Reporter of Decisions

MAINE SUPREME JUDICIAL COURT

Decision: 2025 ME 22 Docket: Lin-24-209

Argued: November 12, 2024 Decided: March 4, 2025

Panel: STANFILL, C.J., and MEAD, HORTON, CONNORS, LAWRENCE, and DOUGLAS, JJ.

JEREMIAH HOGAN et al.

v.

LINCOLN MEDICAL PARTNERS et al.

HORTON, J.

[¶1] Jeremiah Hogan, Siara Jean Harrington, and their child (collectively, Hogan) appeal from a judgment of the Superior Court (Lincoln County, *Billings, J.*) dismissing—based on federal statutory immunity—a notice of claim alleging that Lincoln Medical Partners; MaineHealth, Inc.; and Andrew Russ, M.D. (collectively, Lincoln Medical) committed various torts when Russ administered a COVID-19 vaccine to the child at a school clinic without parental consent. Because we agree with the trial court that federal law confers immunity on Lincoln Medical and preempts state law that would otherwise allow Hogan to sue, we affirm the judgment.

I. BACKGROUND

[¶2] We draw the facts from Hogan's notice of claim, viewed in the light most favorable to Hogan. *See Dutil v. Burns*, 674 A.2d 910, 911 (Me. 1996). At a school clinic held in November 2021, Lincoln Medical administered the Pfizer-BioNTech mRNA COVID-19 vaccine to Jeremiah Hogan and Siara Jean Harrington's five-year-old child without having obtained parental consent to the vaccination.

[¶3] On May 4, 2023, Hogan filed a notice of claim pursuant to the Maine Health Security Act, see 24 M.R.S. § 2853 (2024), in the Superior Court against the doctor who administered the vaccine (Russ), the corporation for which the doctor worked (Lincoln Medical Partners), and that corporation's parent company (MaineHealth, Inc.). Framed as a multi-count civil complaint for medical malpractice, Hogan's notice alleged claims against all defendants on behalf of the child for professional negligence, systemic professional negligence, battery, and false imprisonment. The notice alleged three additional tort claims against all defendants on behalf of the parents: intentional infliction of emotional distress, negligent infliction of emotional distress, and tortious interference with parental rights. Finally, the notice

alleged negligent supervision against the corporate defendants on behalf of the child and parents.

[¶4] After the court (*Mullen, C.J.*) appointed a chair for the prelitigation screening panel, Lincoln Medical moved to dismiss the notice of claim, arguing that it was immune from suit under the federal Public Readiness and Emergency Preparedness (PREP) Act; *see* 42 U.S.C.A. §§ 247d-6d, 247d-6e (Westlaw through Pub. L. No. 118-158). The screening panel chair ordered that the matter be referred to the Superior Court for consideration of the motion.

[¶5] After receiving an opposing memorandum from Hogan and a reply memorandum from Lincoln Medical, the court (*Billings, J.*) entered a judgment on April 18, 2024, granting Lincoln Medical's motion to dismiss. The court interpreted the federal statute to provide immunity to each named defendant, with no applicable exceptions.

[¶6] Hogan timely appealed. *See* 14 M.R.S. § 1851 (2024); M.R. App. P. 2B(c)(1).

II. DISCUSSION

[¶7] We begin by summarizing the federal statutes at issue. The PREP Act provides for immunity 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 under subsection (b) has been issued with respect to such countermeasure.

42 U.S.C.A. § 247d-6d(a)(1).1 "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" Id. § 247d-6d(a)(2)(B). One "covered countermeasure" is a drug or biological product "authorized for emergency use" under specified statutes, including 21 U.S.C.A. § 360bbb-3 (Westlaw through Pub. L. No. 118-158) (codification of section 564 of the Federal Food, Drug and Cosmetics Act, added by Pub. L. No. 108-136 (Nov. 24, 2003)). 42 U.S.C.A. § 247d-6d(i)(1)(C). One type of "covered person" is "a qualified person who prescribed, administered, or dispensed such countermeasure." *Id.* § 247d-6d(i)(2)(B)(iv). "[A] licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed" is a "qualified person" under the statute. Id. The statute's definition of "person" includes both § 247d-6d(i)(8)(A). individuals and corporations. *Id.* § 247d-6d(i)(5).

¹ The term "loss" includes "any type of loss," including emotional injury and the fear of injury. 42 U.S.C.A. § 247d-6d(a)(2)(A) (Westlaw through Pub. L. No. 118-158).

- [¶8] For immunity to apply, the countermeasure must have been administered to a member of the population specified in a declaration issued by the Secretary of Health and Human Services to address the category of disease specified in the declaration. *Id.* § 247d-6d(a)(3)(B), (a)(3)(C)(i), (b). It must also have been administered during the declaration's effective period and in a location covered by the declaration. *Id.* § 247d-6d(a)(3)(A), (a)(3)(C)(ii).
- [¶9] As an exception to the immunity conferred in § 247d-6d(a)(1), Congress has authorized "an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct . . . by such covered person." Id. § 247d-6d(d)(1) (emphasis added). For purposes of the statute, a "serious physical injury" is one that
 - (A) is life threatening;
 - **(B)** results in permanent impairment of a body function or permanent damage to a body structure; or
 - **(C)** necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.
- Id. § 247d-6d(i)(10). "[W]illful misconduct" under the statute is an act or omission that is taken--
 - (i) intentionally to achieve a wrongful purpose;
 - (ii) knowingly without legal or factual justification; and

(iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

Id. § 247d-6d(c)(1)(A).

[¶10] The plaintiff has "the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury." $Id. \S 247d-6d(c)(3)$. If a person suffers serious physical injury or death, suit may generally not be commenced until after the plaintiff has pursued recovery from a "Covered Countermeasure Process Fund," which is designed to compensate those who have encountered adverse effects from countermeasures. $Id. \S 247d-6e(a)$, (b)(1), (5)(A), (d)(1), (e)(3).

[¶11] The provision in the PREP Act conferring immunity on "covered persons" includes a provision preempting conflicting state law:

Preemption of State law

During the effective period of a declaration under subsection (b), 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

(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, or under the Federal Food, Drug, and Cosmetic Act.

Id. § 247d-6d(b)(8).

[¶12] Hogan does not dispute either that the Secretary issued a declaration or that the vaccine was administered by a qualified person as a countermeasure during the time and in a location covered by the declaration. See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (Mar. 10, 2020). Having filed the claims in state court, Hogan cannot and does not contend that the claims fall within the sole exception to the immunity conferred in § 247d-6d(a)(1)—the authorized "exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct . . . by such covered person." Id. § 247d-6d(d)(1). The issue is therefore limited to whether the federal immunity statute

immunizes Lincoln Medical against Hogan's claims and preempts state law that would otherwise allow a lawsuit.

[¶13] In general, "the construction of federal regulations or policies [is a] matter[] of federal rather than state law." *Littlefield v. State, Dep't of Hum. Servs.*, 480 A.2d 731, 736 (Me. 1984). Thus, in determining whether the federal immunity provision constrains state actions, we interpret the statute with the goal "to effectuate the legislative intent and purposes of the United States Congress." *Id.*

[¶14] "The starting point in discerning congressional intent is the existing statutory text.... It is well established that when the statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms." *Lamie v. U.S. Tr.*, 540 U.S. 526, 534 (2004) (quotation marks omitted); *see also Wisconsin Cent. Ltd. v. United States*, 585 U.S. 274, 284 (2018) ("[W]ords generally should be interpreted as taking their ordinary, contemporary, common meaning... at the time Congress enacted the statute." (quotation marks omitted)). "The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the

broader context of the statute as a whole." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997).

A. Immunity

[¶15] The language at issue here is plain, broad, and unambiguous with respect to immunity from tort liability. A covered person is immune from suit and liability under state law "with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration" of the emergency-authorized countermeasure—here, the vaccine. 42 U.S.C.A. $\S 247d-6d(a)(1)$; see id. $\S 247d-6d(i)(1)(C)$. The immunity "applies to any claim for loss that has a causal relationship with the administration to . . . an individual of" the vaccine. Id. $\S 247d-6d(a)(2)(B)$.

[¶16] Hogan alleges only injuries that were caused by the administration of the vaccine. Even construed strictly because it is in derogation of the common law, the immunity statute is clearly broad in scope. *See Jamison v. Encarnacion*, 281 U.S. 635, 640 (1930) ("The rule that statutes in derogation of the common law are to be strictly construed does not require such an adherence to the letter as would defeat an obvious legislative purpose or lessen the scope plainly intended to be given to the measure."); *Johnson v. S. Pac. Co.*, 196 U.S. 1, 17 (1904) ("[C]onceding that statutes in derogation of the common

law are to be construed strictly, [t]hey are also to be construed sensibly, and with a view to the object aimed at by the legislature." (quotation marks omitted)). We interpret the PREP Act's immunity provision based on its plain language and conclude that all defendants are immune from Hogan's "claims for loss caused by, arising out of, relating to, or resulting from the administration" of the vaccine to the child. 42 U.S.C.A. § 247d-6d(a)(1). This interpretation is consistent with other state appellate courts' construction of the immunity provision when parents alleged torts arising from a lack of consent to vaccinate children. See Parker v. St. Lawrence Cnty. Pub. Health Dep't, 954 N.Y.S.2d 259, 260-61, 263 (N.Y. App. Div. 2012); M.T. v. Walmart Stores, Inc., 528 P.3d 1067, 1071, 1080-81 (Kan. Ct. App. 2023); de Becker v. UHS of Del., Inc., 555 P.3d 1192, 1203 (Nev. 2024); Happel v. Guilford Cnty. Bd. of Educ., 899 S.E.2d 387, 389-90, 393-94 (N.C. Ct. App. 2024); Politella v. Windham Se. Sch. Dist., 325 A.3d 88, 91-92, 98 (Vt. 2024).

[¶17] Hogan argues that this interpretation of federal law fails to harmonize the statute with the Emergency Use Authorization (EUA) statutes allowing the use of otherwise unapproved drugs or biological products that it is reasonable to believe may be effective during a public health emergency declared by the Secretary. *See* 21 U.S.C.A. § 360bbb-3(c). The PREP Act

references the EUA statute for purposes of explicitly including, within the scope of the term "covered countermeasure," a countermeasure authorized for emergency use.² 42 U.S.C.A. § 247d-6d(i)(1)(C); 21 U.S.C.A. § 360bbb-3. Accepting the allegations of the notice of claim as true, the provider's failure to obtain parental consent in this individual instance does not make the administered vaccine—approved for emergency use under § 360bbb-3—any less of a "covered countermeasure" under § 247d-6d(i)(1)(C).

[¶18] The PREP Act also does not, as Hogan asserts, violate international law prohibiting non-consensual human medical experimentation. The administration of a vaccine approved for emergency use is not an experiment but an authorization to use a countermeasure that has been approved to combat a public health emergency. *See* 21 U.S.C.A. § 360bbb-3. The notice of claim alleges no facts, such as the subsequent monitoring or testing of the child, that would suggest medical experimentation.³

The statute allowing EUAs requires the Secretary of Health and Human Services to establish conditions on the authorization, to the extent practicable, "to ensure that individuals to whom the product is administered are informed . . . of the option to accept or refuse administration of the product." 21 U.S.C.A. § 360bbb-3(e)(1)(A)(ii)(III) (Westlaw through Pub. L. No. 118-158). Although the statute imposes a burden on the Secretary, it does not create a cause of action to enforce that obligation, and in any event, Hogan has not sued the Secretary of Health and Human Services.

³ Although Hogan also contends that the immunity provision is, as applied, inconsistent with constitutional principles of due process, the fundamental rights of parents to make decisions regarding the care and management of their children, *see Troxel v. Granville*, 530 U.S. 57, 66 (2000), are not absolute, *see Dorr v. Woodard*, 2016 ME 79, ¶ 13, 140 A.3d 467, and the federal government has a compelling interest in legislating to address public health emergencies, *see Roman Cath. Diocese*

B. Federal Preemption

[¶19] Hogan argues that the federal immunity statute has not preempted state common law. "A conflict warranting preemption may be direct in that the state regulation obviously contradicts federal regulation, or it may arise from congressional intent, either express or implied, to occupy a particular area." *State v. Lauriat*, 561 A.2d 496, 496-97 (Me. 1989) (quotation marks omitted). "Preemption, however, is not a favored concept, and federal regulation will be deemed to be preemptive of state regulatory powers only if grounded in persuasive reasons—either the nature of the regulated subject matter permits no other conclusion or that Congress has unmistakably so ordained." *Id.* (quotation marks omitted).

[¶20] "In determining whether a federal law preempts a state law cause of action, the determinative inquiry is 'Congress' intent in enacting the federal statute at issue." *Parker*, 954 N.Y.S.2d at 261 (quoting *Shaw v. Delta Air Lines*,

of Brooklyn v. Cuomo, 592 U.S. 14, 18 (2020) ("Stemming the spread of COVID-19 is unquestionably a compelling interest"). We reach the same conclusion whether the statute is subject to rational-basis or strict-scrutiny review. See Jacobson v. Commonwealth of Massachusetts, 197 U.S. 11 (1905) (applying a rational-basis analysis to determine whether a state vaccine requirement was constitutional); Pitts v. Moore, 2014 ME 59, ¶ 12 & n.3, 90 A.3d 1169 (setting forth the strict-scrutiny standard requiring a compelling government interest for the government to interfere with the fundamental right to parent). As to Hogan's assertion that the immunity provision violates the child's constitutional right of bodily integrity, "[i]n the context of COVID-19, courts across the country have concluded that Jacobson established that there is no fundamental right to refuse vaccination." Williams v. Brown, 567 F. Supp. 3d 1213, 1226 (D. Or. 2021); see also Norris v. Stanley, 567 F. Supp. 3d 818, 821 (W.D. Mich. 2021) ("Plaintiff is absolutely correct that she possesses those rights [to privacy and bodily integrity], but there is no fundamental right to decline a vaccination.").

Inc., 463 U.S. 85, 95 (1983)). "Where, as here, a federal law contains an express preemption clause, "[the] 'focus [is] on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *Id.* (quoting *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 594 (2011)).

The statute at issue here plainly provides that no state may "enforce" or "continue in effect" laws that "relate[] to" the administration of covered countermeasures by qualified persons and differ from or conflict with the federal statute. 42 U.S.C.A. § 247d-6d(b)(8). The Supreme Court has recognized that "the phrase 'relate to' in a preemption clause 'express[es] a broad pre-emptive purpose." Coventry Health Care of Mo., Inc. v. Nevils, 581 U.S. 87, 95-96 (2017) (quoting Morales v. Trans World Airlines, Inc., 504 U.S. 374, 383 (1992)). Although Hogan is correct that there are limits on the extent to which a state law will be regarded as "relat[ing] to" a specific federal measure, see N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655-56 (1995) (quotation marks omitted), Maine's common law torts clearly fall within the PREP Act's prohibition to the extent that they allow recovery for claims against defendants administering vaccines who, under the federal statute, are immune from suit or liability, see 42 U.S.C.A. § 247d-6d(a)(1), (b)(8).

The entry is:

Judgment affirmed.

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