

IN THE COURT OF APPEALS OF NORTH CAROLINA

No. COA23-487

Filed 5 March 2024

Guilford County, No. 22 CVS 7024

EMILY HAPPEL, individually, Tanner Smith, a minor, and EMILY HAPPEL on behalf of TANNER SMITH as his mother, Plaintiffs,

v.

GUILFORD COUNTY BOARD OF EDUCATION and OLD NORTH STATE MEDICAL SOCIETY, INC., Defendants.

Appeal by Plaintiffs from an order entered 1 March 2023 by Judge Lora C. Cubbage in Guilford County Superior Court. Heard in the Court of Appeals 28 November 2023.

Walker Kiger, PLLC, by David Steven Walker, for Plaintiffs-Appellants.

Tharrington Smith, LLP, by Stephen G. Rawson, for Guilford County Board of Education, Defendants-Appellees.

Rossabi Law Partners, by Gavin J. Reardon and Amiel J. Rossabi, for Old North State Medical Society, Inc., Defendants-Appellees.

WOOD, Judge.

Tanner Smith (“Tanner”) and his mother, Emily Happel (“Emily”) (collectively, the “Plaintiffs”) appeal the trial court’s dismissal of their claims against the Guilford County Board of Education (the “Board”) and Old North State Medical Society, Inc. (“ONS Medical Society”) (collectively, the “Defendants”) based on, among other things, statutory immunity under the federal Public Readiness and Emergency

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Preparedness Act (“PREP Act”). After careful review of the relevant statutes and case law, we affirm the trial court’s order.

I. Factual and Procedural History

On 14 August 2021, Tanner was fourteen years old and a football player at Western Guilford High School, a school within the Guilford County Schools system. By letter dated 19 August 2021, Guilford County Schools informed Emily and Brett Happel (“Brett”), Tanner’s stepfather, that Tanner may have been affected by a “recent COVID-19 cluster” involving football team members at his school, and that the Guilford County Public Health Department recommended and requested COVID-19 testing for individuals potentially infected, regardless of vaccination status. The letter stated that unless parents allowed their children to be tested, Guilford County Schools would not allow players “to return to practice until cleared by a public health professional.” The letter further stated that COVID-19 testing would be available on 20 August 2021 at no cost at Northwest Guilford High School. The letter indicated ONS Medical Society would conduct the testing and “consent for testing is required.”

On 20 August 2021, Brett drove Tanner to the testing site at Northwest Guilford High School. Brett remained inside his vehicle while Tanner went into the testing facility, which was also a COVID-19 vaccination site. Inside, clinic workers gave Tanner a form to fill out, which he believed to be something related to the COVID-19 test. Tanner was seated in the facility while a clinic worker tried unsuccessfully to call Emily to obtain consent to administer a COVID-19 vaccine to

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him. The workers did not attempt to contact Brett. After failing to make contact with Tanner’s mother, one of the workers instructed the other worker to “give it to him anyway.” Tanner stated he did not want a vaccine and was only expecting a test, but one of the workers administered a Pfizer COVID-19 vaccine to him.

Plaintiffs initiated this lawsuit on 19 August 2022, alleging three causes of action: (1) battery; (2) violations of Emily’s constitutional liberty and parental rights and of Tanner’s bodily autonomy rights under N.C. Const. art. I, §§ 1, 13, and 19; and (3) violations of both of Plaintiffs’ federal constitutional rights.¹ On 21 November 2022, the Board filed its answer, a motion to dismiss pursuant to Rules 12(b)(1) and (6), and a cross-claim against ONS Medical Society. On 30 December 2022, ONS Medical Society filed its answer and a motion to dismiss pursuant to Rules 12(b)(1) and (6).

The trial court held a hearing on 30 January 2023 and filed its written order on 1 March 2023 dismissing Plaintiffs’ complaint as to both Defendants. On 9 March 2023, Plaintiffs filed timely written notice of appeal pursuant to N.C. Gen. Stat. § 7A-27(b) (2022).

II. Analysis

Plaintiffs argue the trial court erred in determining that the PREP Act, which is codified at 42 U.S.C. § 247d-6d (addressing liability immunity) is applicable to this

¹ Plaintiffs abandon their federal constitutional claims on appeal.

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case and provides immunity to both Defendants. Due to the sweeping breadth of the federal liability immunity provision in the PREP Act, we are constrained to disagree.

We review “a trial court’s decision to grant or deny a motion to dismiss based upon the doctrine of governmental or legislative immunity . . . de novo.” *Providence Volunteer Fire Dep’t, Inc. v. Town of Weddington*, 382 N.C. 199, 209, 876 S.E.2d 453, 460 (2022).

Our state law requires that “a health care provider shall obtain written consent from a parent or legal guardian prior to administering any vaccine that has been granted emergency use authorization and is not yet fully approved by the United States Food and Drug Administration to an individual under 18 years of age.” N.C. Gen. Stat. § 90-21.5(a1) (2021).

Enacted 30 December 2005, the PREP Act provides that when the Secretary of Health and Human Services (the “Secretary”) “makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency,” the Secretary may make a “declaration” recommending “the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures.” 42 U.S.C. § 247d-6d(b)(1). Additionally, the Secretary may declare that the provisions of subsection (a) apply “to the activities so recommended.” *Id.* Subsection (a), in turn, provides liability immunity:

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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 under subsection (b) has been issued with respect to such countermeasure.

42 U.S.C. § 247d-6d(a)(1) (emphasis added).

As for the scope of liability immunity, the PREP Act defines *loss* in the following manner:

For purposes of this section, the term “loss” means *any type of loss*, including—

- (i) death;
- (ii) physical, mental, or emotional injury, illness, disability, or condition;
- (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and
- (iv) loss of or damage to property, including business interruption loss.

42 U.S.C. § 247d-6d(a)(2)(A) (emphasis added). The PREP Act defines the scope of such immunity as follows:

The immunity . . . 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 design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

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42 U.S.C. § 247d-6d(a)(2)(B) (emphasis added). “[T]he sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct.” 42 U.S.C. § 247d-6d(d)(1).

Additionally, we must consider two more definitions under 42 U.S.C. § 247d-6d. The PREP Act defines *covered person*, “when used with respect to the administration or use of a covered countermeasure,” as the following:

- (A) the United States; or
- (B) a person or entity that is—
 - (i) a manufacturer of such countermeasure;
 - (ii) a distributor of such countermeasure;
 - (iii) a program planner of such countermeasure;
 - (iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or
 - (v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

42 U.S.C. § 247d-6d(i)(2). A covered countermeasure includes a drug, biological product, or device that is authorized for emergency use. 42 U.S.C. § 247d-6d(i)(1).

Finally, the PREP Act contains a broad provision preempting state law, which states:

During the effective period of a declaration under subsection (b) of this section, or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

- (A) is different from, or is in conflict with, any requirement applicable under this section; and

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(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter.

42 U.S.C. § 247d-6d(b)(8).

On 17 March 2020, in response to COVID-19, the Secretary issued a declaration pursuant to 42 U.S.C. § 247d-6d(b)(1) recommending the use of covered countermeasures, defined as “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.” Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198-01, 15,202. The declaration provides guidance on who is a covered person under the PREP Act:

The PREP Act’s liability immunity applies to “Covered Persons” with respect to administration or use of a Covered Countermeasure. The term “Covered Persons” has a specific meaning and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States. The PREP Act further defines the terms “manufacturer,” “distributor,” “program planner,” and “qualified person” as described below.

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A program planner means a *state or local government*, including an Indian tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or *provides a facility to administer or use a Covered Countermeasure* in accordance with the Secretary's Declaration. Under this definition, a *private sector employer or community group* or other "person" can be a program planner when it carries out the described activities.

Id. at 15,199. (Emphasis added.)

Here, the trial court took "judicial notice of the fact that the required declaration by the U.S. Department of Health and Human Services was in place for the Pfizer COVID-19 vaccine at the time of the vaccination at issue in this case." Plaintiffs do not dispute that the Pfizer COVID-19 vaccine was a covered countermeasure.

As for whether Defendants are covered persons under the PREP Act, we hold ONS Medical Society is a covered person as a program planner that administered a vaccine clinic, and individually administered vaccines to individuals, within the meaning of 42 U.S.C. § 247d-6d(i)(2)(B)(iii). The declaration clearly provides that a program planner may be a private sector employer or community group when it carries out the "described activities" including administration of a covered countermeasure. ONS Medical Society is a community group that did just that. Regarding the Board, Plaintiffs argue "[i]t is unclear under what theory the Board

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was a covered person under the trial court’s reasoning.” According to Plaintiff, the “only acceptable theory is that it is because of the Board’s involvement in the partnership with ONS [Medical Society] in operating and providing the locations for the vaccine clinics.” The Board contends Plaintiffs’ argument essentially accepts the trial court’s determination that the Board is a covered person, and therefore, it did “not respond further on this point.” This Court, however, must determine whether the Board meets the criteria of “a covered person” as defined under the PREP Act. We are convinced by the Secretary’s interpretation in the declaration that a covered person under the PREP Act includes a “state or local government . . . [that] provides a facility to administer or use a Covered Countermeasure.” Declaration, 85 Fed. Reg. at 15,199. We hold this language includes the Board, which provided a facility—Northwest Guilford High School—for the administration of the COVID-19 vaccines.

Finally, we must determine whether the scope of immunity covers the potential liability at issue in this case. We hold that it does because, as the trial court noted, the immunity provided by the Act is extremely broad. The PREP Act provides immunity “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. 42 U.S.C. § 247d-6d(a)(1) (emphasis added). *Loss* “means any type of loss.” 42 U.S.C. § 247d-6d(a)(2)(A). Specifically, the scope of immunity applies to “any claim for loss that has a causal relationship with the administration to or use by an individual of a covered

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countermeasure, including a causal relationship with the . . . administration . . . of such countermeasure.” 42 U.S.C. § 247d-6d(a)(2)(B). Wisely or not, the plain language of the PREP Act includes claims of battery and violations of state constitutional rights within the scope of its immunity, and it therefore shields Defendants from liability for Plaintiffs’ claims.

Plaintiffs argue that the PREP Act does not cover their claims because they do not arise *because of* COVID-19, but merely *happen to* relate to COVID-19. We would be inclined to agree if the PREP Act did not define the scope of immunity so broadly. Because there does not appear to be any Fourth Circuit or North Carolina federal district cases on point, ONS Medical Society draws our attention to three out-of-state cases.

First, in *Parker v. St. Lawrence Cnty. Pub. Health Dep’t*, a pre-COVID-19 case, the defendant health department held a vaccination clinic due to the outbreak of the H1N1 influenza virus, and a nurse employed by the health department administered a vaccination to a child without obtaining an executed parental consent form from the plaintiff parent. 102 A.D.3d 140, 141, 954 N.Y.S.2d 259, 260–61 (2012). The plaintiff-parent alleged both negligence and battery. The court in *Parker* held, “[c]onsidering . . . the sweeping language of the statute’s immunity provision, . . . Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures . . . including one based upon a

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defendant's failure to obtain consent." *Id.* at 143–44, 954 N.Y.S.2d at 262. Therefore, the court dismissed the plaintiff's complaint. *Id.* at 144–45, 954 N.Y.S.2d at 263.

Second, in *Cowen v. Walgreen Co.*, the plaintiff alleged that she visited a Walgreens store for a flu vaccination but that a Walgreens employee administered a COVID-19 vaccination to the plaintiff without her knowledge. No. 22-CV-157-TCK-JFJ, 2022 WL 17640208, at *2 (N.D. Okla. Dec. 13, 2022) (N.D. Okla. Dec. 13, 2022). As here, the plaintiff in *Cowen* argued "that her claims should be construed . . . broadly because her injury could have happened whether she received a COVID-19 vaccine or any other vaccine." *Id.* The court in *Cowen* noted that "[i]n the PREP Act, Congress plainly provided immunity under both 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.'" *Id.* at *3. (Quoting 42 U.S.C. § 247d-6d(a)(1)) (emphasis in original). The court in *Cowen* held, "While it is true that other vaccinations or procedures might have also been administered, this does not change the fact that Plaintiff's injuries actually resulted from administration of the COVID-19 vaccine. The PREP Act therefore applies." *Id.*

Finally, in *M.T. v. Walmart Stores, Inc.*, the plaintiff mother sued defendant Walmart after one of its pharmacists administered a COVID-19 vaccine to her minor child without her consent. 63 Kan. App. 2d 401, 402, 528 P.3d 1067, 1070 (2023). The court in *M.T.* noted that the scope of immunity under the PREP Act "is broad and applies to 'any claim for loss that has a causal relationship with the

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administration to or use by an individual of a covered countermeasure.’” *Id.* at 406, 528 P.3d at 1073. (Quoting 42 U.S.C. § 247d-6d(a)(2)(B)). The court held that the PREP Act applied to the plaintiff mother’s lawsuit, stating:

The text of the [PREP] Act is unambiguous: The [PREP] Act applies to all claims causally related to the administration by a covered person of a covered countermeasure. The question presented by this interlocutory appeal is thus whether a claim based on the administration of a covered countermeasure without parental consent is causally related to the administration of a covered countermeasure. Reframed this way, the answer is yes.

Id. at 426–27, 528 P.3d at 1084.

We conclude that these cases are instructive persuasive authorities supporting our holding that the broad scope of immunity provided by the PREP Act applies to both Defendants in this case. Although Plaintiffs’ claims could arise no matter what type of vaccine Tanner was given without parental consent, the PREP Act provides immunity to Defendants because it shields them from “any claim for loss that has a causal relationship with the administration” of the COVID-19 vaccine. 42 U.S.C. § 247d-6d(a)(2)(B).

We note our General Assembly amended N.C. Gen. Stat. § 90-21.5 in 2021 to add subsection (a1), which requires parental consent before a vaccine granted emergency use authorization may be administered to a minor. Its intent is to prevent the egregious conduct alleged in the case before us, and to safeguard the constitutional rights at issue—Emily’s parental right to the care and control of her

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child, and Tanner's right to individual liberty. *See* N.C. Const. art. I, §§ 1, 19; *Petersen v. Rogers*, 337 N.C. 397, 400–01, 445 S.E.2d 901, 903 (1994). Notwithstanding, the statute remains explicitly subject to “any other provision of law to the contrary” under the broad provision preempting state law in the PREP Act. 42 U.S.C. § 247d-6d(b)(8). The PREP Act provides only one exception for a “Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct.” 42 U.S.C. § 247d-6d(d)(1). Because Plaintiffs have not made any such allegations in their complaint, we are constrained to conclude the PREP Act preempts the protections provided pursuant to N.C. Gen. Stat. § 90-21.5(a1).

III. Conclusion

“We are not to question the wisdom or policy of the statute under consideration, but should enforce it as it is written, unless we conclude that there is an unmistakable conflict with the organic law.” *Faison v. Bd. of Comm'rs of Duplin Cnty.*, 171 N.C. 411, 415 88 S.E. 761, 763 (1916). Bound by the broad scope of immunity provided by the PREP Act, we are constrained to hold it shields Defendants, under the facts of this case, from Plaintiffs’ claims relating to the administration of the COVID-19 vaccine. Accordingly, we affirm the trial court’s dismissal of Plaintiffs’ claims.

AFFIRMED.

Judges COLLINS and CARPENTER concur.