

**IN THE COURT OF APPEALS OF OHIO
THIRD APPELLATE DISTRICT
DEFIANCE COUNTY**

HARRY PUGH,

PLAINTIFF-APPELLANT,

CASE NO. 4-23-04

v.

**OKULEY'S PHARMACY AND HOME
MEDICAL, ET AL.,**

OPINION

DEFENDANTS-APPELLEES.

**Appeal from Defiance County Common Pleas Court
Trial Court No. 22-CV-45717**

Judgment Reversed and Cause Remanded

Date of Decision: September 11, 2023

APPEARANCES:

Michelle L. Traska for Appellant

David R. Hudson and Taylor Knight for Appellees

WALDICK, J.

{¶1} Plaintiff-appellant, Harry Pugh (“Pugh”), brings this appeal from the February 23, 2023, judgment of the Defiance County Common Pleas Court granting the motion to dismiss of defendants-appellees, Okuley’s Pharmacy and Home Medical, Inc., Okuley’s Pharmacy, Inc., Unique Prescriptions, Inc., Kieu M. Okuley, and John Does 1-8 (collectively, “Okuley defendants”). For the reasons that follow we reverse the judgment of the trial court.

*Background*¹

{¶2} Appellee Kieu Okuley is a pharmacist and owns the defendant companies. Appellee Okuley operated labs with the purpose of synthesizing pharmaceuticals or other medical materials. Pugh was an employee of the Okuley defendants.

{¶3} Around March of 2020, due to the COVID-19 pandemic creating a shortage of hand sanitizer, the Okuley defendants began to manufacture and sell hand sanitizer. Initially the Okuley defendants produced hand sanitizer from isopropyl alcohol.

{¶4} Eventually, the Okuley defendants determined that using ethanol from a local bio-refinery would be more cost-effective than isopropyl alcohol. However,

¹ The “factual” narrative herein is taken largely from the complaint. As this matter concerns the review of a motion to dismiss, we must accept as true all the facts in the complaint for purposes of this appeal. *Perrysburg Twp. v. Rossford*, 103 Ohio St.3d 79, 2004-Ohio-4362, ¶ 5.

the ethanol would need to be filtered to “remove odors,” so Pugh devised a filtration process that did not utilize any electrical power. According to Pugh, this process was too slow for the Okuley defendants and the Okuley defendants sought to make the filtration process faster through the use of an electric-powered pump. This filtration process was conducted in the basement lab of the Okuley defendants “compounding pharmacy.”

{¶5} On April 15, 2020, the first day Pugh used the ethanol in combination with an electric pump, “some combination of ethanol vapors, spray, or both caught fire, exploded, and severely burned” Pugh. Notably, Pugh was not provided with any training and he was not given any protective equipment.

{¶6} On April 18, 2022, Pugh filed a complaint against the Okuley defendants “for monetary damages arising out of employer’s intentional tort.” (Doc. No. 1).

{¶7} Before filing an answer, the Okuley defendants filed a motion to dismiss pursuant to Civ.R. 12(B)(1), and Civ.R. 12(B)(6). The Okuley defendants argued that Pugh’s claims were barred by the immunity and preemption provisions of the federal Public Readiness and Emergency Preparedness Act (“PREP Act”). The Okuley defendants contended that manufacturing hand sanitizer was expressly authorized, approved and requested by the FDA and the Ohio Board of Pharmacy as an emergency response effort to COVID-19. The Okuley defendants argued that

under the PREP Act, they were immune from “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 * * * has been issued with respect to such countermeasure.” 42 U.S.C. 247d-6d(a)(1). The Okuley defendants indicated that they were covered under the PREP Act and thus immune from suit. Further, the Okuley defendants argued that the PREP Act also preempted any state court claim for negligence or a violation of a state law that arose out of the administration or use of covered countermeasures.

{¶8} Pugh filed a response contending, *inter alia*, that Pugh was not “using” the covered countermeasure or having it “administered” to him, thus the PREP Act was not relevant here under its own plain language. Simply put, Pugh argued that the claims granted immunity under the PREP Act involved the “use or administration” of the hand sanitizer, which was not what occurred here.

{¶9} On February 23, 2023, the trial court filed a judgment entry analyzing the issues and ultimately granting the Okuley defendant’s motion to dismiss. The trial court determined that under the PREP Act, the Okuley defendants were a “covered person,” and that the hand sanitizer they produced constituted a “covered countermeasure.” The trial court then indicated the question that remained was whether the claims here were 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.”

{¶10} The trial court focused on the phrase “relating to,” determining that this phrase broadened the scope of immunity, and would include injuries that occurred during the manufacturing of the ethanol-based hand sanitizer. Thus the trial court granted the Okuley defendant’s motion to dismiss. Pugh now appeals the trial court’s judgment, asserting the following assignments of error for our review.

First Assignment of Error

The trial court erred by extending the PREP Act language beyond the scope contemplated by the statute to include employee injuries outside of the administration or use of a covered countermeasure.

Second Assignment of Error

The trial court was mistaken to conclude the PREP Act preempts all causes of action, including those for employer intentional tort.

First Assignment of Error

{¶11} In his first assignment of error, Pugh argues that the trial court erred by dismissing his complaint. More specifically, he contends that the trial court erred by extending the PREP Act language beyond the use or administration of a covered countermeasure to the manufacturing of a countermeasure.

Standard of Review

{¶12} An order granting a motion to dismiss is subject to de novo review, without any deference to the trial court’s determination. *Perrysburg Twp. v.*

Rossford, 103 Ohio St.3d 79, 2004-Ohio-4362, ¶ 5. Further, in reviewing whether a motion to dismiss should have been granted, we accept as true all factual allegations in the complaint. *Id.* Moreover, in order to dismiss a complaint under Civ.R. 12(B), “it must appear beyond doubt from the complaint that the plaintiff can prove no set of facts entitling him to recovery.” *O’Brien v. University Community Tenants Union, Inc.*, 42 Ohio St.2d 242 (1975), at syllabus.

Analysis

{¶13} The PREP Act provides a general grant of immunity in 42 U.S.C. 247d-6d(a)(1) as follows:

Subject to the other provisions of this section, 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 * * * has been issued with respect to such countermeasure.

{¶14} Here, the parties do not dispute on appeal that the Okuley defendants fall under the definition of a “covered person” pursuant to the PREP Act. Similarly, the parties do not dispute that hand sanitizer constitutes a “covered countermeasure” under the PREP Act. The primary dispute between the parties concerns whether Pugh was injured by the “administration to” or “use by an individual” of the covered countermeasure.

{¶15} Unfortunately, the PREP Act does not specifically define “administration to or the use by an individual of a covered countermeasure.”

However, the PREP Act does assign the Secretary of Health and Human Services the responsibility to define pertinent conditions of the PREP Act, and the Secretary did define “administration” of a covered countermeasure as follows:

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 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.

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

{¶16} In reviewing the definition provided, we emphasize that at the outset the Secretary states: “The definition of “administration” extends *only to physical provision of a countermeasure to a recipient.*” (Emphasis added.) Under this plain, clear, and unambiguous language, the PREP Act was designed to prevent lawsuits that would arise from the physical provision of covered countermeasures to the end-user (such as a vaccine recipient or the person using the hand sanitizer). There is no indication that the PREP Act intended to preclude liability of manufacturers to its employees who are not being administered or using the covered countermeasure.

{¶17} However, the Okuley defendants contend that a portion of the definition above does provide immunity to manufacturers. The Okuley defendants rely on the portion that states: “these liability claims are precluded * * * if the claims are due to manufacture * * * of countermeasure programs at distribution and dispensing sites.” The Okuley defendants argue that since they were engaged in the manufacture of a covered countermeasure, they should be immune from any lawsuits absent willful misconduct.

{¶18} We find that the Okuley defendants take the “manufacture” phrase out of its context, which still requires the administration to or use by, effectively, an end-user (or “recipient”). A manufacturer would be protected from a negligent act that impacted the end-user or recipient, such as (potentially) faulty *manufacturing* of a vaccine that caused an injury *to a vaccine recipient* or faulty *manufacturing* of hand sanitizer that caused burns *to the individual receiving the hand sanitizer*. But we see no indication in the PREP Act itself that it was intended to protect employers from any and all workplace injuries so long as the injuries occurred while manufacturing a covered countermeasure.

{¶19} In reaching our decision, we note, as the trial court did, that there is no caselaw directly addressing the issue in this case. There are cases, primarily federal, that touch on issues in the PREP Act, but they are readily distinguishable and do not further define “administration to, or the use by an individual.” *See, e.g., Hudak v. Elmcroft of Sagamore Hills*, 58 F.4th 845, 856 (6th Cir.2023); *Friedman v. Montefiore*, 6th Cir. No. 22-3703, 2023 WL 4536084, *1. Thus we must revert to our interpretation of the plain language of the PREP Act, and here, we find that the injuries to Pugh were not related to the “administration to” or “use by an individual” of the covered countermeasure because Pugh was not “administering” or “using” hand sanitizer at the time of his injury. Therefore, Pugh’s first assignment of error is sustained.

Second Assignment of Error

{¶20} In his second assignment of error, Pugh argues that the trial court erred by concluding that the PREP Act preempted the claims in this case. As we have already found that the PREP Act does not cover the acts alleged in this case, the PREP Act cannot preempt the claims raised by Pugh. Therefore, this assignment of error is also sustained.

Conclusion

{¶21} Having found error prejudicial to Pugh, the assignments of error are sustained and this cause is reversed and remanded to the trial court for further proceedings.

***Judgment Reversed and
Cause Remanded***

WILLAMOWSKI and ZIMMERMAN, J.J., concur.

/jlr