule 12 dismissal of Ms. Goins's medical malpractice suit.

I. Standard of Review

We "review a district court's ruling on a Rule 12(b)(6) motion *de novo*." *Kaminski*, 865 F.3d at 344 (citing *State Farm, Ltd. v. Nat. Res. Conservation Serv.*, 767 F.3d 554, 558 (6th Cir.

[6] The providers assert that Tri-State's purported immunity is an "extension" of Dr. Warren's. Appellant Br. at 18. We do not reach this issue because we conclude Dr. Warren is not immune.

2014)). We take the factual allegations in the complaint and reasonable inferences from them as true, viewing them in the light most favorable to the plaintiff. *Id.*

PREP Act immunity is an affirmative defense. *See, e.g.*, *Nemeth v. Montefiore*, No. 1:21-CV-02064, 2022 WL 4779035, at *6 (N.D. Ohio Oct. 3, 2022). To prevail on an affirmative defense at the motion to dismiss stage, "the plaintiff's own allegations [must] show that a defense exists that legally defeats the claim for relief." *Estate of Barney v. PNC Bank, Nat'l Ass'n*, 714 F.3d 920, 926 (6th Cir. 2013) (quoting *Marsh v. Genentech, Inc.*, 693 F.3d 546, 554–55 (6th Cir. 2012)). In these situations, "the complaint is said to have a built-in defense and is essentially self-defeating." 5B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1357 (3d ed. 2004).

II. Dr. Warren's Immunity

The providers' only argument on appeal is that Dr. Warren is immune from suit because the endoscopy and biopsy he performed on Ms. Goins addressed a side effect of her vaccine. The PREP Act extends immunity to "a covered person," defined as a healthcare professional that administered the "covered countermeasure." 42 U.S.C. § 247d-6d(a)(1), (i)(2)(B)(iv), (i)(8)(A).[7] A "covered countermeasure" includes either an affirmative countermeasure that addresses the public health emergency itself, or medical care to address a side effect of the affirmative countermeasure.[8] Specifically, the side effect provision defines a countermeasure as an FDA-approved "drug, . . . biological product, . . . or device" that is used "to diagnose, mitigate, prevent,

[7] The Act's other definitions of "covered person" and "covered countermeasure" are not at issue in this appeal.

[8] The providers do not challenge the district court's conclusion that Dr. Warren cannot be a "covered person" under the Act solely because he was generally authorized to administer COVID-19 vaccines. Order, R. 32, PageID 543–47.

treat, or cure a serious or life-threatening disease or condition caused by" the affirmative countermeasure, here the COVID-19 vaccine. *Id*. § 247d-6d(i)(7)(A)(ii). So, the question is whether it is "definitively ascertainable from the allegations of the complaint" that the endoscopy and biopsy fit that provision because they addressed a vaccine side effect. *Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603, 613 (6th Cir. 2009) (quoting *In re Colonial Mortg. Bankers Corp.*, 324 F.3d 12, 16 (1st Cir. 2003)); *see also Estate of Barney*, 714 F.3d at 926. It's not.

The providers focus on the allegations that: Ms. Goins went to the Saint Elizabeth emergency room because she began to experience irregular blood glucose readings shortly after receiving the second dose of her COVID-19 vaccine; and that after Dr. Warren performed the endoscopic biopsy and rendered his diagnosis, unspecified "doctors stated it could have been a reaction to her . . . COVID-19 vaccine." Compl., R. 1-2, PageID 39. But we must read these allegations in the context of the entire complaint. Dr. Warren performed the diagnostic procedures "to determine if an insulinoma was 'hiding' in [Ms. Goins's] pancreas." *Id*. at PageID 38–39. Dr. Warren then performed the biopsy because Ms. Goins's pancreas was "hyperechoic." *Id*. Following these procedures, Dr. Warren diagnosed Ms. Goins with "non-specific slightly hyperechoic pancreatic parenchyma with no identifiable mass." *Id*. at PageID 39. None of the allegations pertaining to Dr. Warren suggest that he was treating Ms. Goins for a purported reaction to her COVID-19 vaccine. Indeed, the complaint does not allege that Dr. Warren even knew Ms. Goins had received the COVID-19 vaccine.

Further, that "doctors" other than Dr. Warren stated that Ms. Goins's symptoms "could have" been caused by the COVID-19 vaccine does not provide a plausible, as opposed to speculative, basis to conclude that the endoscopy and biopsy diagnosed or treated a side effect of the vaccine. *Id*. That is especially true when Ms. Goins alleges that her doctors had "never seen

anything like" her symptoms and challenged each other to "break" the case of the mysteriously fluctuating blood glucose level. *Id.* at PageID 38. At this stage, "mere speculation is insufficient" to establish a fact dispositive to an affirmative defense. *Hensley*, 579 F.3d at 613.

None of the providers' contrary arguments is persuasive. First, the providers characterize the endoscopy and biopsy as procedures meant to "diagnose" a possible side effect of the vaccine, highlighting that the provision of the Act encompasses diagnostic care. 42 U.S.C. § 247d-6d(i)(7)(A)(ii). We recognize that diagnostic care is within the scope of the Act, and that the process of medical diagnosis is often uncertain. But we must evaluate the allegations in the complaint. Here they allege only that Dr. Warren diagnosed Ms. Goins with "non-specific slightly hyperechoic pancreatic parenchyma with no identifiable mass," and never identifies this diagnosis as being a side effect of the vaccine. Compl., R. 1-2, PageID 39; *Hampton*, 83 F.4th at 764–65 (denying PREP Act immunity because allegations in the complaint "[did] not describe a causal relationship between" the countermeasure and the loss).

Similarly, the providers argue that we must recognize that the diagnostic care provision immunizes care meant to "rule-out" that a patient's ailments are the result of the vaccine, because when a vaccine is quickly approved, doctors cannot yet know the symptoms it might cause. But that proposal is too broad. And contrary to the text of the Act, it detaches immunity from conditions actually "caused by" a countermeasure. Indeed, the providers would have us hold that the PREP Act immunizes any medical professional providing care to a patient who thinks their symptoms could be a reaction to a COVID-19 vaccine, no matter how far-fetched the self-diagnosis. When more than eighty percent of the country has received at least one dose of the COVID-19 vaccine, such a rule would too easily allow the dismissal of valid medical malpractice actions without any plausible factual allegation that the COVID-19 vaccine caused the underlying symptoms. Centers

for Disease Control and Prevention, *COVID-19 Vaccinations in the United States*, COVID Data Tracker (May 11, 2023), https://perma.cc/9BJD-D44Q.

Finally, the providers rely upon an opinion of the General Counsel of the Department of Health and Human Services, which advises that epinephrine, when administered to treat an anaphylactic reaction to a COVID-19 vaccine, is a covered countermeasure under the Act. Dep't Health & Human Servs., *Advisory Opinion 20-03 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration Under the Act* 4 (2020) (AO 20-03).[9] But the opinion supplies no help to the providers because it assumes that an anaphylactic reaction is "caused by" the COVID-19 vaccine. *Id*. The opinion also notes that anaphylaxis is a recognized, but rare, vaccine side effect. *Id*. at 3–4. Here, the complaint does not contain any nonspeculative causal allegations, so it cannot sustain the providers' immunity defense at the motion to dismiss stage.

CONCLUSION

We AFFIRM the district court's order denying the providers' motion to dismiss and remanding the case to the Boone County Circuit Court.

[9] *See also Eleventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 88 Fed. Reg. 30769, 30771, 30771 n.5 (incorporating AO 20-03 by reference).