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In The

SUPREME COURT OF THE UNITED STATES

DARIO and SHUJEN POLITELLA and Their Minor Child, L.P.,

Petitioners.

v.

WINDHAM SOUTHEAST SCHOOL DISTRICT and THE STATE OF VERMONT, et al,

Respondents.

On Petition For Writ Of *Certiorari*To The Vermont Supreme Court

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED FOR REVIEW

In Vermont, a young schoolboy was injected with a emergency use "covered countermeasure" against his and his parents' express refusals. Officials claimed "mistake"; the family filed suit. The trial court dismissed all claims and on appeal, the Vermont Supreme Court opined that all Respondents are immune from suit under the "Public Readiness and Preparedness Act ("PREPA"). The Vermont Supreme Court misapprehended PREPA's scope, and the framework it intends. A decision that defines the scope of PREPA preemption and immunity would be very useful to courts, authorities and litigants who struggle beneath the current tangled jurisprudence, much of it poorly reasoned.

Under PREPA, "a covered person shall be immune from suit and liability" for "all claims... caused by, arising out of, relating to, or resulting from" administration of a "covered countermeasure." This immunity is conditioned on compliance with emergency use protocols and all public health guidance of the "Authority Having Jurisdiction."

Question: whether the Vermont Supreme Court has construed PREPA's immunity beyond Congress' intention?

PARTIES TO THE PRECEEDINGS BELOW

Petitioners are the Politella family: L.P. (a young boy) and his parents. As Plaintiffs in Vermont Superior Court, Civil Division, Windham Unit, their Complaint and Amended Complaint were dismissed for failure to state a claim due to a lack of subject matter jurisdiction based on federal preemption under PREPA. In Vermont Supreme Court, they were Appellants in an unsuccessful appeal.

Respondents are the Windham Southeast School District and the State of Vermont, along with their agents. These are: Patricia Walior, First Grade Teacher; Amy Mejer, School Nurse; Jon Sessions, Vice Principal; Kelly Dias, Principal; Mark Speno, Windham Southeast School District Superintendent; John and/or Jane Does #1, #2, #3, #4, & #5; Susan Slowinski, M.D., and Dianne Champion, Vermont Department of Health Public Health Director.

These named parties were sued in their official capacities, and appeared collectively as Defendants in the Windham County Superior Court. On appeal, they were Appellees in Vermont Supreme Court, and did prevail.

RELATED PROCEEDINGS BELOW

1. Dario Politella, et al v. Windham Se. Sch. Dist., et al, (Vermont Super. Ct., 22-CV-01707 (Dec. 26, 2022, order dismissing complaint)) and (June 25, 2023, dismissing amended complaint). Appendix (a), (b) and (c).

In Windham Superior Court, there were pleadings pursuant to Respondents' Rule 12 motion. Petitioners do not request this Court review these trial court pleadings.

2. Dario Politella, et al v. Windham Se. School District, et al (Vermont S. Ct., 2024 VT 43, __ A.3d. __, WL 3545717 (July 26, 2024, decision affirming), and (Aug. 23, 2024, re-argument denied). Appendix (d) and (e).

In Vermont Supreme Court, there were procedural and supplemental filings and orders regarding timing, *etc*. Oral argument was heard, *en banc*, but the transcript was unavailable, when this petition was filed. Appellants' and Appellees' Briefs are included as Appendix (f), (g) and (h).

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JURISDICTIONAL STATEMENT

This Court's jurisdiction to review the decision of the Vermont Supreme Court rests on 28 U.S.C. §1257(a).

The Vermont Supreme Court denied a rehearing, August 23, 2024. This Petition was timely filed within ninety calendar days of denial, per 28 U.S.C. §2101(c).

STATEMENT OF THE CASE

A. <u>Introductory Statement</u>— Petitioners respectfully request this Honorable Court to review a recent opinion of the Vermont Supreme Court that misapprehends PREPA immunity to affirm dismissal in derogation of their rights. The issue echoes in courtrooms nationwide, with differing results, and this will fester without this Court's direction.

At a minimum, this Honorable Court should vacate and remand with instructions so the Vermont Court can take into account its guidance regarding PREPA's scope. However, it would be best to grant *certiorari* and restore protections to victims similarly situated across the U.S.

The Windham Court misapprehended the scope of PREPA preemption, which is akin to that detailed in <u>Bates v. Dow Agrosciences LLC</u>, 544 U.S. 431, 452 (2005), *i.e.*, it preempts any state "statutory or common-law rule that would impose a...requirement that diverges from those set out in" PREPA, regarding labels, packaging, storage, prescription, distribution, administration, *etc.* of a covered countermeasure.

On appeal, the Vermont Court piled further harm on a victimized child and his family by immunizing state actors who— incentivized to pursue federal objectives in a public school — broke the law and breached their duties. Respondents are not immune. The opinion is erroneous.

The Vermont Supreme Court's ruling conflicts with established law and yields a horrible result. State actors who misrepresent and fail in their duty to safeguard a boy and inject him with an emergency countermeasure for pay, against prohibitions — while usurping fundamental rights and violating state law and PREPA — do not get immunity under PREPA. The outcome is unconscionable.

B Three Years Ago - On October 29, 2021, Pfizer, Inc. received emergency authorization ("EUA") from the U.S. Food & Drug Administration ("FDA") for use of its BioNTech in children ages 5–11, which required consent. 21 U.S.C. §360bbb-3(a)(6)(e) (1)(A)(ii)(III). Vermont sought to excite demand by announcing its funding incentives to inject children with BioNTech, a month before the EUA.¹

^{1 &}quot;I have Directed the Agency of Education to reserve \$2 million in [ostensible American Rescue Plan Act "ARPA"] grant dollars for schools who achieve high vaccination rates. There will be benchmarks with corresponding awards as a school reaches higher percentages. Funds will be awarded to schools when they reach those thresholds...." Governor Phil Scott and Dr. Mark Levine Discuss Delta, Vaccine Effectiveness and Pandemic Divisiveness at Weekly Covid-19 Briefing, Wed., Sept. 28, 2021.

What happened thereafter was nightmarish. On November 12, 2021, Respondents held a clinic. L.P. was seized from his classroom, taken by unknown "Does" and forcibly injected— under his protest, against his parent's wishes and without their consent, and against the EUA.

Oddly, this scenario had been discussed, just days before. Given BioNTech's novelty and his son's age, Mr. Politella had not registered L.P. for the injection, and on November 10, 2021, he spoke with Vice Principal Sessions regarding inadvertent injection, as he did not want L.P. to receive a shot. Mr. Politella worried about his son's safety in a busy clinical *milieu* and wondered if he should keep him out of school that day. Mr. Sessions stated that there were not as many signed up for the injection as expected, so there was no risk of L.P.'s accidental injection at school.

Mrs. Politella relied on Mr. Sessions' assurance, and brought L.P. to school. Unfortunately, the "mistake" that Mr. Sessions stated could not happen did occur, violating Vermont law, the EUA, and the Politellas' parental rights.

When Mrs. Politella picked L.P. up at school, he had another boy's name on his shirt. L.P. told her that officials stated he had been a "very brave boy" that day at school.

Mrs. Politella soon began to realize that her son had been injected at school, and she became very distressed. It was so obvious that L.P. feared he had done something to upset his mother. Not until the next day did Mr. Politella receive any messages from Respondents about their error.

Meanwhile, Mrs. Politella grew increasingly upset, as no one would explain how this mistake happened. Convinced that officials did not know who her son was, and therefore were unable to keep him safe and could not honor specific directions regarding his care, Mrs. Politella took L.P. out of school and enrolled him privately, incurring expenses.

C <u>Superior Court Proceedings</u> – Petitioners filed suit alleging, *inter alia*, Vermont Title 18 violation, fraud, battery, infliction of emotional distress, premises liability, and gross negligence. On Rule 12 Motions, the court held that Petitioners failed to state a claim for relief for a lack of subject matter jurisdiction by preemption. All claims were dismissed without a hearing. An amended complaint alleged, under Vermont's Constitution, unlawful seizure², and recited Respondents' glaring failures to: (a) vet and

^{2 &}quot;Article 11 "unequivocally sets forth a single specific right of the people to be free from unwarranted searches and seizures [so] that provision is manifestly self-executing." Zullo v. State 205 A.3d 466 (Vt. 2019) at ¶35.

train personnel; (b) verify that L.P. was the proper child before seizing him; (c) ask L.P. for his name, date of birth or any identifying material; (d) respect L.P.'s protests, as they took him out of class and injected him; (e) identify L.P. as unregistered and lacking the required consent; (f) compare L.P.'s nametag with those boys, already injected; (g) notice that the other boy had already been injected; (h) implement procedures and take reasonable precautions to avoid mix-ups; (i) exercise the requisite proficiencies, (i.e., unprofessional conduct); (j) comply with EUA protocols; and, (k) protect L.P from unsafe conditions at the school.

The Court dismissed the amended complaint, ruling that the claims "cannot be litigated in this forum", as they arise from "affirmative administration of a Covid-91 (sic) [countermeasure] and [PREPA preemption] mandated the conclusion that they could not be litigated in this Court." 3

^{3 &}lt;u>Politella et al v. Windham S.E. Sch Dist., et al,</u> "Entry Regarding Motion", (Vt. Sup. Ct. June 25, 2023, 22-CV-01707)

D. <u>Vermont Supreme Court</u>- Petitioners appealed. Briefs were filed and arguments held. The Court affirmed on immunity grounds. Associate Justice Carroll, writing for a unanimous Court, held that preemption arguments were "misplaced", and did not analyze them, despite the lower court's reliance upon this doctrine in its dismissals.

The Court opined that when PREPA "immunizes a defendant, [it also] bars all state-law claims against that defendant...." It held that "every defendant in this case" is immune, "and this fact alone is enough to dismiss [it]."⁴

The Court relied upon Parker v. St. Lawrence Cnty. Pub. Health Dept to rule that PREPA preempts "all state law tort claims arising from" administration of a covered countermeasure, "including one based upon...failure to obtain consent." 102 A.D.3d 140, 954 N.Y.S.2d 259 (N.Y. App. 2012). The Vermont Supreme Court also relies upon Happel, et al v. Guilford Bd. Of Educ. No. 86P24, 901 S.E. 2d 231 (2024), currently taken up on appeal by the North Carolina Supreme Court regarding PREPA immunity in the context of a statutory violation, and still undecided.

⁴ Politella et al v. Windham S.E. Sch Dist., et al, ___ A.3d. ___, 2024 VT 43, WL 3545717, at ¶9. (Vt S. Ct.)

E. <u>Conclusion</u> – Petitioners question the motivation of Vermont and its schools, and have lost trust in its court system to fairly administer justice. Congress did not draft PREPA to preempt fundamental rights and very colorable claims against state actors who deny them. It intended for PREPA to embody informed consent and a right of refusal for emergency countermeasures, and did not intend to immunize those who violate these strict requirements. The Vermont Court fails to grasp PREPA immunity, and its opinion undermines constitutional liberties under law.

It applies a federal law to dismiss state law claims against state actors who —while incentivized by federal funding—violated both state and federal Constitutional protections.

This travesty can be repeated, and should be fixed. The U.S. Health & Human Services ("HHS") "emergency" ends December 31, 2024, but PREPA's declared activation leaves many cases behind. An opinion from this Honorable Court would provide a clarifying effect. Currently, PREPA jurisprudence (such as the Vermont Court's opinion), fails to state essential aspects of its immunity and preemption. Vacatur of the Vermont Court's opinion is warranted here, especially as public health emergencies will be declared in the future, during which PREPA will apply. This requires a clear legal framework that everyone could work within.

PETITION FOR A WRIT OF CERTIORARI

Reasons for Granting the Petition.

I. The Issue Presented Is Recurring, and This Case Provides An Excellent Vehicle for Resolving It.

Courts have inconsistently applied PREPA and its consent requirements, and deny justice to plaintiffs: in Wyoming, to prisoners; in Nevada, sick hospitalpatients; in Vermont, North Carolina, Kansas and Maine, children.⁵ Injection of a countermeasure without consent violates PREPA and the EUA, but courts still get this wrong— or worse, cannot seem to make it right. *See* e.g., Storment v. Walgreen, Co., 2022 WL 2966607 at *3 (D.N.M. July 27, 2022). This is "unfortunate and certainly deserving of a remedy, but it cannot be divorced from the administration of a covered countermeasure-the Covid-19 vaccine...."

There is little doubt that nonconsensual injection is an increasingly pressing issue, implicating fundamental rights across the U.S. The harms of an

⁵ See <u>Bird v. Martinez-Ellis</u>, 2022 U.S. App. LEXIS 35749 (Oct. 26, 2023, 10th Cir.); <u>De Becker v. UHS of Delaware, Inc.</u> (Sept 19, 2024, No. 85968, 140 Nev. _____); <u>Happel v. Guilford Cty Bd. Of Educ.</u>, 900 S.E.2d 666, (N.C. 2024), <u>M.T. v. Walmart Stores, Inc.</u>, 63 Kan. App 2d 401, 528P3d 1067 (Kan App. 2023). <u>Hogan, et al</u>, v. <u>Lincold Med. Partners, et al</u>, Lin-24-209 (Me. S. Ct., 2024).

unconstitutional seizure and medical intervention against parental refusal become more egregious, sandwiched between the reckless misrepresentation, failures and mistakes of school officials and the erroneous dismissal by the state's highest court.

Courts fail to harmonize PREPA's immunity clause (42 U.S.C. §247d-6d(a)(2)(A)) with EUA informed consent and refusal (21 U.S.C. §360bbb 3(a)(6)(e)(1)(A)(ii)(III)).

This statutory scheme is ignored by courts, as in this case, and thus, nonconsensual medical treatments metastasize.

In this case, officials, without verifying his identity and without parental consent, seized a boy at school and injected him. The Vermont Supreme Court has effectively deprived Petitioners of their legal right to bring this claim before a court under Vermont's own state constitution.

In Vermont and in other courts, *Parker* immunity is improperly applied as legal precedent. This cycle of poorly reasoned opinions must be broken, and the underlying constitutional error, corrected.

Young children do not "shed their constitutional rights...at the schoolhouse gate" (<u>Tinker v. Des Moines Indep. Cmty. Sch. Dist.</u> 393 U.S. 503, 506 (1969)).

II. Courts Misapprehend PREPA Immunity

a. PREPA Immunity is Conditional.

PREPA immunizes "covered persons" for claims of "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)

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."

42 U.S.C. § 247d-6d (a)(2)(B) (Emphasis added).

"Congress enacted the PREP Act in 2005 to encourage the expeditious development and deployment of medical countermeasures during a public health emergency by allowing the [HHS Secretary] to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines."

<u>Cannon v. Watermark Retirement</u> <u>Communities, Inc.</u>, 45 F.4th 137, 139 (D.C. Cir. 2022).

PREPA was triggered in 2020. The HHS Secretary declared an emergency. 85 Fed. Reg. 7316 (Feb. 7, 2020). EUA products were authorized. 85 Fed.Reg.18250 (Apr. 1, 2020). PREPA gave immunity to any "covered person" who administered "covered countermeasures" in compliance with PREPA, the EUA and all applicable public guidance.

PREPA has an immunity exception: claims alleging serious injury or death caused by "willful misconduct." 42 U.S.C. §247d-6d(d)(1). These go to U.S. District Court for the District of Columbia. 42 U.S.C. §247d-6d(e)(1). If immunity applies, these claims may be brought to the Countermeasures Injury Compensation Program ("CICP"), for some administrative remedy. 42 U.S.C. §247d-6e(a).

"In each case, whether immunity is applicable will depend on the particular facts and circumstances." See Advisory Opinion, infra at n.6. "[T]o qualify for PREP Act immunity" under PREPA, a "covered person must comply with the public-health guidance issued by an Authority Having Jurisdiction ["AHJ"]." Immunity applies where "all requirements" of the Act and declarations "are met." Shapnik v. Hebrew Home for the Aged at Riverdale, 535 F.Supp.3d 301 (S.D.N.Y. 2021), notes PREPA immunity is not absolute, but is conditioned upon compliance:

a "person must act in compliance with publichealth guidance from the applicable Authority Having Jurisdiction. [One] that fails to follow applicable guidance does not have PREP Act immunity."

Id. (citing Secretary's Declaration, Oct. 23, 2020) (emphasis added).

⁶ HHS Office of the Secretary, "Advisory Opinion 20-04 on the [PREPA] and the Secretary's Declaration Under the Act, October, 2020, as modified on October 23, 2020."

⁷ HHS Office of the Secretary, "Advisory Opinion on the [PREPA] and the March 10, 2020 Declaration Under the Act, April 17, 2020, as modified on May 19, 2020."

In Vermont (the "JHA"), Title 18 gives "applicable guidance." It provides that a "patient has the right to refuse treatment to the extent permitted by law. In the event the patient refuses treatment [then they] shall be informed of the medical consequences of that action...."

18 V.S.A. §1852(A)(5) (effective September 1, 2005).

This language is mimicked in the EUA statute.

"...individuals to whom the [countermeasure] is administered [shall be] <u>informed...of the option to accept or refuse administration of the product [and] of the consequences, if any, of refusing administration of the product..." (Emphasis added).</u>

21 U.S.C. §360bbb-3(a)(6)(e)(1)(A)(ii)(III).

It is also enshrined in the "Common Rule" regarding informed consent ethics for experimental drugs. 45 CFR 46. PREPA "merely creates an ordinary" defense. Leroy v. Hume, 21-2158-cv (2nd Cir. Apr. 13, 2023). Petitioners may "prevail notwithstanding" that the Respondents are "covered", if they failed to follow public health guidance. Shapnick, 535 F.Supp.3d at 321. Immunity is conditional.

PREPA immunity is conditioned upon compliance with informed consent under the EUA. Respondents did not obtain such consent and were grossly negligent; they injected the wrong boy. They failed to take precautions, required by state and federal law, to avoid this mistake. They did not have consent mandated by the EUA, state law or the Common Rule. The Vermont Supreme Court, dismissing on immunity grounds, supports what PREPA clearly prohibits, while ignoring what it clearly requires.

The Vermont Court is wrong; Respondents are not immune when they violated their duty to protect L.P. It is undisputable that Vermont law, PREPA, the EUA and the Common Rule require informed parental consent to inject a covered countermeasure into a young boy. This is "public health guidance" with which Respondents did not comply. They were "responsible for" taking reasonable precautions "to facilitate" safe emergency use of the countermeasure. See Advisory Opinion at n.6. Respondents failed to do this and therefore, they have no immunity under PREPA.

In <u>Kehler v. Hood</u>, 2012. WL 1945952 (E.D. Mo.) 4:11CV1416 (2012), the court dismissed claims against a manufacturer (immune under PREPA) and remanded all remaining state law claims (against a doctor and hospital who administered a covered countermeasure) back to state court to determine if immunity was warranted for conduct before the administration of the countermeasure (*i.e.*, the failure to obtain the required prior informed consent).

This is the right approach. *Kehler* demonstrates that PREPA immunity is conditioned on compliance, and creates a question of fact if this defense is raised. Under *Kehler*, Respondents' abrogation of Petitioners' right to informed consent regarding administration of an EUA "covered countermeasure" precludes immunity under PREPA. Many cases demonstrate that immunity is not absolute, but dependent upon facts and circumstances.

In <u>Barron v. Benchmark Senior Living, LLC</u>, 22-cv-318-SE (D.N.H. Feb. 6, 2023), immunity was in question, where the complaint alleged a failure to follow medical protocols (citing <u>Coleman v. Intensive Specialty Hosp. LLC</u>, No. CV 21-0370, (W.D. La. Dec. 19, 2022)).

In <u>Hatcher v. HCP Prairie Vill. KS OPCO</u> <u>LLC</u>, 515 F.Supp.3d 1152, 1160 (D. Kan. 2021) (D.C. Cir. Sept. 28, 2021), immunity was at issue because the complaint had alleged, *inter alia*, "that safety protocols were not carried out", *i.e.*, there was a lack of compliance with guidance.

In Nowacki v. Gilead Sciences, et al., 2:23-cv-10276 (E.D. Mich., 2023), immunity did not extend to producers whose countermeasure and procedures (glass particles in the vaccine) did not comply with FDA requirements (much like the EUA's informed consent and right of refusal found in 21 U.S.C. §360bbb-3(a)(6)(e)(1)(A)(ii)(III)).

The option to accept or refuse administration is the *sine qua non* of immunity under PREPA. This option was denied by Respondents, and thus, they are not immune.

Fraud will also deny PREPA immunity. In <u>Coleman v. Sharp Memorial Hosp.</u>, No. 37-2023-00033307-CU-PO-CTL, 2024 Cal. Super. LEXIS 10893 (Cal. Sup. Ct. March 29, 2024), claims were not based on a countermeasure, but "rather on the...concealment of facts;" *i.e.*, fraudulent use of hospital procedures, which the court reasonably found to be outside the scope of PREPA immunity. *Id.* at *4.

PREPA immunity is conditioned upon compliance with public health guidance, traditional other informed consent and acknowledged constitutional liberties of bodily integrity. This case involves a medical battery, unlawful seizure, and injection of a child by state actors against his protests. Reckless misrepresentation by the vice principal regarding safety or gross negligence by officials is beyond the scope of PREPA immunity, as these do not involve an administration of the countermeasure. because none was contemplated or constitutionally authorized at any time.

Respondents' noncompliance with guidance and the EUA is inconsistent with the Vermont Court's ruling that Respondents are immune from suit. The implications of this holding are noxious, and this Court should reverse this erroneous ruling and provide accurate jurisprudence.

III. Courts Misapprehend PREPA Preemption.

a. Only Willful Misconduct Resulting in Death or Serious Bodily Injury is Federally Preempted.

This Court let stand a decision of the U.S. Court of Appeals for the Ninth Circuit, which found that PREPA's scheme is insufficient to completely preempt all state law claims. See Saldana v. Glenhaven Healthcare, LLC, 27F.4 679 (9th Cir. 2022) cert. denied, 598 U.S. ____, 143 S.Ct 444 (Nov. 21, 2022). In the Second Circuit, Solomon v. Saint Joseph's Hospital HCS of Long Island, Inc. (21-CV-2729, affirmed March 7, 2023 (2nd Cir. 2023)) holds that "state-law claims are not completely preempted." It is settled: PREPA preemption is not complete. This "is in line with every other Court of Appeals that has addressed the issue." Id.8 State courts should hear claims as are raised in this case, particularly those on constitutional grounds.

Federal courts recognize that "nothing in the PREP Act suggests that Congress was attempting to eliminate state-law causes of action for non-immunized claims." <u>Solomon</u> at 62 F.4th 61. *Parker* erroneously holds that all state law claims are completely preempted. This has led to unjust, unconstitutional results, as witnessed in this case.

⁸ Maglioli v. Alliance HC Holdings LLC, 16 F.4th 393 (3rd Cir. 2021); Mitchell v. Advanced HCS, L.L.C., 28 F.4th 580 (5th Cir. 2022); Hudak v. Elmcroft, 58 F.4th 845 (6th Cir. 2023); Martin v. Petersen Health Ops., LLC, 37 F.4th 1210 (7th Cir. 2022); Cagle v. NHC HealthCare, LLC, 22-2757 (8th Cir. 2023); Est. of Schleider v. GVDB Ops, LLC, No. 21-11765 (11th Cir., October 31, 2024).

It is settled that "the only exclusive federal cause of action established" under PREPA is "willful misconduct" found in 42 U.S.C. §247d-6d(c). *Id.* Vermont recognizes the "presumption that the power of the state has not been superseded by a federal act, and that a "party seeking to overcome this presumption bears a heavy burden." <u>In re Investigation Into Regulation Of Voice Over Internet Protocol Services</u>., 2013 VT 23 at ¶14, 193 Vt. 439 (2013).

the Vermont Court ignores that presumption to opine that when PREPA "immunizes a defendant, [it] bars all state-law claims against that defendant...." Politella, 2024 VT 43, 2024 WL 3546717, pg. 6. This misstates the law; PREPA immunity (where applicable and based upon compliance) only preempts claims within the ambit of the Act for product liability and related claims, not traditional torts uncontemplated by PREPA's purpose or its express language. PREPA preempts only one cause of action and state courts should have this basic principle set down for all to see and understand in very clear terms. Until then, unjust results, as seen in this case, will proliferate.

b. States Are Preempted From Regulating Countermeasures, Not From Hearing State Law Claims.

PREPA's preemption provision states that during the effective period of a declared public health emergency:

"[N]o 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"

42 U.S.C. § 247d-6d(b)(8)(A) & (B).

Given this Court's plurality opinions regarding the federal preemption issue, this much is clear: Petitioners' state law claims are not expressly preempted by the Act.

Courts recognize that PREPA does preempt claims, but preempts state requirements for the design, development, etc., of "covered countermeasures." PREPA preempts state implementation of "different standards regarding" their "administration or use." Turner v. The Bristol At Tampa Rehab. & Nursing Ctr., 8:21-cv-0719-KKM-CPT (M.D. Fla. Sep 20, 2021). PREPA "only addresses" a state's "ability to 'establish, enforce, or continue in effect" any "requirement concerning covered countermeasures." Id. This language is not novel; many statutes incorporate substantially similar phrasing. The language "does not address" private causes of action arising under state law." Id. (*Emphasis* added).

The U.S. Department of Justice parsed this language:

"We conclude that the Act expressly preempts state and local requirements to the extent that they would effectively prohibit qualifying pharmacists from ordering and administering Covid-19 tests and vaccines authorized by the Secretary's declaration."⁹

"...we think it evident under the statute that the Secretary had the authority to act quickly to expand the number of covered persons who may administer necessary countermeasures to deal with that crisis, and <u>Congress specified</u> that state or local health officials lack authority to take measures that would conflict with such an action." Id. (emphasis added.)

It is useful to note that the actions of "state or local health officials" are barred; not claims, courts or plaintiffs. Petitioners' state law claims are not expressly preempted.

The *Parker* Court was mistaken when it held "that Congress intended to preempt all state law tort claims... including one based upon a defendant's failure to obtain consent." <u>Parker</u> at 954 N.Y.S. 2d 262. *Parker* is poorly reasoned, yet endures since 2012. This flawed precedent 'snowballs' into other venues, like the Vermont Supreme Court, to deprive plaintiffs of their

⁹ Mascott, J., U.S. Deputy Asst. Attorney "General Preemption of State and Local Requirements Under a PREP Act Declaration; Memorandum Opinion For the (HHS) General Counsel", January 19, 2021.

legal remedies. This Court could provide certainty regarding the limited scope of PREPA's preemption and conditional immunity scheme, to prevent further injustices, as are witnessed in this case.

This Honorable Court should vacate the Vermont Court's decision, as it construes PREPA beyond Congress' intent and nullifies state law protecting informed medical consent, fundamental liberties, parental rights and bodily autonomy. This Court should reverse and remand to the Vermont Court with instructions to apply PREPA, so that proper constitutional limits and state sovereignty apply.

IV. <u>Petitioners' Claims Do Not "Relate To" The</u> Administration Of A Covered Countermeasure.

PREPA immunity revolves around "claims for loss relating to' administration of a countermeasure, and this Court "singled out" the phrase "relate to" as particularly sensitive to context." <u>Hampton v. State of California</u>, 83 F.4th 754, 764 (9th Cir. 2023) (citing <u>Dubin v. U.S.</u>, 599 U.S. 110, 143 S. Ct. 1557, 1565 (2023). "That the phrase refers to a relationship or nexus of some kind is clear.... [y]et the kind of relationship required, its nature and strength, will be informed by [its] context." *Id.* (citing <u>N.Y.S.</u>

Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995)).

"It is not enough that some countermeasure's use could be described as relating to the events underpinning the claim in some broad sense." <u>Hampton</u> at 83 F.4th 764.

Respondents are not entitled to PREPA immunity, which requires "causal relationship" to a countermeasure. See, e.g., Manyweather v. Woodlawn Manor, Inc., 40 F.4th 237, 245–46 (5th Cir. 2022); Estate of Schleider v. GVDB Operations, LLC, No. 21-11765 (October 31, 2024, 11th Cir. 2024). Pirotte v. HCP Prairie Vill. KS OPCO LLC, 580 F. Supp. 3d 1012, 1023–24 (D. Kan. 2022).

When considered in context "relating to' takes on a more targeted meaning." <u>Hampton</u>, *supra* at 83 F.4th 764 (citing <u>McDonnell v. U.S.</u>, 579 U.S. 550, 568-69, 136 S.Ct. 2355 (2016)) "A word is known by the company it keeps." (*Id.* citing Jarecki v. G.D. Searle & Co., 367 U.S. 303, 307, 81 S.Ct. 1579 (1961))). The phrases "caused by," "arising out of," and "resulting from — all connote some type of causal relationship." *Id.* A direct connection is required.

Petitioners do not allege loss from "administration" of a countermeasure, but rather sue as parents seeking to hold state actors liable within the

"context" of their enumerated failures, ((a) through (k) in their Amended Complaint) to protect L.P. on school premises, and for unlawfully seizing him. *Cf.* "Est. of Maglioli v. Andover Subacute Rehab. Ctr., 478 F.Supp. 3d. 518, 529 (D.N.J. 2020), aff'd *sub nom*. Maglioli v. All. HC Holdings LLC, 16 F.4th 393 (3rd Cir. 2021) (failure to exercise due care not preempted where a countermeasure injury is not alleged); *Cf.* Coleman v. Intensive Specialty Hosp., LLC, No. 21-0370, 2022 WL17779323, at *5 (W.D. La., Dec. 19, 2022) (breach of care not covered where injury or death is not alleged).

PREPA immunity does not apply constitutional violations such as Petitioners have raised under Article 11. Respondents' "general lack of action is not a covered countermeasure under" PREPA. Heights of Summerlin, LLC v. Eighth Judicial Dist. Court of the State, 140 Nev. Adv. Op. 65, 86214 (Nev. Oct. 3, 2024). Petitioners allege "lack of an adequate Covid-19 policy, rather than a drug or device" led to the harm. Id. A "Covid-19 response policy is not a covered countermeasure. To put it simply, a program or policy is not a product, drug, or device." Crupi v. Heights of Summerlin, LLC, 2:21-cv-00954-GMN-DJA, 12 (D. Nv. Feb. 17, 2022). Respondents' abject failure to meet public health standards and protocols while running their school vaccination clinic is not "a product, drug or device." Id.

Circumstances in this case involve a marked "lack of an adequate" implementation, regarding consent and identifying those who have affirmatively provided it. *Id*.

Respondents' "general lack of action", regarding the clear duty to safeguard L.P at school, especially after Mr. Politella spoke with Vice Principal Sessions about risks, is not a "countermeasure." The facts in this case do not show any causal relationship between the countermeasure and a deprivation of liberty by seizure. Nor was Mr. Sessions' reckless misrepresentation caused by a countermeasure. The losses here are intangible (except tuition), yet real; but do not 'relate to' administration of a countermeasure.

PREPA contemplates tort, commercial and property losses, and injury or death, which are not the intangible, dignitary harm of unlawful seizure, battery, or emotional distress. The losses here are not within PREPA's "relating to" language, as there is no harm alleged from the shot. The harm 'relates to' reckless misrepresentations, grossly negligent conduct before the shot was administered, and process failures resulting in L.P.'s lost liberty and dignity.

Regarding misrepresentation: if PREPA immunized deceptive "inducement and sanctioned illusory promises, then no one would agree to [participate in such] high risk activities...." <u>Dressen</u>

v. Astrazeneca, AB, et al, 2:24-cv-00337-RJS (D. Utah, Nov. 4, 2024). If fraud is immune, it would invite "rank abuse among covered entities to make illusory promises to unwitting" parents and citizens. *Id*.

The *laissez-faire* regime that "covered entities" have enjoyed during the public health emergency "due to their widespread tort immunity" is "undermined if the *express* promises they make along the way were not enforceable." *Id.* Here, Mr. Sessions promised that L.P. would be safe, and PREPA should not allow Respondents "to shirk this and any other promise made…merely because" an illusory promise of safe premises "ultimately relates to the administration or use of a" covered countermeasure. *Id.*

V. <u>Most Respondents Are Not 'Covered</u> <u>Persons'</u>

"Close reading" of the statute reveals that most Respondents are not "covered." Goins v. Saint Elizabeth Med. Ctr. 640 F.Supp.3d 745, 756 (E.D. Ky.) (2022) (aff'd, 6th Cir. Jan 22, 2024). Vice Principal Sessions was not one who "prescribed, administered, or dispensed" the shot. Id. (citing 42 U.S.C. §247d-6d(i)(2)(B)(iv). Use of the phrase "prescribed, administered, or dispensed," in the simple past tense, refers to an action completed at a definite time—when the [injection] was prescribed, administered,

or dispensed." *Id.* (citing Farrell, R.Why Grammar Matters: Conjugating Verbs in Modern Legal Opinions, 40 Loy.U. Chi. L.J. 1, 19 (2008)).

When the injection was administered is important; a "covered person" is not "covered", ex post facto. Named Respondents are not "covered", as they did not administer any shots, and all their misconduct preceded it. When Vice Principal Sessions misrepresented premises safety, he had not "prescribed, administered, or dispensed" any covered countermeasure, nor had any Respondent. Only "Does # 1 through 5", who took L.P. from class and injected him, had "prescribed, administered, or dispensed" it. As Petitioners argued, the Does are likely the only ones to be "covered."

PREPA "does not insulate all covered persons from suit merely because they administered" countermeasures. <u>Vaughan v. Genesis HealthCare</u>, <u>Inc.</u>, C.A. S22C-07-005 MHC (Del. Sup Ct. Feb 06, 2024). PREPA does not provide "blanket immunity to... a facility...merely on account of that entity's having... administered...countermeasures..." *Id.* Immunity is conditional and situational, not absolute.

Petitioners may "prevail notwithstanding" that the Respondents are "covered", if they failed to follow public guidance. <u>Shapnick</u>, 535 F.Supp.3d at 321. Immunity is conditional, based on facts and circumstances. PREPA "merely creates" a defense to

be raised in a suit. <u>Leroy v. Hume</u>, 21-2158-cv (2nd Cir. Apr. 13, 2023). The facts will determine whether it applies, based upon compliance.

The court determines whether claims fall within the "immunity provision." <u>Conyers v. Isabella Geriatric Ctr.</u>, 2024 NY Slip Op 33661(unpublished), No. 153668/2022, (N.Y. Sup. Ct. Oct. 15, 2024) In this case, the "claims pertain only to...failures to act, and such allegations do not amount to the administration of countermeasures." *Id.* (*citing* <u>Dupervil v Alliance Health Operations, LLC</u>, 516 F.Supp.3d 238, 255 [ED NY 2021]). Thus, the entity "is not entitled to [PREPA] immunity." *Id.* In this case, many Respondents failed to act; very few "administered" a shot.

VI. The Vermont Supreme Court's Ruling Has Deprived Petitioners Of Rights Recognized By This Court.

a. Regarding The Fourth Amendment

The Fourth Amendment to the U.S. Constitution provides the right to be secure...against unreasonable... seizures..." <u>Vernonia School Dist. v. Acton</u>, 515 U.S. 646, 115 S.Ct 2386 (1995). This extends to seizures "by state officers" *Id.* citing <u>Elkins v. U.S</u>, 364 U.S. 206, 213, 80 S. Ct. 1437 (1960). This

includes "public school officials." *Id.* (citing <u>New Jersey v. T. L. O</u>.), 469 U.S. 325, 336, 105 S. Ct. 733 (1985).

Whether a seizure is reasonable "is judged by balancing its intrusion on [the seized person's] Fourth Amendment interests against its promotion of legitimate governmental interests." *Id.* (citing Delaware v. Prouse, 440 U.S. 648, 654, 99 S. Ct. 1391 (1979)).

It is undeniable that what happened to L.P. in this case constituted his unreasonable seizure by state actors without "legitimate governmental interest." He is subject to the control of his parents, who affirmatively told school officials that he was not to be injected at the school clinic.

"Historically, damages have been regarded as the ordinary remedy for an invasion of personal interests in liberty." Bivens v. Six Unknown Agents of Federal Bureau of Narcotics, 403 U.S. 388, 396, 91 S.Ct. 1999 (1971)(citing Nixon v. Condon, 286 U.S. 73, 52 S.Ct. 484 (1932)). It is "well settled that where legal rights have been invaded, and a federal statute provides for a general right to sue for such invasion...courts may use any available remedy to make good the wrong done." *Id.* (citing Bell v. Hood, 327 U.S., at 684, 66 S.Ct., at 777).

State officials, in a public health crisis with a duty "to guard and protect" the "safety and the health of the people," are permitted to take actions deemed necessary. <u>Jacobson v. Massachusetts</u>, 197 U.S. 11, 28 (1905).

But, what happened in this case had no "real or substantial relation" to an emergency, and clearly was "beyond all question, a plain, palpable invasion of rights secured by the fundamental law", *i.e.*, the Fourth Amendment. *Id*.

Petitioners raised a claim under Article 11 of the Vermont Constitution for seizure, analogous to a Fourth Amendment breach. The Vermont Court held Respondents immune. Petitioners ask this Court to decide if Congress intended PREPA to nullify state constitutional rights and use "any available remedy to make good the wrong done." *Id*.

b. Regarding The Tenth Amendment

The Tenth Amendment reserves to the States or the People, "powers not delegated" to the U.S. government "by the Constitution, nor prohibited by it to the States." The Vermont Court flouts this arrangement by shielding state actors' misconduct under federal law, which could not be Congress' intent, nor the intent of the Tenth Amendment.

Respondents deprived petitioners of their Vermont Article 11 (and also their Fourth Amendment) right to be free from unlawful seizure, and this Honorable Court can recognize the dysfunction manifested where state entities, using federal dollars, violate their own state constitution, statute and common law in furtherance of federal schemes in public schools. This Court may review a state Supreme Court opinion which blatantly ignores Tenth Amendment principles of balanced power, fundamental to our republic.

Governance by dual sovereigns safeguards against tyranny. The Vermont Supreme Court, under PREPA, finds a "covered countermeasure exception" to the rights and liberties protected by the U.S. Constitution. It is not an opinion that should remain as binding legal authority.

The Vermont Court's dismissal on federal immunity grounds runs contrary to the Tenth Amendment. Under the Vermont Court's reasoning, state-run entities cannot be found liable in state court under the state constitution, statute or common law, because PREPA states otherwise.

Such an "expansive interpretation" of PREPA immunity, where "hardly [any type of misconduct] fall[s] outside the federal statute's domain," promotes unacceptable levels of raw federal power. <u>Jones v. U.S.</u>, 529 U.S. 848, 857 (2000).

c. Regarding Petitioners' Parental Rights

Petitioners have an interest in L.P.'s "care, custody and control." Troxel v. Granville, 530 U.S. 57, 65, 120 S.Ct. 2060 (2000). It is "the oldest... fundamental liberty interest[] recognized by this Court." *Id.* It includes a right to direct "upbringing and education." *Id.* (citing Meyer v. Nebraska, 262 U.S. 399, 43 S.Ct. 625 (1923) and Pierce v. Society of Sisters, 268 U.S. 534, 45 S. Ct. 571 (1925)).

American society has "a strong tradition of parental concern for the nurture and upbringing of their children." *Id.* (citing Wisconsin v. Yoder, 406 U.S. 205, 232, 92 S. Ct. 1526 (1972). It recognizes "broad parental authority over minor children." *Id.* (citing Parham v. J.R, 442 U.S. 584, 602, 99 S. Ct. 2493 (1979)). Beyond the "specific freedoms protected by the Bill of Rights, the 'liberty' [most] specially protected...includes the right []to direct the education and upbringing of one's children." *Id.* (citing Washington v. Glucksberg, 521 U.S. 702, 720, 117 S. Ct. 2258 (1997).

As parents, Mr. and Mrs. Politella had the right to decide whether L.P. would receive an injection. There is no disputing their decision that L.P. should *not* receive it. However, their right to make this decision was denied.

There is no disputing that L.P. has received elective medical treatment at school, without parental consent. In fact, this happened against their express prohibition. And, it <u>might</u> have been a mistake, but Respondents' egregious misconduct could not serve any legitimate state interests.

The Vermont Court allows Respondents to deny the "oldest of the fundamental liberty interests recognized by this Court." <u>Troxel</u>. L.P.'s injection over objection stripped Petitioners of one of the "basic rights of man"... far more precious than property rights." <u>Yoder</u>, at 406 U.S. 232.

Petitioners as parents, and their minor child L.P. as an individual, have the constitutionally-protected liberty to be free from unauthorized medical treatments by the State. The smallpox outbreak addressed by *Jacobson* was very different from illegal experiments on Americans at Tuskegee. Judicial approbation of the Vermont Supreme Court's determination in this case permits gross violation of constitutional liberties on both parents and child, and is a vast departure from decades of accepted medical ethics.

As Judge Collins noted in his concurring opinion in <u>Health Freedom Defense Fund, Inc. v.</u> Carvalho (No. 22-55908 9th Cir. 2024):

...a distinct and more recent line of Supreme Court authority, in which the Court has stated that "[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from [the Court's] prior decisions."

Id. (citing Cruzan ex rel. Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261, 278–79 (1990) ("not only Jacobson, but a series of later "cases support the recognition of a general liberty interest in refusing medical treatment").

...the Court explained that *Cruzan's* posited "right of a competent individual to refuse medical treatment" was "entirely consistent with this Nation's history and constitutional traditions," in light of "the common-law rule that forced medication was a battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment."

Id. (citing Glucksberg supra, at 521 U.S. 724 (1997).

Congress did not express any intention to eliminate such fundamental liberties in PREPA, nor are these rights implicated if the Vermont Supreme Court's opinion herein is duly determined to be an erroneous extension of PREPA immunity. The Vermont Court's decision— by immunizing Respondents for gross misconduct— construes PREPA in derogation of some of the most basic protected liberties in our American society. This Honorable Court should not let infringement of liberties stand as law. The Vermont Court departs severely from this Court's jurisprudence, and its decision has the potential to encourage further incidents of medical treatment of children without parental consent.

A moral hazard arises where lower court opinions expanding immunity beyond Congressional intent stand as precedent. This Honorable Court should reverse the Vermont Supreme Court's decision and remand it with instructions on PREPA's scope of conditional immunity.

VII. Conclusion.

As the issues are important, and the Vermont Court construes PREPA in opposition to its own constitutional provisions, this Honorable Court's opinion is requested.

WHEREFORE, for all the foregoing reasons, this Court should grant this petition for a writ of *certiorari*.

Respectfully submitted,

John Klar, Esqr. Counsel of Record for Petitioners November 19, 2024 No.

In The

SUPREME COURT OF THE UNITED STATES

DARIO and SHUJEN POLITELLA and

Their Minor Child, L.P.,

Petitioners.

v.

WINDHAM SOUTHEAST SCHOOL DISTRICT and THE STATE OF VERMONT, et al,

Respondents.

CERTIFICATE OF WORD COUNT

Pursuant to this Court's Rules, I certify that this Petition, drafted using Century 12-point typeface, has a total of 6638 words, including footnotes, excluding sections exempted by Rule 33.1(d) This Certificate was prepared in reliance upon the word-count function of MS-Word 2021, which was used to prepare the document. I declare under penalty of perjury that the foregoing is true and correct.

John Klar, Esqr. Counsel for Petitioners

APPENDIX A

VERMONT SUPREME COURT

JULY 26 2024 2024 VT 43

ENTRY ORDER FILED IN CLERK'S OFFICE

SUPREME COURT DOCKET NO. 23-AP-237

MAY TERM, 2024

Dario Politella and Shujen Politella v.

Windham Southeast School District et al.

CASE NO. 22-CV-01707

APPEALED FROM:

Superior Court, Windham Unit, Civil Division

In the above-entitied cause, the Clerk will enter:

Affirmed.

FOR THE COURT:

Karen R. Carroll, Associate Justice

Concurring:

Paul L Reiber, Chief Justice

Harold E. Eator/ Jr., Associate Justice

William D. Cohen, Associate Justice

Nancy Waples, Associate Justice

NOTICE: This opinion is subject to motions for reargument under V.R.A.P. 40 as well as formal revision before publication in the Vermont Reports. Readers are requested to notify the Reporter of Decisions by email at: JUD.Reporter@vtcourts.gov or by mail at: Vermont Supreme Court, 109 State Street, Montpelier, Vermont 05609-0801, of any errors in order that corrections may be made before this opinion goes to press.

VERMONT SUPREME COURT

FILED IN CLERK'S OFFICE

2024 VT 43 JULY 26 2024

No. 23-AP-237

Dario Politella and Shujen Politella v.

Windham Southeast School District et al.

May Term, 2024

Supreme Court On Appeal from

Superior Court, Windham Unit, Civil Division

Hon. Michael R. Kainen, Judge

Ronald A. Ferrara and Matthew W. Goins, Law Clerk (On the Brief) of Fitts, Olson, Giddings & Ferrara, PLC, Brattleboro, for Plaintiffs-Appellants. Kristin C. Wright of Lynn, Lynn, Blackman & Manitsky, P.C., Burlington, for Defendant

for Defendant-Appellee School District

Charity R. Clark, Attorney General, and David McLean, Assistant Attorney General, Montpelier,

for Defendant-Appellee State of Vermont.

PRESENT: Reiber, C.J, Eaton, Carroll, Cohen and Waples, JJ.

¶ 1 CARROLL, J. Plaintiffs Dario and Shujen Politella appeal an order dismissing their amended complaint for lack of subject-matter jurisdiction. Plaintiffs' son, L.P., was mistakenly given a single dose of the Pfizer BioNTech COVID-19 vaccine at a state-sponsored vaccine clinic at L.P's school. Plaintiffs sued various named and unnamed state and school defendants. We conclude that defendants are immune from suit under the Federal Public Readiness and Emergency Preparedness Act (PREP Act). We therefore affirm.

I. Background

- ¶2. Plaintiffs' complaint alleged the following. Plaintiffs lived in Brattleboro with their son, L.P., who was six years old in 2021. L.P. attended Academy School in the Windham Southeast School District. The Vermont Department of Health and the school district entered into an agreement to host a COVID-19 vaccination clinic at Academy School in November 2021. Students needed parental consent to be vaccinated. Plaintiffs did not consent to have L.P. vaccinated.
- ¶ 3. A few days before the clinic, L.P.'s father dropped off L.P. at school and spoke with Academy School's assistant principal. Father reiterated to the assistant principal that plaintiffs did not consent to have L.P. vaccinated. The assistant principal said that he understood and stated that L.P. could not be vaccinated without plaintiffs' consent. In the same interaction, the assistant principal said that the school had not received as many vaccine registrations as he would have liked.

¶ 4. Despite the above, L.P. was vaccinated on the day of the clinic. An unidentified worker removed L.P. from class and applied a handwritten label to L.P.'s shirt that read, "L.K." and displayed "L.K's" date of birth. L.K. was a five-year-old student at Academy School who was not in L.P.'s class. L.K. had already been vaccinated the same day. L.P. "verbally protested," saying, "Dad said no." Nonetheless, clinic workers gave L.P. a stuffed animal to distract him, told L.P. that he was "a brave little boy," and administered one dose of the Pfizer BioNTech COVID-19 vaccine¹ A clinic worker filed out a vaccine card with "L.K.'s" name, the date of administration, the vaccine lot number, and the type of vaccine dose and put the card in L.P.'s backpack. At some point, the clinic workers and school officials realized the mistake. School officials called plaintiffs to apologize. Plaintiffs removed L.P. from Academy School soon afterward. Plaintiffs did not allege that L.P. suffered harm as result of receiving the vaccine.

¹ Plaintiffs do not name the vaccine in the original or amended complaints. Plaintiffs reference certain reports regarding the safety of the Pfizer vaccine in their motion papers. In their main appeal brief, plaintiffs appear to concede that the countermeasure involved was the Pfizer vaccine.

¶5. Based on these and other allegations, plaintiffs filed an eight-count complaint in the civil division. Each count was based in state law.² Plaintiffs named as defendants the State of Vermont and the school district, the school district superintendent, the principal and assistant principal, a teacher, the school nurse, Vermont's Deputy Health Commissioner, L.P.'s pediatrician, and five unnamed state employees or volunteers. Plaintiffs described each individual defendant as either employed by the school, the school district, the State of Vermont, or as "de facto agents of the State." Prior to answering the complaint, the State defendants moved to dismiss for lack of subject-matter jurisdiction and for failure to state a claim. The school defendants filed an answer and moved for judgment on the pleadings. Both groups of defendants argued that they were immune from state-law claims under the PREP Act, 42 U.S.C. §247d-6d (providing liability immunity), and

² Plaintiffs pleaded the following causes of action: a violation of Vermont's Healthcare Bill of Rights, 18 V.S.A. §1852, gross negligence, negligent undertaking, premises liability, battery of minor, consumer fraud, common-law fraud, and intentional infliction of emotional distress.

therefore all claims were preempted. Plaintiffs opposed on the basis that defendants were not immune under the PREP Act and it did not preempt their claims.

- ¶6. The court concluded that the PREP Act provided immunity for State and school defendants involved in administering the vaccine to L.P., and that case law from other jurisdictions supported that conclusion. Deciding that defendants' affirmative defense of federal preemption warranted dismissal, it granted the motions to dismiss and for judgment on the pleadings, and granted plaintiffs leave to amend.
- ¶7. Plaintiffs filed an amended complaint containing a new count styled, "Private Right of Action-Constitutional." This count alleged a violation of Article 11 of the Vermont Constitution. The trial court concluded that because this claim was also based in state law, it too was preempted by the PREP Act. The court otherwise found that the amended complaint relied on the same allegations plaintiffs originally pleaded; in effect, that LP. was wrongfully administered a COVID-19 vaccine.

Concluding that it had no jurisdiction over preempted claims, the court again dismissed the amended complaint for lack of subject-matter jurisdiction and granted the motion for judgment on the pleadings. Plaintiffs appealed.

- ¶8. Plaintiffs essentially present two issues for our review: (1) defendants' alleged conduct does not fall under the PREP Act immunity provision, and (2) the PREP Act does not preempt plaintiffs' claims. They cite cases from other jurisdictions in support of their arguments. Plaintiffs contend that the court erred in dismissing the case for lack of subject-matter jurisdiction. They ask us to reverse and remand for additional proceedings.
- ¶9. We conclude that the PREP Act immunizes every defendant in this case and this fact alone is enough to dismiss the case. Plaintiffs" arguments about preemption are misplaced, and therefore we need not decide today the extent of the PREP Act's preemptive effect. We conclude that when the federal PREP Act immunizes a defendant, the PREP Act bars all state-law claims against that defendant as a matter of law.

We therefore affirm the dismissal because plaintiffs have failed to state a claim upon which relief can be granted and not for lack of subject-matter jurisdiction. See State v. VanBuren, 2018 VT 95, 170, 210 Vt. 293, 214 A.3d 791 (explaining that this Court can affirm trial court's decision on any basis). For the same reason, we also affirm the court's grant of judgment on the pleadings in favor of the school defendants.

II. Discussion

A. Standard of Review

¶10. We review anew a trial court's decision on motions to dismiss failure to state a claim and for judgment on the pleadings. Negots. Comm. of Caledonia Cent. Supervisory Union v. Caledonia Cent. Educ. Ass'n, 2018 VT 18, ¶¶8, 12, 206 Vt. 636, 184 A.3d 236. We will affirm a dismissal order only when there are "no facts or circumstances" entitling the nonmoving party to relief. Davey v. Baker, 2021 VT 94, q2, 216 Vt. 53, 274 A.3d 8:7 (quotation omitted).

To this end, we "take all uncontroverted factual allegations of the complaint as true and construe them in the light most favorable to the nonmoving party." Caledonia Cent. Educ. Ass'n, 2018 VT 18, ¶10 (quotation and alteration omitted). Similarly, we will affirm a judgment on the pleadings when the movant is entitled to judgment as a matter of law on the pleadings alone. *Id*. We accept as true all well-pleaded factual allegations contained in the nonmoving party's pleadings, including any reasonable inferences to be drawn from them, and accept as false all contrary allegations in the movant's pleadings. Huntington Ingalls Indus.. Inc. v. Ace Am. Ins. Co., 2022 VT 45, 4 17, 217 Vt. 195, 287 A.3d 515. "The only difference between" a motion to dismiss for failure to state a claim and judgment on the pleadings "is the timing of the motion to dismiss." Hunter v. Ohio Veterans Home, 272 F. Supp. 2d 692, 694 (N.D. Ohio 2003).

B. The PREP Act

¶11. Congress passed the PREP Act in 2005. The Act authorizes the Secretary of Health and Human Services to issue a declaration when the Secretary makes a "determination that a disease or other health condition or threat to health constitutes a public health emergency." 42 U.S.C. §247d-6d(b)(1).

In the declaration, the Secretary "may specify [the manufacture, testing, development, distribution, administration, or use" of a "covered countermeasure." Id. A vaccine is a covered countermeasure. *Id.* §247d-6d(i)(1)(C).

During a public-health emergency, certain "covered persons" are immune from all claims causally related to the administration of a covered countermeasure, Id. §247d-6d(a)(2). The immunity in §247d-6d(a)(1) "applies to any claim for loss that has a causai relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with . . . dispensing, prescribing, administration, licensing, or use of such countermeasure." Id. §247d-6d(a)(2)(B). "The Secretary controls the scope of immunity through the declaration and amendments, within the confines of the PREP Act. "Saldana v. Glenhaven Healthcare LLC, 27 F.4th 679, 687 (9th Cir. 2022) (quotation omitted).

- ¶13. The "sole exception" to the PREP Act's grant of immunity is a federal cause of action against a covered person whose "willful misconduct" causes "death or serious physical injury." *Id.* §247d-6d(d) (1). An action of this type may only be filed in the U.S. District Court for the District of Columbia. *Id.* §247d-6d(e)(1).
- ¶14. In March 2020, the Secretary issued a declaration addressing the COVID-19 pandemic. Declaration Under the Public Readiness See and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 1,598-01 (Mar. 17, 2020) [hereinafter March 2020] COVID-19 Declaration. Among other provisions, the Secretary declared that covered countermeasures included "any antiviral, and other drug, any biologic, any diagnostics, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19." Id. at 15,202. The Secretary declared that administration of a covered countermeasure included "physical provision of a countermeasure to a recipient, such as vaccination ... and ... activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing." *Id.* at 15,200.

¶15. With this background in mind, we turn to plaintiffs' amended complaint to determine whether it can survive the pleadings stage. See <u>Huey v. Bates</u>, £35 Vt. 160, 161, 375 A.2d 987, 988 (1977) (explaining rule that, for purposes of appellate review, motions to dismiss constitute admission that all well-pleaded facts alleged by plaintiff are true).

C. Defendants' Immunity Under the PREP Act

- ¶16. To avoid dismissal on immunity grounds, plaintiffs would have had to present well-pleaded allegations showing that (1) at least one defendant was not a covered person, (2) some conduct by a defendant was not causally related to administering a covered countermeasure, (3) the substance injected into L.P. was not a covered countermeasure, or (4) there was no PREP Act declaration in effect at the time L.P. was injected. We address each in turn.
- ¶17. All defendants in this matter are covered persons as defined by the PREP Act. "Program planners" are covered persons under the PREP Act. 42 U.S.C. §247d-6d(i)(2)(B)Gii).

A program planner "means a State or local government,...a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration...of a security countermeasure or a qualified pandemic or epidemic product." *Id.* §247d-6d(i)(6). An "official, agent, or employee" of a program planner is also a covered person. *Id.* §247d-6d(i)(2)(B)(v).

¶18. As noted above, plaintiffs named the school district, the State, and various individuals as defendants. Plaintiffs alleged that defendants were "de facto agents of the State" in the case of individual persons, or "de facto landlords of the State's vaccine clinic," in the case of the school district. Taking plaintiffs' allegations as true, the State and the school district are program planners as defined by the PREP Act, and the individual persons plaintiffs allege to be employees and "de facto agents" are agents or employees of program planners. It follows that every defendant is a covered person under the Act.

See <u>Happel v. Guilford Cnty. Bd. of Educ.</u>, 899 S.E.2d 387, 392 (N.C. Ct. App. 2024) (holding that "community group" that administered COVID-19 vaccine to student at student's school without parental consent was program planner under PREP Act), review on additional issues allowed in part, 900 S.E.2d 666 (N.C. 2024), and appeal dismissed, 900 8.E.2d 668 (N.C. 2024).

¶19. Plaintiffs' allegations relating to consent and alleged misconduct of defendants in vaccinating L.P. are causally related to the administration of a covered countermeasure. As disclosed in the March COVID-19 declaration. "administration" includes the "physical provision of a countermeasure to a recipient," and "activities related to management and operation of programs and locations for providing countermeasure to recipients, such as decisions and actions involving security and queuing." 85 Fed. Reg. at 15,200. For example, plaintiffs' allegations recounting how L.P. was removed from his class and brought to the clinic are "activities related to management and operation" of a state-sponsored vaccine clinic and include "decisions and actions involving security and queuing." Id.

The unidentified clinic workers present with L.P. while he was injected with the vaccine were involved in the "physical provision of a countermeasure to a patient." *Id.* Even the assistant principal's comments to father about L.P.'s status and his expressions of disappointment in the number of vaccine registrations are comments relating to the "administration and operation" of the clinic. *Id.* Despite plaintiffs' arguments to the contrary, they have alleged only tortious conduct that is causally related to the administration of the vaccine to L.P. See 42 U.S.C. §247d-6d(a)(2)(B); see also Parker v. St. Lawrence Cnty. Pub. Health Dep't., 954 N.Y.S.2d 259, 262 (App. Div. 2012) (holding that PREP Act immunized defendants who administered covered countermeasure without parental consent).

¶20. Plaintiffs characterize the Pfizer BioNTech COVID-19 vaccine as "experimental," but they do not dispute that L.P. was injected with the Pfizer vaccine. Nor do they dispute that the Pfizer vaccine is a covered countermeasure. See 85 Fed. Reg. at 15, 98-0: (declaring that covered countermeasures included "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, or the transmission of SARS-CoV-2 or a virus mutating therefrom"); see also M.T. ex rel. M.K. v. Walmart Stores, Inc., 528 P.3d 1067, 1074 (Kan. Ct. App. 2023) ("Application of the PREP Act does not turn on the effectiveness of the countermeasure.").

- ¶21. Finally, as outlined above, <u>supra</u>, §14, there was undisputedly a COVID-19 PREP Act declaration in effect in November 2021 when the vaccine was administered to L.P.
- ¶22. Plaintiff's claims are entirely based on the alleged actions of covered persons who administered a covered countermeasure to L.P. during the effective period of a PREP Act declaration. As a result, each defendant is immune from plaintiffs' state-law claims, all of which are causally related to the administration of the vaccine to L.P. 42 U.S.C. §247d-6d(a)(1) (immunizing "covered person . . . from suit and liability under Federal and State law with respect to <u>all</u> 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" (emphasis added)).

¶23. Other courts faced with similar facts have come to the same conclusion. In M.T. ex rel. M.K., a Walmart employee vaccinated a fifteen-year-old in Kansas without parental consent. 528 P.3d at 071. The child's mother alleged that another Walmart employee told the child that she did not need consent because she was fifteen, which was not true under Kansas law. The mother sued Walmart under state law. The trial court dismissed all but the mother's claims relating to consent and parental rights, and both parties appealed. Id. at 1072. The appeals court concluded that Congress intended the PREP Act's immunity provision to apply to all claims based on the administration of a covered countermeasure, including those without parental consent. Id. at 1084. The court reversed and remanded with instructions to dismiss all claims. Id. at 1085.

¶24. In <u>Cowen, v. Walgreen Co.</u>, the plaintiff filed state-law claims against Walgreen Co. after she was administered a Moderna COVID-19 vaccine instead of a flu vaccine without her knowledge or consent and was allegedly injured. No. 22-CV-157-TCK-JF 2022 WL 17640208, at *2 (N.D. Okla. Sept. 13, 2022).

The plaintiff argued that defendant was not protected from liability by the PREP Act because her injuries "could have resulted from any vaccination or other medical procedure at Walgreens." *Id.* at *3. Sitting in diversity, the district court concluded that because the plaintiff's injuries actually resulted from the administration of the Moderna vaccine, the PREP Act applied. *Id.* It therefore dismissed her complaint. *Id.*

¶25. A case decided by the New York Supreme Court, Appellate Division, Parker, 954 N.Y.S.2d at 260, bears striking resemblance to the facts plaintiffs allege here. In response to an outbreak of the HINI influenza virus, the Secretary issued a PREP Act declaration in 2009 recommending the administration of Peramivir, an antiviral drug, as a covered countermeasure. A vaccination clinic was held at the school of the plaintiff's child. The plaintiff did not consent to the administration of Peramivir. The child was nevertheless vaccinated. The plaintiff sued the county health department and other defendants, asserting state-law claims for negligence and battery.

The Appellate Division concluded that the PREP Act's plain language expressed Congress's intent to preempt claims involving covered persons administering a countermeasure without parental consent. *Id.* at 263.

¶26. Plaintiffs' attempts to distinguish Parker are meritless. Plaintiffs focus on the fact that the defendants in Parker were "qualified persons" under the PREP Act. *Id.* at 261-62; see 42 U.S.C. §247d-6d(i) (2)(iv),(i)(8) (defining qualified person, in part, as "a licensed health countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed"). Plaintiffs argue that defendants in this case were not "qualified," asserting that defendants "received NO training" about consent required to administer vaccines. As discussed above, however, plaintiffs' allegations establish that defendants are all covered persons under a separate provision of the Act. Their specific training or lack thereof is irrelevant.

¶27. Plaintiffs also assert that Peramivir is a "traditional vaccine" whereas the Pfizer vaccine is experimental. To the extent this is an argument that the Parker court would have ruled differently if the Pfizer COVID-19 vaccine had been involved instead of Peramivir, this has no basis in the PREP Act. See M.T. ex rel. M.K., 528 P.3d at 1074 ("Application of the PREP Act does not turn on the effectiveness of the countermeasure"). The Pfizer vaccine was a covered countermeasure at the time it was administered to L.P. See supra, ¶20.

¶28. Plaintiffs argue that "the New York state of emergency was in full swing" at the time of the vaccine administration in Parker. They contrast that with the fact that Vermont's professional or other individual who is authorized to prescribe, administer, or dispense such public-health emergency declaration was not in effect when L.P. was in injected. True or not, this observation is immaterial.³

³ Neither party has directed the Court to a citation supporting plaintiffs' allegation. We decline to take judicial notice of whether Vermont had a public-health emergency declaration in effect in November 2021 because the answer has no bearing on our analysis.

Nothing in the PREP Act turns on whether a state declaration is in effect. See 42 U.S.C. §247d-6d(b) (1) (authorizing Federal Health and Human Services Secretary to issue declaration on "determination that a disease or other health condition or threat to health constitutes a public health emergency"). *Parker* and the other case law cited above support our conclusion that defendants are immune from liability under the PREP Act.

- D. Preemption of State-Law Claims Against Persons Immune from Liability
- ¶29. Plaintiffs argue that their claims can nevertheless proceed because the PREP Act only preempts claims against covered persons for willful misconduct.⁴ They point to various federal decisions concluding that the PREP Act does not preempt state-law claims.

⁴ Plaintiffs have not pleaded a willful misconduct claim.

cases are inapposite because they address the question of whether the PREP Act creates federal-question subject-matter jurisdiction over certain health-care-related claims. See, e.g., Solomon v. St. Joseph Hosp., 62 F.4th 54, 60-6: (2d Cir. 2023) (distinguishing between "complete preemption," which provides subject-matter jurisdiction and "ordinary preemption," which is affirmative defense). None of these cases supports the proposition that plaintiffs can proceed in state court against defendants who are completely immunized from liability under the Act. See Solomon, 62 F.4th at 60; Maglioli v. All. HC Holdings LLC, 16 F.4th 393, 406-13 (3d Cir. 2021); Mitchell v. Advanced HCS, LLC, 28 F.4th 580, 584-88 (5th Cir. 2022); Cagle v. NHC Healthcare-Maryland Heights, LLC, 78 F.4th 1061, 1065-67 (8th Cir. 2023); Saldana, 27 F.4th at 687-88.5

⁵ The trial court and state defendants correctly observe that these cases are largely based on allegations of nonfeasance by health-care facilities in the early days of the pandemic. They do not involve alleged misfeasance by covered persons administering covered countermeasures. While true, we think the clearer distinction is that offered by the circuit courts themselves: the PREP Act completely preempts only one claim but may provide a complete defense in state court if defendants can establish their immunity.

These decisions hold that absent a claim for willful misconduct, the PREP Act does not provide a basis for federal- question jurisdiction when the plaintiff has pleaded only state-law claims.

¶30. However, the PREP Act does contain an express preemption provision. See 42 U.S.C. §247d-6d(b)(8) ("During the effective period of a declaration...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 ... is different from, or is in conflict with, any requirement applicable under this section."). Other state courts faced with similar facts have concluded that state-law claims against immunized defendants cannot proceed in state court in light of the PREP Act's immunity and preemption provisions, including claims based on the failure to secure parental consent. See, e.g., Happel, 899 S.E.2d at 393-94 ("We conclude that ... the broad scope of immunity provided by the PREP Act applies to... [defendants in this case."); M.T. ex rel. M.K., 528 P.3d at 426-27 (same); Parker, 954 N.Y.S.2d at 263 (same).

We agree and hold that the PREP Act's immunity and preemption provisions bar plaintiffs' state-law claims.

¶31. Plaintiffs have accordingly failed to state a claim upon which relief can be granted because their lawsuit cannot proceed as a matter of law. <u>See Birchwood Land Co. v. Krizan</u>, 20:5 VT 37, q 6, 98 Vt. 420, 15 A.3d 1009 (explaining that we will uphold dismissal motion only where "it is beyond doubt that there exist no facts or circumstances that would entitle the plaintiff to relief." (quotation omitted)).

Affirmed.

FOR THE COURT:

Karen R. Carroll Associate Justice

APPENDIX B

Filed: August 23, 2024

VERMONT SUPREME COURT

Case No. 23-AP-237

ENTRY ORDER AUGUST TERM, 2024

Dario Politella & Shujen Politella v.

Windham Southeast School District et al.

APPEALED FROM:

Superior Court, Windham Unit, Civil Division

CASE NO. 22-CV-01707

In the above-entitled cause, the Clerk will enter:

Plaintiffs' motion for reargument fails to satisfy the criteria set forth in V.R.A.P. 40, and it is therefore denied.

BY THE COURT:

Paul L. Reiber. Chief Justice

Harold E. Eaton, Jr. Associate Justice

Karen R. Carrol Associate Justice

William D. Cohen, Associate Justice

Nancy J Waples, Associate Justice

