ORIGINAL

Teena M. Bergdall, R.N.



THIS OPINION HAS BEEN RELEASED FOR PUBLICATION BY ORDER OF THE COURT OF CIVIL APPEALS

IN THE COURT OF CIVIL APPEALS OF THE STATE OF OKLAHOMA

	DIVISION IV (2024) COL	FILED URT OF CIVIL APPEALS TATE OF OKLAHOMA
FLORETTA FRANKLIN, as mo	,	JAN 9 2025
Plaintiff/Appellant,))	JOHN D. HADDEN CLERK
vs.) Case No	0. 122,030
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Dan L. Holloway HOLLOWAY, BETHEA & OTHERS, PLLC Oklahoma City, Oklahoma	For Plai	ntiff/Appellant
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OPINION BY GREGORY C. BLACKWELL, JUDGE:

Oklahoma City, Oklahoma

Plaintiff and appellant, Floretta Franklin, appeals the court's journal entry granting the defendants' motion to dismiss. The court found that it lacked subject matter jurisdiction over plaintiff's negligence claim because defendants were immune from suit under the United States Public Readiness and Emergency Preparedness (PREP) Act. 42 U.S.C. § 247d-6d. Upon review, we find that the PREP Act does not apply to this action and, therefore, the court has subject matter jurisdiction, and the defendants are not immune from suit.

BACKGROUND

The following facts are taken from the petition or are otherwise undisputed in the record. On September 4, 2021, the plaintiff's daughter, Latoya O. Perry, was admitted to OU Medical Center in Oklahoma City for treatment of "Covid-19 pneumonia." It was recommended that Ms. Perry spend twenty days in isolation for treatment of her infection. At the time of her admission, Ms. Perry was thirty-seven years old, disabled, and had required a tracheostomy to maintain her airway since she was two years old. Ms. Perry generally used an "uncuffed" tracheostomy tube. However, during her admission, doctors determined that it was advisable to exchange her regular tube with a "cuffed" variety in the event she needed to be placed on a ventilator. The cuffed tracheostomy tube would

¹ We note various documents were attached to the motion to dismiss, the response, and the reply. Such attachments do not convert the motion into one for summary judgment when the question is one of the court's jurisdiction. See 12 O.S. § 2012(b) (noting that such a conversion is appropriate "on a motion asserting the defense numbered 6 of this subsection"). We rely on these documents and other averments outside the pleadings only to the extent they present undisputed facts or are otherwise contained in or can be reasonably inferred from the pleadings.

allow for ventilator support, whereas the "uncuffed" variety would not. The swap was made, and Ms. Perry was, at least for a time, place on a ventilator.

- By September 18, Ms. Perry had shown significant signs of improvement and had been weaned off the ventilator. On September 19, while nurse Teena Bergdall was cleaning Ms. Perry, Ms. Perry's tracheostomy tube became dislodged, which blocked her airway. Although the tracheostomy tube was eventually reinserted, Ms. Perry suffered anoxic brain injury during time it was displaced.
- The plaintiff filed suit against Ms. Bergdall, OU Medicine Inc., who apparently owns and operates OU Medical Center, and OU Health Partners Inc. for negligence.² The defendants filed their own respective answers and a joint motion to dismiss. The motion to dismiss alleged, among other things, that the plaintiff's negligence claim should be dismissed because the court lacked subject matter jurisdiction under the PREP Act. *See* 42 U.S.C. § 247d-6d. After reading the briefs and conducting a hearing on the motion to dismiss, the court agreed with the defendants and granted the motion, finding that the PREP Act preempted state court jurisdiction and provided the defendants with immunity

² According to a footnote in defendants' motion to dismiss, OU Health Partners was misnamed in the suit and did not file an answer per agreement of the parties. Doc. 4, *Defendants' Joint Motion to Dismiss*, pg. 1. The defendants allege that the plaintiff agreed to stay the action against OU Health Partners pending confirmation of their involvement in relation to plaintiff's claims. *Id.* Additionally, the court's journal entry reflects that OU Health Partners was never served by agreement of the parties, nonetheless, the joint motion to dismiss was brought "on behalf of all defendants." Doc. 7, *Journal Entry of Judgment*, pg. 1.

from common law tort claims under the facts alleged. The plaintiff timely appealed.³

STANDARD OF REVIEW

The subject of this appeal is the defendants' joint 12 O.S. § 2012(B)(1) motion to dismiss, which was granted by the trial court for lack of subject matter jurisdiction. The purpose of a motion to dismiss is to test the law that governs the claim in litigation rather than to examine the underlying facts of that claim. Samson Res. Co. v. Newfield Expl. Mid-Continent Inc., 2012 OK 68, ¶ 10, 281 P.3d 1278, 1281. As such, whether a claim should have been dismissed for lack of subject matter jurisdiction is a question of law this Court reviews de novo. Id.

ANALYSIS

¶6 On appeal, the plaintiff raises several propositions in error, all of which turn on whether the PREP Act provides complete immunity to the defendants, as the trial court held.⁴ As such, that is the sole question we will address in this appeal.

³ The plaintiff filed a motion to strike the appellees' joint reply to plaintiff's response to the motion to dismiss that is contained in the supplemental record on appeal. The basis of the motion is that the trial court, pursuant to local rules, should have stricken the reply because it was longer than five pages. Whether the trial court erred in refusing to strike the reply is not properly before this court. Modifications of the appellate record must proceed under Supreme Court Rules, not "pursuant to Rule 37 of the Rules of the Seventh Judicial District," as the appellant implies. *See* Okla.Sup.Ct.R. 1.32. As shown in the appellees' joint response, it is clear that the trial court in fact considered the motion and denied it below. Such was within the trial court's discretion. *Renegar v. Fleming*, 1949 OK 209, 211 P.2d 272. The reply is properly a part of the appellate record and appellant's motion to strike is therefore denied.

⁴ "State courts addressing immunity defenses under the PREP Act are required to answer only whether the plaintiff's claims fall within the PREP Act's immunity provision." See 42 U.S.C. 247d–6d(a)(1). "If the answer is no ... there is no federal law left to apply and the case can proceed under state law." Kluska v. Montefiore St. Luke's Cornwall, 227 A.D.3d 690, 692, 211 N.Y.S.3d 422, 424–25 (2024) (citing Solomon v. St. Joseph Hosp., 62 F.4th 54,

¶7 Congress enacted the PREP Act in 2005 to encourage the "expeditious development and deployment" of vaccines, devices, and medications, and more during a public health emergency. Allison M. Whelan, *The Prep Act and the Countermeasures Injury Compensation Program: Past, Present, and Future, 71* DePaul L. Rev. 689, 693 (2022). The law immunizes "covered person[s]" (including, for example, vaccine manufacturers and administers of vaccines) from state tort liability for harm caused by "covered countermeasures" (including, for example, vaccines and other health care devices designed to mitigate disease or symptoms of disease) during a declared public health emergency. The Covid-19 pandemic that began in the United States in 2020 was the onset of one such emergency.

¶8 Although the harmed party is not without recourse—the law simultaneously created a fund that the harmed party can apply to collect from—the immunity is quite broad. In relevant part, the PREP Act states:

[A] covered person 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) [by the Secretary of Health and Human Services] has been issued with respect to such countermeasure.

42 U.S.C. § 247d-6d(a)(1).

⁶¹ n.4). However, when the PREP Act applies, it provides broad immunity "from suit and liability under Federal and State law," 42 U.S.C. § 247d-6d(a)(1), and the remedy available to an injured plaintiff is an administrative "Covered Countermeasure Process Fund." The only exception is if there is "death or serious physical injury proximately caused by willful misconduct," *id.* § 247d-6d(d)(1), in which case an action may "be filed and maintained only in the United States District Court for the District of Columbia." *Id.* § 247d-6d(e)(1). *Gerber v. Forest View Ctr.*, 21CV05359KAMJRC, 2022 WL 3586477, at *3 (E.D.N.Y. Aug. 22, 2022). Thus, if the PREP Act applies, the trial court properly granted the motion to dismiss based on lack of jurisdiction. If the PREP Act does not apply, the dismissal must be reversed.

Without deciding the questions, for purposes of this opinion, we take as a given that the defendants are "covered person[s]," that the cuffed tracheostomy tube was a "covered countermeasure," and that the required declaration had been made at the time of the events in question. Our focus necessarily becomes whether the claim for loss here was one "caused by, arising out of, relating to, or resulting from the administration to or the use by an individual" of the cuffed tracheostomy tube. *Id.* As to this question, as relevant here, the act clarifies:

The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the ... administration ... or use of such countermeasure.

Id. § 247d-6d(a)(2)(B).

¶10 Under the plain language of the statute, we find that the plaintiff's harm as alleged in this case was not casually related the "administration" or "use" of the cuffed tracheostomy tube. As to "use," it is plain that the opposite is true.

⁵ The PREP Act defines a "covered person" as manufacturers, distributors, program planners, and qualified persons who prescribed, administered, or dispensed covered countermeasures. 42 U.S.C. § 247d-6d(i)(2). Further, a "qualified person" includes any licensed health professional or other person authorized to prescribe, administer, or dispense covered countermeasures. *Id.* § 247d-6d(i)(8).

⁶ The PREP act defines a "covered countermeasure" as a "qualified pandemic or epidemic product," "security countermeasure," "drug, ... biological product, ... or device ... that is authorized for emergency use," or a "respiratory protective device that is approved by the National Institute for Occupational Safety and Health ... and that the Secretary determines to be a priority for use during a public health emergency" 42 U.S.C.A. § 247d-6d. A qualified pandemic or epidemic product is further defined, as relevant to the present case, as a product used to "mitigate" or "treat" a pandemic or epidemic to limit the harm caused. *Id.* § 247d-6d(7)(A)(i)(I-II).

⁷ This is not disputed. The relevant declaration was made on March 17, 2020. See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 FR 15198-01.

The alleged harm was caused when the tube was *not* in use. Indeed, it was precisely the fact that tube was not being used that caused the alleged harm. Further, Ms. Perry would have suffered the exact same harm if she had been using her prior, uncuffed tracheostomy tube at the time it was dislodged.

¶11 The case as to "administration" is equally simple. The harm here was not caused when the tube was being inserted, or even shortly thereafter. Nor was the harm alleged to have occurred in any way *because of* any negligent installation of the tracheostomy tube. Rather, the harm was alleged to have occurred when the device was negligently dislodged. As such, we find that the harm was not caused by the administration of the tracheostomy tube, the relevant countermeasure here.

¶12 We note that, while the PREP Act does not specifically define the phrase "administration to" or "use ... of," the act did authorize the Secretary to define certain terms of the act, some of which are applicable here. One such term is "administration of a covered countermeasure." While not dispositive or binding

⁸ In full, the definition is:

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

The definition of "administration" extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the

on us in any way,⁹ we find our reading consistent with the Secretary's. Notably, according to the Declaration, the administration only extends to "physical provision of a countermeasure ... such as vaccination or handing drugs to patients." *Id.* Thus, as noted above, had the loss in this case occurred while the new cuffed tracheostomy tube was being inserted, it would likely be covered under the PREP Act. However, the cuffed tracheostomy tube had been inserted days prior to the patient's harm and her injury was not a result of the device malfunctioning; rather, it is alleged that the device became dislodged or negligently moved out of position and not replaced.

Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 FR 15198-01 (emphasis supplied).

terms of a Declaration issued under the Act. Under the definition, these liability claims are precluded if they allege an injury caused by a countermeasure, or if the claims are due to manufacture, delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a Declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

⁹ Oklahoma Gas & Elec. Co. v. State ex rel. Oklahoma Corp. Comm'n, 2023 OK 33, ¶ 8, 535 P.3d 1218, 1222–23 ("Statutory interpretation does not require the Commission's special expertise, therefore no deference is owed to the Commission on that account."); Loper Bright Enterprises v. Raimondo, 144 S. Ct. 2244, 2273, 219 L. Ed. 2d 832 (2024) ("Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority").

¶13 The Declaration lists various examples of claims that are precluded by the PREP Act: negligence by a manufacturer in creating a vaccine, negligence by a health care provider in prescribing the wrong dose of medication, and claims related to the management of a countermeasure distribution program, such as a slip-and-fall injury, vehicle collision, lax security, or crowd control, but only if injury occurring at the site is directly related to the countermeasure activities. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 FR 15198-01. Because of the clear purpose of the act—again, the "expeditious development and deployment" of vaccines, devices, and medications, and more during a public health emergency, Allison M. Whelan, The Prep Act and the Countermeasures Injury Compensation Program: Past, Present, and Future, 71 DePaul L. Rev. 689, 693 (2022)—it makes sense that the PREP Act offers covered persons immunity from those types of claims. Without such immunity, there could be significant and detrimental delay in developing aids to combat a pandemic or epidemic. ¶14 However, the Declaration also identifies the kind of liability claims that are not covered: those that allege injury occurring at the site that was *not* directly related to the countermeasure activities. For example, a slip and fall case "with no direct connection to the countermeasure's administration or use" would not fall under the PREP Act. We find the present case more consistent with this

example.10

¹⁰ An accident that occurs in the parking lot of a "drive-thru" vaccine administration site proves a useful analogy here. If the accident occurred because a covered person was

Ms. Perry's death was not directly caused by any countermeasure activities. Had her injury occurred while the cuffed tracheostomy tube was being inserted or even as a result of complications with the new device itself, any claim for negligence against Ms. Bergdall or OU Medicine would fall under the PREP Act, assuming all other statutory prerequisites were met. However, her injury occurred as a result of the nurse dislodging it or moving it out of place, allegedly negligently. This specific injury had nothing to do with Ms. Perry's contracting of Covid-19. She had a tracheostomy tube since the age of two. She could have been at OU Medicine for treatment of a variety of issues or illnesses such as receiving stitches, kidney failure, or gall bladder removal and had the exact same incident occur. Regardless of what she was being treated for and regardless of the size of the tube, the tracheostomy tube could have become dislodged during cleaning, moving the patient, or any number of activities, at any given time, during a hospital stay for any given reason. As such, Ms. Perry's injury did not result from a defective countermeasure device, improper insertion or installation of said device, or from her Covid-19 illness in any way. Thus, according to the plain language of the statute, consistent with the Secretary's Declaration, Ms. Franklin's claim for loss was not caused by, did not relate to, or did not result from the administration or use of a covered countermeasure. 11 Accordingly, the

negligently directing traffic, where such direction was needed to provide for the orderly administration of vaccines at the site, such an accident might well be covered. If the accident occurred because of negligent maintenance of the parking lot that had nothing to do with the administration of the vaccine, it is not covered under the act. In our view, this case falls under the latter example.

Other courts are in accord. See, e.g., Mills v. Hartford Healthcare Corp., 298 A.3d 605, 634 (2023) (holding that allegations that "the defendant engaged in tortious conduct

trial court's order dismissing the case must be reversed and the matter is remanded for additional proceedings.

¶16 REVERSED AND REMANDED.

HIXON, J., concurs, and HUBER, P.J., dissents.

HUBER, J., dissenting:

I respectfully dissent. The trial court correctly found that the PREP Act $\P 1$ applied to the plaintiff's claims and provided the defendants with immunity from common law tort claims. It is undisputed that Ms. Perry's uncuffed tracheostomy was exchanged for a 5.0 cuffed tracheostomy tube to provide ventilation and adequate oxygenation to mitigate the potential harm from her COVID-19 diagnosis and to assist her recovery from COVID-19. As the Majority acknowledges, Ms. Perry's claims and injuries are related to the dislodgment of the cuffed tracheostomy tube. The Majority also acknowledges, for purposes of the Opinion, that a cuffed tracheostomy is a covered countermeasure under the PREP Act. The Majority finds that the claim for loss does not result "from the administration to the use bv an individual" the tracheostomy. However, it necessarily follows that plaintiff's claims for loss have to do with Ms. Perry contracting COVID-19 and arise out of and are directly

that constituted a distinct and independent cause of the plaintiff's injuries that itself has no causal relationship to the countermeasure" precludes Prep Act immunity). *Cf. Goins v. Saint Elizabeth Med. Ctr.*, 640 F. Supp. 3d 745, 756 (E.D. Ky. 2022) (finding that doctors that provided treatment after a patient's receipt of a Covid-19 vaccine, but who took no part in the "prescription, administration, or dispensation of the vaccine" were not "covered persons" within the meaning of the act).

related to the use of the covered countermeasure, the cuffed tracheostomy. Had she not contracted Covid-19, she would not have been in the hospital and would not need use of a cuffed tracheostomy, which ultimately led to her injuries.

¶2 I would find that Ms. Perry's injuries stemmed from "the administration to or use by an individual of a covered countermeasure" as required by the PREP Act, that defendants are therefore entitled to immunity, and the trial court lacked subject matter jurisdiction. I would affirm the trial court's decision.

January 9, 2025