No. 24-1242

IN THE

Supreme Court of the United States

JEREMIAH HOGAN, SIARA JEAN HARRINGTON, AND J.H.,

Petitioners,

v.

LINCOLN MEDICAL PARTNERS, MAINEHEALTH, INC., AND ANDREW RUSS, M.D.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE MAINE SUPREME JUDICIAL COURT

BRIEF IN OPPOSITION

RUSSELL B. PIERCE, JR.
Counsel of Record
NORMAN, HANSON & DETROY, LLC
220 Middle Street
Two Canal Plaza, P.O. Box 4600
Portland, ME 04112
(207) 774-7000
rpierce@nhdlaw.com

Counsel for Respondents

120636

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTION PRESENTED

The Public Readiness and Emergency Preparedness Act, or "PREP Act," provides that, during public health emergencies declared under federal law, certain persons "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," which includes a vaccine. 42 U.S.C. § 247d-6d(a)(1).

The question presented is whether the Maine Supreme Judicial Court correctly interpreted and applied the PREP Act by concluding that the Act provided immunity to the Respondents for the State law tort claims asserted against them arising from the alleged administration of a COVID-19 vaccine to Petitioners' minor child.

RULE 29.6 STATEMENT

Respondent MaineHealth is a Maine non-profit corporation and as such there is no entity or individual owning 10% or more of its stock or ownership interest. Lincoln Medical Partners is a wholly owned subsidiary of MaineHealth.

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INTRODUCTION

The *Public Readiness and Emergency Preparedness Act*, or "PREP Act" means what it unambiguously says: certain persons "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" during declared public health emergencies. 42 U.S.C. § 247d-6d(a)(1). Petitioners ask this Court to review whether the Maine Supreme Judicial Court correctly interpreted and applied the PREP Act to Petitioners' eight common law tort claims. Yet each of Petitioners' claims were "claims for loss caused by, arising out of, relating to, or resulting from the administration" of a COVID-19 vaccine to Petitioners' minor child during the declared public health emergency of the COVID-19 pandemic.

The Maine Supreme Judicial Court considered the contentions raised by Petitioners throughout the state court proceedings and correctly interpreted and applied the PREP Act's plain language, including its immunity provision, to the Petitioners' case. The Maine court concluded that each Respondent was immune from suit and from liability for the Petitioners' State law claims arising out of the alleged administration of the Pfizer-BioNTech mRNA COVID-19 vaccine to Petitioners' minor child, J.H. Respondents administered the vaccine in November 2021 at a public school's vaccine clinic. (Petitioners' Appendix ("Pet. Ap."), at 9-13.)

Certainly, the Maine court's holding is not an outlier; numerous courts in other jurisdictions have reached the same conclusion. *See, e.g.*, *de Becker v. UHS of Delaware, Inc.*, 555 P.3d 1192, 1203 (Nev. 2024) (holding that "the

PREP Act bars a claim for failing to obtain informed consent before administering a covered countermeasure"), *cert. denied sub nom. de Becker v. UHS of Delaware, Inc.*, 145 S. Ct. 1064 (2025); *Politella v. Windham Se. Sch. Dist.*, 325 A.3d 88, 95-96 (Vt. 2024) (concluding that defendants who allegedly administered vaccine to student without parental consent were immune from plaintiffs' state-law claims under PREP Act), *cert. denied*, 145 S. Ct. 1180 (2025). Consistent with the PREP Act's application in these other courts, the Maine court correctly determined that each of the Respondents here are "covered" or "qualified" persons who are alleged to have caused harm to Petitioners through the administration of the Pfizer-BioNTech mRNA COVID-19 vaccine and that, as a result, each Respondent is immune from suit and liability pursuant to the plain terms of the PREP Act.

Now, in support of their Petition, Petitioners raise new, unpreserved legal and factual arguments or direct the Court to portions of the PREP Act's legislative history. They never raised these arguments in the Maine court. And in any event, there are independent State law governmental immunities under the Maine Tort Claims Act, that the Maine court did not reach procedurally and which separately defeat Petitioners' case. 14 M.R.S. §§ 8107 & 8111.

Petitioners likewise attempt to demonstrate a "conflict" among the States in applying the PREP Act, but fall short of presenting any conflict deserving this Court's consideration, particularly now when the federal COVID-19 public health emergency has ended.

For these reasons, and for those reasons articulated by the Maine court, the Petition should be denied.

STATEMENT OF THE CASE

A. Legal Background

In 2005, Congress enacted the PREP Act "to encourage the expeditious development and deployment of medical countermeasures during a public health emergency by allowing the [Health and Human Services] Secretary to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines." *Cannon v. Watermark Ret. Communities, Inc.*, 45 F.4th 137, 139 (D.C. Cir. 2022) (quotation marks and alteration omitted). As relevant here, "[t]he purpose of the Act's immunity provision is to insulate covered individuals and entities from liability for their administration or use of countermeasures, such as vaccines . . . that are designed to combat [a] pandemic," including the COVID-19 pandemic during 2021. *Ruiz v. ConAgra Foods Packaged Foods, LLC*, No. 21-CV-387-SCD, 2021 WL 3056275, at *2 (E.D. Wis. July 20, 2021).

Under the plain language of the PREP Act, "a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure." 42 U.S.C. § 247d-6d(a)(1); *see Solomon v. St. Joseph Hosp.*, 62 F.4th 54, 58 (2d Cir. 2023) (recognizing that Section 247d-6d(a)(1) provides "broad immunity"). For purposes of the phrase "claims for loss," the term "loss" is defined, in part, as "any type of loss, including . . . physical, mental,

or emotional injury, illness, disability, or condition" or the "fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring." 42 U.S.C. § 247d6d(a)(2)(A). Moreover, the immunity provided under the PREP Act "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 . . . distribution . . . marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." *Id.* § 247d6d(a)(2)(B) (emphasis added). As the Maine court recognized, the PREP Act's statutory text is "is plain, broad, and unambiguous with respect to immunity from tort liability." (Pet. Ap. 8.)

Like any comprehensive federal law, the PREP Act provides numerous statutory definitions. Relevant here, a "covered countermeasure" is defined, in part, as a "a qualified pandemic or epidemic product." *Id.* § 247d-6d(i)(1). In turn, a "qualified pandemic or epidemic product" means "a drug . . . biological product . . . or device" whether or not authorized for emergency use, that is:

> (i) a product manufactured, used, designed, developed, modified, licensed, or procured—
>
> (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or
>
> (II) to limit the harm such pandemic or epidemic might otherwise cause;
>
> (ii) a product manufactured, used, designed, developed, modified, licensed, or procured to

> diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or
>
> (iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii).

Id. § 247d-6d(i)(7). A "covered person," as that term is used "with respect to the administration or use of a covered countermeasure," is defined as "a person or entity that is . . . a qualified person who prescribed, administered, or dispensed such countermeasure; or . . . an official, agent, or employee of a person or entity." *Id.* § 247d-6d(i)(2). A "qualified person" means "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; or . . . a person within a category of persons so identified in a declaration by the Secretary." *Id.* § 247d-6d(i)(8). Moreover, a "person" broadly includes "an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department." 42 U.S.C. § 247d-6d(i)(5).

Because of this broad immunity provided under the PREP Act, the Act requires individuals to seek relief for claims, like the claims asserted by the Petitioners, through the "Covered Countermeasure Process Fund," which provides "timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to [a] declaration." *Id.* § 247d-6e(a); *see* 42 C.F.R. § 110.1, *et seq.* This federal remedy "shall be exclusive

of any other civil action or proceeding for any claim or suit." *Id.* § 247d-6e(d). To begin the process of seeking compensation from the Fund, an individual must file a "Request Form" or letter of intent "within one year of the date of the administration or use of a covered countermeasure that is alleged to have caused the injury." 42 C.F.R. § 110.42(a). For any individual who "qualifies for compensation" under the Fund, "the individual has an election to accept the compensation or to bring an action" for "willful misconduct" pursuant to section 247d-6d(d). 42 U.S.C. § 247d-6e(d)(5); *see infra*. However, if an "individual elects to accept the compensation, the individual may not" bring a claim for willful misconduct. *Id.* § 247d-6e(d)(5).

Thus, under the Act, "the sole exception to the immunity from suit and liability of covered persons set forth in [§ 247d-6d(a)(1)] shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct." 42 U.S.C. § 247d-6d(d)(1). "Willful misconduct" is defined as an act or omission 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). "Serious physical injury" means an injury that is "life threatening," "results in permanent impairment of a body function or permanent damage to a body structure," or "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); *see* 42 C.F.R. § 110.3(z) (defining "serious injury"). If a "willful misconduct" claim is asserted, the only forum with jurisdiction to hear such a claim is the U.S. District Court for the District of Columbia, which is required, initially,

to appoint a three-judge panel to conduct a review of any complaint asserting a "willful misconduct" claim. *Id.* § 247d-6d(e)(1), (5).

In short, the PREP Act "provides protections from liability upon the declaration of a public health emergency by the Secretary of the Department of Health and Human Services." *Copan Italia S.p.A. v. Puritan Med. Prod. Co., LLC,* No. 1:18-CV-00218-JDL, 2022 WL 1773450, at *1 (D. Me. June 1, 2022). As one court succinctly explained, the PREP Act "provides two avenues of recourse: the Covered Countermeasure Process Fund, and for cases of willful misconduct, a federal suit in the District of Columbia. Otherwise, a 'covered person' under the Act is completely immune from suit for conduct relating to covered countermeasures." *Goins v. Saint Elizabeth Med. Ctr.*, No. CV 22-91-DLB-CJS, 2022 WL 17413570, at *4 (E.D. Ky. Nov. 9, 2022) (citations omitted).

1. The Secretary's COVID-19 Declaration

As noted, the broad immunity afforded by the PREP Act arises once "a declaration" is issued by the Secretary of the Department of Health and Human Services ("Secretary"). *Id.* § 247d-6d(a)(1); *see Maney v. Brown*, 91 F.4th 1296, 1297 (9th Cir. 2024) (recognizing that immunity under PREP Act "lies dormant" until the Secretary acts). Under subsection (b) of the PREP Act, the Secretary "may make a declaration, through publication in the Federal Register" if the Secretary determines "that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency." 42 U.S.C. § 247d-6d(b)(1). In a declaration, the Secretary

may recommend "the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stat[e] that subsection (a) is in effect with respect to the activities so recommended." *Id*. The Secretary has further discretion to identify the "categories of diseases, health conditions, or threats to health" covered by the declaration, "the period or periods during which . . . subsection (a) is in effect," and, among other things, "the geographic area or areas for which subsection (a) is in effect." *Id*. § 247d-6d(b)(2). During the effective period of any declaration issued by the Secretary, "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 [42 U.S.C. § 247d-6d]; and
>
> (B) relates to 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 [42 U.S.C. § 247d-6d] or any other provision of this chapter.

Id. § 247d-6d(b)(8).

At the onset of the COVID-19 pandemic, the Secretary first issued a PREP Act Declaration on March 17, 2020.[1] *See*

1. In Maine, a "State of Civil Emergency to Further Protect Public Health" was proclaimed by Maine Governor Janet T. Mills on March 15, 2020, two days before the Secretary's Declaration,

Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020) ("March 2020 Declaration").[2] At that time, the Secretary "determined that the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease COVID-19 constitutes a public health emergency." March 2020 Declaration, § IV. As declared by the Secretary, the "Recommended Activities" subject to protection under the PREP Act during the COVID-19 pandemic included "the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures." March 2020 Declaration, §§ III-IV. As the term is used in both the PREP Act and the March 2020 Declaration, the "administration" of a covered countermeasure is defined, in part, as the "physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures." March 2020 Declaration, § IX.

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permitting, among other things, the Maine Department of Health and Human Services to exercise its emergency powers under Maine law. *See* March 15, 2020, Proclamation of Governor Janet T. Mills.

2. After the initial March 2020 COVID-19 Declaration, the Secretary issued additional amended Declarations. As relevant to this matter, the 9th Amended Declaration became effective on September 14, 2021, and was in effect during the relevant time period alleged in the Petitioners' Notice of Claim. *See Notice Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 86 Fed. Reg. 51160-02 (Sept. 14, 2021).

Thus, upon issuance of the March 2020 Declaration, the PREP Act, including its immunity provision, became effective. *See* March 2020 Declaration, § IV; 42 U.S.C. § § 247d-6d(a)(1).

B. Factual and Procedural Background

Because this case comes to the Court at the pleading stage, well-pled facts are taken as true and drawn from the State court's decision. Petitioners alleged that, during a public school's clinic in November 2021, the Respondents administered the Pfizer-BioNTech mRNA COVID-19 vaccine to J.H., who was five years old at the time, without having obtained parental consent to administer the vaccination. (Pet. Ap. 2, 13-14.) Respondents administered the vaccine as part of the public school's clinic. (*Id.*) Respondent MaineHealth is a Maine non-profit corporation, which operates Respondent Lincoln Medical Partners and employs the individual Respondent, Dr. Russ. (*Id.*)

Petitioners served their Notice of Claim under the Maine Health Security Act on May 23, 2023.[3] They

3. The Petitioners' Notice of Claim is analogous to a complaint and is the mandatory procedural device under the Maine Health Security Act to commence an action for professional negligence against a health care provider or practitioner. *See* 24 M.R.S. § 2853. In Maine, in this case Petitioners were required to follow both the procedure for commencing their action under the Maine Health Security Act as well as complying with notice of claim provisions of the Maine Tort Claims Act (14 M.R.S. §§ 8101, et seq.). *Hinkley v. Penobscot Valley Hospital*, 794 A.2d 643, 647 (Me. 2002). Petitioners did not comply with the latter statutory obligations.

alleged that Respondents committed various torts when the COVID-19 vaccine was administered to J.H. (Pet. Ap. 2.) They asserted the following claims on behalf of J.H.: professional negligence, "systemic" professional negligence, battery and false imprisonment; and they asserted additional claims on their own behalf for intentional infliction of emotional distress, negligent infliction of emotional distress, tortious interference with parental rights, and negligent supervision. (*Id.*)

Shortly thereafter, Respondents filed a motion to dismiss Petitioners' Notice of Claim in the Maine Superior Court on the basis that Respondents are immune from suit and liability under the PREP Act. (Pet. Ap. 2, 13.) The Maine trial court granted Respondents' motion to dismiss on April 16, 2024, concluding, in accordance with the plain language of the PREP Act, that Respondents "are covered persons who administered a covered countermeasure and are thus immune from liability as to [Petitioners'] claims for loss." (Pet. Ap. 21.) Petitioners then appealed the dismissal of their Notice of Claim to the Maine Supreme Judicial Court, Maine's court of last resort. (Pet. Ap. 3.)

Following appellate briefing and oral argument held on November 12, 2024, the Maine Supreme Judicial Court affirmed the trial court's order on March 4, 2025. (Pet. Ap. 1.) After thoroughly analyzing the PREP Act's statutory text and determining that the text "is plain, broad, and unambiguous with respect to immunity from tort liability," the Maine court determined that Petitioners "allege[d] only injuries that were caused by the administration of the vaccine." (Pet. Ap. 4-8.) Accordingly, the Maine court concluded "that all [Respondents] are immune from [Petitioners'] 'claims for loss caused by, arising out

of, relating to, or resulting from the administration' of the vaccine."[4] (Pet. Ap. at 8 (citing 42 U.S.C. § 247d-6d (a)(1)). Additionally, the Maine court addressed Petitioners' argument that the PREP Act's immunity provision was "inconsistent with constitutional principles of due process," recognizing that the "fundamental rights of parents to make decisions regarding the care and management" of a child are "not absolute," (Pet. Ap. at 10 (citing *Dorr v. Woodard*, 140 A.3d 467, 471 (Me. 2016)), and that the government had a "compelling interest in legislating to address public health emergencies," (*id* (citing (Pet. Ap. at 10 (citing *Roman Cath. Diocese of Brooklyn v. Cuomo,* 592 U.S. 14, 18 (2020)). The Maine court likewise concluded that the PREP Act's immunity provision did not violate the child's right to bodily integrity. (Pet. Ap. 10.)

As to preemption, the Maine court determined that the PREP Act "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 Act. (Pet. Ap. 11 (quoting 42 U.S.C. § 247d-6d(b)(8))). Accordingly, the court concluded that "Maine's common law torts clearly fall within the PREP Act's prohibition to the extent that they allow recovery for claims against [Respondents] administering vaccines who, under the federal statute, are immune from suit or liability." (Pet. Ap. 12.)

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4. In doing so, the Maine court also rejected Petitioners' arguments that the PREP Act must be "harmonize[d]" with the Emergency Use Authorization statutes, *see* 21 U.S.C. § 360bbb-3(c), and the argument that the PREP Act "violate[d] international law prohibiting non-consensual human medical experimentation." (Pet. Ap. 9-10.) These arguments have not been preserved in the Petition.

On June 2, 2025, Petitioner filed in this Court a petition for a writ of certiorari. On July 1, 2025, Respondents submitted a waiver of their right to respond. After the Petition was distributed for conference on July 16, 2025, the Court requested a response from Respondents on July 30, 2025. The Clerk of Court later granted Respondents' motion to extend time to file a response, extending the response deadline to September 26, 2025.

REASONS FOR DENYING THE PETITION

A. The Petition raises new legal and factual arguments never presented to or reviewed by the Maine courts.

As the Court has repeatedly instructed, this Court is "a court of final review and not first view." *Zivotofsky v. Clinton*, 566 U.S. 189, 201 (2012) (quotation marks omitted); *see Cutter v. Wilkinson*, 544 U.S. 709, 718 n.7 (2005); *OBB Personenverkehr AG v. Sachs*, 577 U.S. 27, 37 (2015) (recognizing as "forfeited" any argument that was "never presented to any lower court"). The Maine Supreme Judicial Court, as the state court of last resort, adheres to this same general rule of appellate practice. *See, e.g.*, *Homeward Residential, Inc. v. Gregor*, 165 A.3d 357, 360 (Me. 2017) ("To preserve an issue for appeal, the party seeking review must first present the issue to the trial court in a timely fashion. Otherwise, the issue is deemed waived." (citation omitted)). Indeed, this Court generally does "not entertain arguments that were not raised below and that are not advanced in this Court by any party . . . because it is not the Court's usual practice to adjudicate either legal or predicate factual questions in the first instance." *Star Athletica, L.L.C. v. Varsity Brands, Inc.*, 580 U.S. 405, 408 (2017) (citation and quotation marks omitted).

Despite this Court's admonition, the Petition ("Pet.") sets forth a plethora of new factual and legal arguments that were not raised before the State trial court or the Maine Supreme Judicial Court and, thus, were not reviewed or analyzed in the first instance at the state level. To begin, the Petition sets forth numerous allegations regarding the "sordid history of pharmaceutical manufacturers," notwithstanding the fact that Petitioners have not asserted a claim against any manufacturer of a vaccine or any other covered countermeasure. (Pet. 6-9.) Not only were these allegations never raised before any State court, these allegations are not asserted in Petitioners' Notice of Claim filed in State court and, thus, are not part of the factual record reviewed at the motion to dismiss stage. *See, e.g.*, *Hughes v. Northwestern Univ.*, 595 U.S. 170, 173 (2022) (accepting the allegations in a complaint as true as part of review of motion to dismiss under Rule 12(b)(6)). Similarly, the Petition appears to challenge predicate facts such as whether Respondent Russ, in particular, is a "covered person" under the PREP Act. (Pet. 20.) However, Petitioners did not dispute this or other facts during the State court proceedings. (*See* Pet. Ap. at 6 "[Petitioners] do[] 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." (emphasis added)).

More pervasive are the numerous new, unpreserved legal arguments that Petitioners raise for the first time before this Court.[5] To wit, Petitioners' newly asserted

5. Similarly, where Petitioners raise these new legal arguments, Petitioners at the same time attempt to fault the Maine court for not analyzing these same legal issues. For instance, the

contentions include: arguments related to the Tenth Amendment and the Commerce Clause (Pet. 12-13); the contention that "Congress lacks constitutional authority to impose medical immunity or 'countermeasure' requirements on the states" (Pet. 21-23); the contention that "[i]nterstate commerce powers do not validate the PREP Act's preemptive grant of immunity" (Pet. 23-28)); and, the contention that the PREP Act reflects an "unconstitutional 'commandeering' of the courts of the states." (Pet. 32-35).

Quite simply, Petitioners ask this Court to grant their Petition based upon novel legal arguments, including constitutional arguments, which were never presented to or reviewed by the State courts. (*See* Pet. Ap.1-12, 13-23). These unpreserved arguments should be deemed waived, as they were not presented to or reviewed in the first instance by any Maine court. *See, e.g.*, *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 529 (2009) (declining to address constitutional questions where questions were not raised or "definitively" answered by lower court). Of course, had any of these legal arguments been presented at *any* stage of the State court proceedings, the State courts would have been in a position to fully review and analyze the Petitioners' contentions. Without this analysis, however, this Court is asked to determine, in the first instance, whether these new arguments have merit. That is, the Court is asked to serve as a court of "*first* view," not one of "final review." *Zivotofsky*, 566 U.S. at 201 (emphasis added).

Petition proclaims that the Maine court purportedly "failed" to render "any analysis of the causality of injuries which arise from independent legal duties (unrelated to countermeasures)," (Pet. 19-21), even when this legal argument was never raised by Petitioners or presented to the Maine court for review.

Accordingly, because Petitioners attempt to assert new, unpreserved factual and legal arguments for the first time in their Petition, without review by the State court, the Court should deny the Petition.

B. The Maine court properly reviewed the constitutional arguments actually raised by Petitioners in the state court proceedings.

The Petitioners devote approximately three pages of their Petition to the constitutional arguments that were presented to the Maine court. (Pet. 29-32.) Even so, the Petition fails to generate errors by the Maine court in its constitutional analysis of the application of the PREP Act to Petitioners' tort claims. (Pet. Ap. 10-11.)

"When constitutional rights are implicated in the application of a statute," Maine courts "must construe a statute to preserve its constitutionality, or to avoid an unconstitutional application of the statute, if at all possible." *Nader v. Maine Democratic Party*, 41 A.3d 551, 558 (Me. 2012) (abrogated on other grounds) (citing *Rideout v. Riendeau*, 761 A.2d 291, 297-08 (Me. 2000)). Maine courts' review of the constitutionality of a statute "is guided by the familiar principle that a statute is presumed to be constitutional and the person challenging the constitutionality has the burden of establishing its infirmity." *Rideout*, 761 A.2d at 297 (quotation marks and alteration omitted). Indeed, "all reasonable doubts must be resolved in favor of the constitutionality of the statute." *Bouchard v. Dep't of Pub. Safety*, 115 A.3d 92, 96 (Me. 2015) (quotation marks omitted). Moreover, a Maine court's "role in reviewing the constitutionality of a statute must necessarily be limited by the facts in the case before [it]" and a court "may not reach beyond

those facts to decide the constitutionality of matters not yet presented." *Rideout*, 761 A.2d at 298. "Thus, when there is a reasonable interpretation of a statute that will satisfy constitutional requirements, [Maine courts] will adopt that interpretation, notwithstanding other possible interpretations of the statute that could violate the Constitution." *Nader*, 41 A.3d at 558 (citations omitted).

In state court, Petitioners asserted eight tort claims in their Notice of Claim, seeking compensation for mental and physical injuries resulting from the alleged administration of a vaccine. (Pet. Ap. 2.) The Petitioners argued to the courts below, and in their Petition, that the PREP Act, as applied to the allegations in this case, would infringe upon Petitioners' constitutional rights because the Act did not provide them any avenues for redress. (Pet. 29.) However, as described above, the PREP Act provides specific avenues to redress claims for loss caused by a covered countermeasure, including the COVID-19 vaccine. *See Goins*, 2022 WL 17413570, at *4 (stating that the PREP Act "provides two avenues of recourse: the Covered Countermeasure Process Fund, and for cases of willful misconduct, a federal suit in the District of Columbia."). Petitioners could have sought relief for any alleged harm under the PREP Act through the "Fund" or, alternatively, through a civil action for "willful misconduct" filed in the U.S. District Court for the District of Columbia. 42 U.S.C. §§ 247d-6d(c)-(e), 247d-6e; *see* 42 C.F.R. § 110.42(a). In this case, no allegation was made in the Notice of Claim that Petitioners exhausted or otherwise pursued these remedies prior to filing suit in the trial court. Thus, to the extent that Petitioners attempted to assert a violation of constitutionally protected rights, including property rights and their right to a jury trial, the Petitioners never alleged that they first sought to remedy their alleged harms

through the specific provisions provided for under the PREP Act. (*See* Pet. Ap. 4-5.) Their failure to do so rebuts any argument that the PREP Act is unconstitutional, as applied, or otherwise leaves Petitioners "without any real remedy." (Pet. 29.)

Petitioners likewise contend that applying the PREP Act immunity provision would violate Petitioners' substantive due process rights in making decisions for their child and in violating their rights to bodily integrity. (Pet. 31-31.) However, the Maine court correctly concluded that a parent's rights to make decisions regarding their child "are not absolute," (Pet. Ap. 10 (citing *Dorr v. Woodard*, 140 A.3d 467, 471 (Me. 2016)), particularly where the "the federal government has a compelling interest in legislating to address public health emergencies." (*Id.* (citing *Roman Cath. Diocese of Brooklyn v. Cuomo*, 592 U.S. 14, 18 (2020))).

To be sure, Petitioners' arguments in state court related to property interests and constitutional rights arose out of the immunity afforded pursuant to the PREP Act. But the logical extension of Petitioners' argument appears to be that a legislative body cannot create statutory immunity under any circumstances because, as applied, the grant of statutory immunity could affect a right to bodily integrity or parental rights. However, PREP Act immunity is no different than the numerous Maine statutes providing tort immunity to persons in various circumstances. For example, under Maine law, 14 M.R.S. § 164 provides immunity to a person who "renders first aid, emergency treatment or rescue assistance to a person who is unconscious, ill, injured or in need of rescue assistance," unless the person rendering first aid caused injuries to other person "willfully, wantonly or

recklessly or by gross negligence." *See also* 24 M.R.S. § 2904 (providing immunity to certain volunteer licensed health care practitioners). And, as argued further below, governmental immunity is the rule in Maine, both for political subdivisions (such as public schools) and for the people and employees who do their work, with any statutory exceptions to that immunity narrowly interpreted. 14 M.R.S. §§ 8101, et seq. (the "Maine Tort Claims Act"); *Klein v. University of Maine System*, 271 A.3d 777 (Me. 2022); *Hamilton v. Woodsum*, 223 A.3d 904 (Me. 2020); *Hinkley v. Penobscot Valley Hosp.*, 794 A.2d 643 (Me. 2002); *Kennedy v. State*, 730 A.2d 1252 (Me. 1999). Accepting Petitioners' arguments would place in doubt and potentially overturn a bedrock of statutory immunities in Maine beyond the PREP Act.

In short, the Maine court appropriately recognized that the PREP Act provides for specific avenues of redress, and does not abolish a person's or a parent's right to consent to medical treatment. It does, however, provide immunity to certain qualified persons during declared public health emergencies for "claims for loss" arising out of the administration of a vaccine, including losses that result from alleged tortious conduct. 42 U.S.C. § 247d-6d(a)(1).

C. The Petitioners' attempt to rely upon the PREP Act's legislative history is unnecessary and unavailing.

"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. Trustee*, 540 U.S. 526, 534 (2004) (quotation marks omitted). When

the text is plain, combing a statute's legislative history is unnecessary because "legislative history is not the law." *Epic Sys. Corp. v. Lewis*, 584 U.S. 497, 523 (2018). Indeed, it "is the business of Congress to sum up its own debates in its legislation, and once it enacts a statute [this Court] do[es] not inquire what the legislature meant; [this Court] ask[s] only what the statute means." *Id.* (quotation marks omitted). Even if "clear legislative history can illuminate ambiguous text," this Court will not permit "ambiguous legislative history to muddy clear statutory language." *Azar v. Allina Health Servs.*, 587 U.S. 566, 579 (2019) (quotation marks omitted).

Petitioners seek to divert the Court from the PREP Act's "plain, broad, and unambiguous" text, as the Maine court concluded (Pet. Ap. at 9), by referencing the PREP Act's legislative history and, in Petitioners' view, Congress's purported "abnormal adoption" of the Act more than 20 years ago. (Pet. 13-16.) Petitioners' congressional concerns were absent when presenting their case to the State courts, and are presented here, before this Court, in the first instance in their Petition. Even if these arguments had been raised, the PREP Act's text is unambiguous, without any need to determine Congress's intent or to review the Act's legislative history. *See, e.g.*, *Redd v. Amazon.com, Inc.*, No. 20-C-6485, 2024 WL 2831463, at *3 (N.D. Ill. June 4, 2024) ("The starting and ending point of the Court's analysis is the plain language of the PREP Act."); *de Becker*, 555 P.3d at 1203 ("Because the allegation about the cause of the de Beckers' loss is related to the administration of remdesivir, a covered countermeasure, the claim is barred under the plain language of the PREP Act.").

The Maine court, like other state and federal courts, correctly interpreted and applied the plain, unambiguous language of the PREP Act, free from any misplaced and slanted foray into the Act's legislative history. The Petition's request to do otherwise is unavailing and unwarranted, particularly when doing so would be an attempt "to muddy clear statutory language." *Allina Health Servs.*, 587 U.S. at 579 (quotation marks omitted).

D. Even if the PREP Act did not immunize Respondents from suit and liability, Petitioners' claims would nonetheless fail under Maine law.

Petitioners' Notice of Claim asserted eight state common law tort claims against Respondents, including professional negligence, "systemic" professional negligence, battery, false imprisonment, intentional infliction of emotional distress, negligent infliction of emotional distress, tortious interference with parental rights (a tort not recognized in Maine[6]), and negligent supervision. (Pet. Ap. 2.) Notwithstanding the immunity afforded to Respondents for these "claims for loss," 42 U.S.C. § 247d 6d(a)(1), Petitioners' state law claims would otherwise fail under Maine law.

All of Petitioners' claims would be subject to dismissal, under state law, pursuant to the Maine Tort Claims Act ("MTCA"), 14 M.R.S. §§ 8101, *et seq.* The MTCA provides that, "[n]otwithstanding any liability that may have

6. Maine courts have never recognized a cause of action for "tortious interference with parental rights." In their Notice of Claim, Petitioners had only cited to a Virginia case involving an unauthorized child adoption, *Wyatt v. McDermott*, 725 S.E.2d 555 (Va. 2012).

existed at common law, employees of governmental entities shall be absolutely immune from personal civil liability" for a variety of acts, including for "[p]erforming or failing to perform any discretionary function or duty." 14 M.R.S. § 8111(1)(C). The MTCA also requires, as a prerequisite to commencing any tort cause of action against governmental entities or persons covered by the MTCA, that a "notice of claim" containing statutorily-mandated contents be served on the governmental entity within one year of the accrual of the cause of action. 14 M.R.S. § 8107. Petitioners alleged claims accrued, if at all, in November 2021 when the vaccine was administered. Petitioners do not allege that they served any compliant notice of claim on the public school under the MTCA within one year – a fatal deficiency in their pleadings, regardless of PREP Act immunity. *Hinkley*, 794 A.2d 643 (Me. 2002) (upholding dismissal for failure to comply with MTCA notice provision in case commenced under the Maine Health Security Act against doctor and hospital who were also covered persons under the MTCA).

The MTCA contains an expansive definition of persons who do work for the government, and who are thereby covered by the MTCA's governmental immunity provisions. 14 M.R.S. § 8111; *see Preti v. Ayotte*, 606 A.2d 780, 782 (Me. 1992) (recognizing that a private attorney working for a city is covered by the MTCA); *accord Hamilton*, 223 A.3d 904 (Me. 2020) (private law firm employee hired by a state college as an investigator, was covered under the MTCA). Under the MTCA, any "person acting on behalf of a governmental entity in any official capacity, whether temporarily or permanently, and whether with or without compensation from local, state or federal funds," is covered by the MTCA. 14 M.R.S.

§ 8102(1). In turn, a "governmental entity" is defined as "the State and political subdivisions," which, includes, among other entities, a "school district of any type." 14 M.R.S. § 8102(2)-(3). As such, any person "acting on behalf" of a school district will be deemed to be covered by the MTCA and entitled to its protections.

Over the years, this definition of persons covered by the MTCA has remained broad. *See Day's Auto Body, Inc. v. Town of Medway*, 145 A.3d 1030, 1033-34, 1037 (Me. 2016)[7] (MTCA applies to independent excavating and general contractor business, after the "Town's fire department summoned [the business] to assist at the fire scene with an excavator"); *Hinkley*, 794 A.2d 643 (Me. 2002) (MTCA applies to a private physician who contracts with a public hospital to supervise physician assistants); *Kennedy*, 730 A.2d 1252 (Me. 1999) (MTCA applies to a private attorney appointed by the court as a guardian ad litem); *Clark v. Maine Medical Center*, 559 A.2d 358 (Me. 1989) (private hospital entitled to MTCA coverage in performing mental health examination at request of State hospital); *Taylor v. Herst*, 537 A.2d 1163 (Me. 1987) (private physicians performing involuntary commitment evaluations are covered by the MTCA); *Libby v. Roy*, No. CV-16-0357, 2017 WL 7736066 (Me. Super. Ct. Dec. 19, 2017) (MTCA applies to a Catholic priest performing services as a chaplain at state prison). Maine courts have concluded that "[t]he key question" in applying the MTCA "is not the characterization of the entity claiming

7. Notably, in that case, the Maine Supreme Judicial Court clarified that a "person" for purposes of the term "employee" under 14 M.R.S. § 8102(1) may include a corporation. *Day's Auto Body, Inc. v. Town of Medway*, 145 A.3d 1030, 1036 (citing 1 M.R.S. § 72(15)).

immunity, but whether that entity was performing a governmental function on behalf of a governmental entity." *Hamilton*, 223 A.3d at 909-10 (emphasis added).

In this matter, there is no question that the public school where the alleged administration of the COVID-19 vaccine was administered to J.H. is a "governmental entity" under the MTCA—it qualifies under the definition of "political subdivision," which in turn includes a "school district of any type." 14 M.R.S. § 8102(2)-(3). In their Notice of Claim, Petitioners alleged that Respondents "operated" and promoted the vaccine clinic at the public school, and the exhibit included with their Notice of Claim reflected that Respondents had, in fact, "partnered with" the public school to conduct the clinic in 2021, with the school itself sharing with parents additional information about the clinic. As such, there is little question under Maine law that the Respondents, who partnered with the public school to operate the school's vaccine clinic, are covered by the MTCA because they are "acting on behalf of a governmental entity," the public school district, in their administration of vaccines during a declared public health emergency. 14 M.R.S. § 8102(1); *see Hamilton*, 223 A.3d at 910.[8]

8. The same is true to the extent the Petitioners' assert that the corporate Respondents are vicariously liable for the acts of the individually named Respondent. (Pet. Ap. 2.) The corporate Respondents have no respondeat superior liability because the individual medical provider in this case would be covered under the MTCA. *See Clark,* 559 A.2d 358 (Me. 1989); *accord Hamilton*, 223 A.3d at 910 (ordering dismissal of claims against private employer, based upon immunity of individual defendant); *see also Libby*, 2017 WL 7736066 at **6-7 (recognizing that "the private employer of [] a person cannot be held liable if the person is not liable").

Accordingly, Petitioners' claims fail under Maine law, even if the PREP Act did not immunize Respondents from the tort claims asserted. Under the Maine Health Security Act's mandatory prelitigation panel procedures in Maine, these other grounds for dismissal under the MTCA are preserved for court decision after the mandatory prelitigation panel screening stage. *See* 24 M.R.S. §§ 2903, 2853(1), & 2853(5) (final two sentences). Hence, with an admitted failure to comply with the MTCA's 1-year notice provision, as well as the application of MTCA immunity, any relief to Petitioners under the PREP Act determinations will still leave them with a case bound for dismissal under state law.

E. There is no split of authority or "conflict" among the States deserving this Court's attention.

The Petition vastly overstates the extent of any "confusion and conflict" among the States in their application of the PREP Act to claims for loss arising from the administration of a vaccine during a declared public health emergency. (Pet. 16-21.) Indeed, the Petition relies upon only three cases decided by State courts to support its "conflict" argument, omitting any reference to the countless courts, both State and Federal, that have applied the PREP Act's immunity provision in the same manner as the Maine court did in this instance.

Petitioners contend that "[i]t is state courts that must decide if a plaintiff's claims fall within the PREP Act's immunity provision." (Pet. 19.) This is precisely what state courts have done, routinely applying the PREP Act to provide immunity to covered persons who are alleged to have caused an injury or "claim for loss" as a

result of the administration of a covered countermeasure, including a COVID-19 vaccine, even where it is alleged that the administration of the vaccine was without consent. Numerous cases from other jurisdictions are illustrative of the uniform application of the PREP Act's immunity provision in similar circumstances. *See, e.g.*, *Politella*, 325 A.3d at 91, 95 (Vt. 2024) (holding that defendants who allegedly administered vaccine to student at school without parental consent were immune from plaintiffs' state-law claims under PREP Act), *cert. denied*, 145 S. Ct. 1180 (2025); *de Becker*, 555 P.3d at 1203 (Nev. 2024) (holding that "the PREP Act bars a claim for failing to obtain informed consent before administering a covered countermeasure" based upon plain language of Act), *cert. denied sub nom. de Becker v. UHS of Delaware, Inc.*, 145 S. Ct. 1064 (2025); *M.T. as next friend of M.K. v. Walmart Stores, Inc.*, 528 P.3d 1067, 1071, 1084 (Kan. Ct. App. 2023) (concluding that, for mother's tort claims for administering the COVID-19 vaccine to her minor child without the mother's consent, "any claim causally related to the administration by a covered person of a covered countermeasure is covered by the [PREP] Act, even claims based on the failure to obtain consent"), *review denied* (Aug. 25, 2023); *Ashley v. Anonymous Physician 1*, 245 N.E.3d 658 (Ind. Ct. App. 2024), *transfer denied*, 253 N.E.3d 524 (Ind. 2025) (concluding that medical providers were immune from liability for the claims of negligence, emotional distress, and loss of consortium and that plaintiff's claims for "willful misconduct" under PREP Act was preempted); *Bird v. State*, 537 P.3d 332, 336 (Wyo. 2023) (denying request for "limited discovery" and applying PREP Act immunity to inmates' claims that health care provider was negligent in administering "emergency use authorized COVID-19 vaccine" without

inmates' express consent); *Parker v. St. Lawrence Cnty. Pub. Health Dep't*, 954 N.Y.S.2d 259, 261, 263 (N.Y. App. Div. 2012) (concluding, during 2009 H1N1 influenza, that parents' claims arising out of negligent administration of vaccine to minor during a school clinic was preempted by PREP Act).

This unanimity in courts in applying the PREP Act is also reflected in federal courts' interpretation and application of the Act in similar circumstances. *See, e.g.*, *Maney v. Brown*, 91 F.4th 1296, 1302-03 (9th Cir. 2024) (concluding that PREP Act "does not categorically exclude constitutional claims" and provided immunity from suit and liability for constitutional claim brought under 42 U.S.C. § 1983 for alleged Eighth Amendment violation); *Diaz v. Moderna US Inc.*, No. C24-0986-KKE, 2024 WL 4253172, at *2 (W.D. Wash. Sept. 20, 2024) ("This Court joins other courts in [the 9th Circuit] in finding that claims against vaccine manufacturers for bodily harm arising from COVID-19 vaccines are barred by the PREP Act."); *Gieser v. Moderna Corp.*, No. 1:24-CV-00458-JLT-CDB, 2024 WL 3077100, at *4 (E.D. Cal. June 20, 2024) (concluding that defendant was immune for plaintiff's alleged personal injuries, including loss of vision resulting from administration of vaccine); *Deborah Fust v. Gilead Scis., Inc.*, No. 2:23-CV-2853 WBS DB, 2024 WL 732965, at *7 (E.D. Cal. Feb. 21, 2024) (concluding that PREP Act "immunizes defendant from suit and liability" for claims related to administration of COVID-19 medication without informed consent); *Perez v. Ransome*, No. 1:22-CV-01087, 2024 WL 198908, at *7 (M.D. Pa. Jan. 18, 2024) (granting motion to dismiss and concluding that defendant was entitled to immunity under PREP Act from plaintiff's state law claim of negligent

medical treatment); *Gibson v. Johnson & Johnson*, No. CV 22-04383, 2023 WL 4851413, at *3 (E.D. Pa. July 28, 2023) (holding that manufacturer of a COVID-19 vaccine was immune from suit under PREP Act); *Cowen v. Walgreen Co.*, No. 22-CV-157-TCK-JFJ, 2022 WL 17640208, at *3 (N.D. Okla. Dec. 13, 2022) (dismissing plaintiff's claims for negligence based on administration of COVID-19 vaccine without consent); *Storment v. Walgreen, Co.*, No. 1:21-CV-00898 MIS/CG, 2022 WL 2966607, at *3 (D.N.M. July 27, 2022) (dismissing plaintiff's claim for injuries suffered in fall in pharmacy parking lot following administration of COVID-19 vaccine); *see also Kehler v. Hood*, 2012 WL 1945952, at *2-3 (E.D. Mo. May 30, 2012) (PREP Act immunity applied to "failure to warn claims" brought against vaccine manufacturer during H1N1 public health emergency).

Perhaps the most illustrative of these cases, for present purposes, is the Vermont Supreme Court's application of the PREP Act in *Politella*, where the Vermont Supreme Court affirmed a trial court's dismissal of a complaint based on PREP Act immunity. *Politella,* 325 A.3d at 95, *cert. denied*, 145 S. Ct. 1180 (2025). There, parents of a six-year-old child asserted eight state law claims against a school district, among others, after the child was allegedly administered a COVID-19 vaccine without the parents' consent and even after the child "verbally protested" receiving the vaccine. *Id.*, 325 A.3d at 91-92. In affirming dismissal of the complaint, the Vermont Supreme Court concluded, in part, that the complaint "alleged only tortious conduct that is causally related to the administration of the vaccine to" the child and that "Plaintiff's claims are entirely based on the alleged actions of covered persons who administered a covered

countermeasure to [the child] during the effective period of a PREP Act declaration." *Id.*, 325 A.3d at 95-96. As such, the Vermont court concluded that each defendant was "immune from plaintiffs' state-law claims, all of which are causally related to the administration of the vaccine," and 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." *Id.*, 325 A.3d at 93, 95-96. The *Politella* plaintiffs' subsequent petition to this Court for review was denied. *See* 145 S. Ct. 1180 (2025).

Of course, these cases do little to lend support to the Petitioners' contention that any "conflict" or "confusion" exists among the States in their interpretation of the PREP Act. Indeed, Petitioners appear to rely on only one case, decided by the Supreme Court of North Carolina, to support their contention that a "conflict" exists in the States' application of the PREP Act. *See Happel v. Guilford Cnty. Bd. of Educ.*, 913 S.E.2d 174, 180 (N.C. 2025) (Pet. 16-21.) However, a careful reading of *Happel* reveals that the North Carolina court's ruling does little to demonstrate a conflict among the states, particularly any purported conflict that would require this Court's resolution.

Happel upheld PREP Act immunity on state tort claims, and decided the remainder of the case only on state constitutional grounds under North Carolina law. *Happel*, 913 S.E.2d at 194-98. In *Happel*, like here and in *Politella*, the plaintiff parents and their child asserted claims against various defendants after the child was allegedly administered a COVID-19 vaccine without parental consent at a school clinic. *Id.* at 181. After the state trial and appellate courts reviewed the plaintiffs' tort

claims and state constitutional claims[9] and determined that the defendants were immune from suit and liability, the North Carolina court was asked to determine whether the defendants were immune, pursuant to the PREP Act, from the plaintiffs' claim for battery and separate claims arising under the state constitution. *Id.* at 181-182.

As to the plaintiffs' tort claim, the North Carolina court affirmed the state appellate court's ruling, holding that the PREP Act "encompasses plaintiffs' battery claim" based upon the plain language of the Act. *Id.* at 194, 198. As to plaintiff's state constitutional claims, the court assumed, for purposes of its opinion, that the plaintiffs had asserted "*Corum* claims," which, under North Carolina precedent, allow for "a common law cause of action when existing relief does not sufficiently redress a violation of a particular [state] constitutional right." *Id.* at 192.[10] Based upon the potential relief available to plaintiffs through their state-law *Corum* claims, the North Carolina court determined that the PREP Act did not bar plaintiffs' state constitutional claims, holding that the Act "does not cover [plaintiffs'] claims under the [North Carolina] constitution." *Id.* at 194.[11]

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9. In *Happel*, the plaintiffs "abandoned their federal constitutional arguments" prior to the North Carolina Supreme Court's appellate review. *Happel*, 913 S.E.2d at 181.

10. *Happel* addressed constitutional claims arising only under the North Carolina constitution. *Happel*, 913 S.E.2d at 180 n.1.

11. The North Carolina court also reviewed cases from other jurisdictions, including *Politella*, determining that "[n]one of the cited cases persuade us that the PREP Act preempts claims brought under our state constitution." *Id.* at 196.

Although Petitioners present *Happel* as a case representing a "conflicting decision[]," the North Carolina court, albeit as an outlier among other state courts, determined only that the plaintiffs' *state* constitutional claims, through the procedural mechanism of a *Corum* claim, were not subject to immunity under the PREP Act. (Pet. 16.) In reality, however, the *Happel* decision is consistent with other state courts in its holding that all tort claims are subject to PREP Act immunity. Presumably, Petitioners would concede that Respondents in this case would be immune from Petitioners' eight tort claims asserted against the Respondents in Maine, even under the *Happel* rationale. Moreover, Petitioners would also presumably concede that they did not assert any constitutional claims, whether state or federal, in their state court Notice of Claim and, thus, did not ask the Maine court (in contrast to the plaintiffs in *Happel*) to weigh in on whether any Maine state constitutional claims could be subject to the PREP Act's statutory protections.

Indeed, whether it is *Happel*, *Politella*, *de Becker*, or Petitioners' claims in this Maine court proceeding, it has been the State courts that have "decide[d] if a plaintiff's claims fall within the PREP Act's immunity provision." (Pet. 19.) Although the North Carolina court determined that certain state constitutional claims, under North Carolina law, fell outside of the PREP Act's immunity provisions, no such Maine constitutional claims were presented to the Maine courts and Maine law does not recognize claims analogous to any type of *Corum* claim. Rather, the Maine court, like *Happel* and countless other states, correctly determined that Petitioners' eight tort claims fell squarely within the PREP Act's immunity provision. (Pet. Ap. 8-9.)

Accordingly, because the States are in harmony in applying the PREP Act to immunize defendants from tort claims, there is no split or conflict deserving of this Court's attention or in need of resolution.

F. The fleeting nature of the PREP Act alleviates the need for this Court to address the Petition's concerns.

The broad immunity afforded by the PREP Act arises only once "a declaration" is issued by the Secretary of the Department of Health and Human Services ("Secretary"). 42 U.S.C. § 247d-6d(a)(1); *see Maney*, 91 F.4th at 1297 (recognizing that immunity under PREP Act "lies dormant" until the Secretary acts). The COVID-19 public health emergency that precipitated the Secretary's original March 17, 2020, Declaration has since come to an end. *See, e.g., Arizona v. Mayorkas*, 143 S. Ct. 1312, 1313 & n.9 (2023) (*Gorsuch, J.* dissenting) (noting that the federal "Secretary of Health and Human Services . . . has issued his own directive announcing the end of the public-health emergency"); *Green v. Wilkinson*, No. 8:24-CV-1182-KKM-LSG, 2025 WL 1361518, at *3 (M.D. Fla. Apr. 23, 2025) (recognizing termination of "the COVID-19 pandemic national emergency on April 10, 2023," and that the "Secretary of Health and Human Services issued a declaration that the public health emergency expired on May 11, 2023." (citing, in part, Pub. L. No. 118-3, 137 Stat. 6 (2023)).

Because the PREP Act's immunity provision "lies dormant" until a declaration is issued by the Secretary and arises only in times of declared public health emergencies, the PREP Act's fleeting nature makes any prospective

ruling in this case largely advisory, or at least without any immediate impact on the lives of citizens until a next declared public health emergency. This legal issue is not going to recur in the near term. It will not arise again unless the Secretary declares a next public health emergency, which could be a very long time from now if ever. Should Congress determine that the PREP Act requires amendment in the meantime, Congress is free to amend or replace the PREP Act as it deems fit.

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be denied.

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Respectfully submitted,

Russell B. Pierce, Jr.
Counsel of Record
Norman, Hanson & DeTroy, LLC
220 Middle Street
Two Canal Plaza, P.O. Box 4600
Portland, ME 04112
(207) 774-7000
rpierce@nhdlaw.com

Counsel for Respondents