

No. 24-1242

In the Supreme Court of the United States

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

v.

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

On Petition for a Writ of Certiorari to the
Maine Supreme Judicial Court

REPLY BRIEF FOR PETITIONERS

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ARGUMENT

Petitioners request a review of the denial of a State court jury trial for, *inter alia*, common-law battery and medical malpractice. The denial was based upon an improper application of the PREP Act.

Petitioners have argued that Congress lacks constitutional authority to impose medical product immunity requirements on the States, that Congress may not commandeer State courts, that interstate commerce powers do not validate the PREP Act's grant of immunity, and that the PREP Act violates constitutional rights.

Respondents have failed to respond to any of the substantive issues raised concerning the PREP Act's constitutionality. Instead, Respondents raise collateral and off-point attacks, discussed below.

A. Petitioners raised their federal claims in the State courts, and have presented additional arguments in support.

At both the State trial court and appellate levels, in opposition to Respondent's motion to dismiss, Petitioners raised constitutional issues, arguing that the PREP Act must be construed in a manner that does not violate the constitution, that it is unconstitutional as applied, that PREP Act immunity would deprive claimants of their property right in such claims and their right to due process, and that such immunity infringes bodily integrity rights.

Respondents now claim Petitioners have raised herein new *arguments* not presented to the lower

state courts,¹ and that this is improper.

Petitioners have indeed asserted *additional* legal arguments supporting the unconstitutionality of using the PREP Act’s immunity provisions to foreclose State tort claims. Presenting new arguments to support an asserted claim is proper. “Once a federal claim is properly presented, a party can make *any* argument in support of that claim.” *Hemphill v. New York*, 595 U.S. 140, 149 (2022) (emphasis added). *See also Citizens United v. FEC*, 558 U.S. 310, 330-31 (2010); *Lebron v. Nat'l R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995) (“Our traditional rule is that ‘once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below’”); *Yee v. City of Escondido*, 503 U.S. 519, 534 (1992) (same).

The federal courts of appeal recognize this rule as well. *See, e.g., Eastman Kodak Co. v. STWB, Inc.*, 452 F.3d 215, 221 (2d Cir. 2006) (“Once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below.”); *Chelf v. Prudential Ins. Co. of Am.*, 31 F.4th 459, 468 (6th Cir. 2022) (“as long as a claim or issue was raised before the district court, a party may ‘formulate any argument it likes in support of that claim here.’”); *Allen v. Santa Clara Cty. Corr. Peace Officers Ass'n*, 38 F.4th 68, 71 (9th Cir. 2022); *United States v. Williams*, 846 F.3d 303, 311 (9th Cir. 2017) (same); *In re Home Depot Inc.*, 931 F.3d 1065, 1086 (11th Cir. 2019); and *Watkins v. United States*, 846

¹ They also claim that Petitioners’ arguments are “novel,” but a careful review will show they are grounded in well-established constitutional doctrines developed over a considerable period of time.

A.2d 293, 297 (D.C. 2004).

Petitioners clearly claimed in the lower courts that sections of the PREP Act were unconstitutional or unconstitutional as applied. Their supporting arguments before this Court may differ and be augmented by additional authority, but the federal claims remain the same. Respondents' contention to the contrary is without merit.

Even if Petitioners were raising an *issue* for the first time in this appeal, the courts of appeal have discretion to consider such issues where they are of constitutional magnitude:

[A]ppellate courts have discretion to address issues not seasonably raised below. ...

Exercise of our discretion is appropriate where, as here: the new issue is purely a question of law; addressing the merits would promote judicial economy as the same issue will likely be raised in other cases; and the claim raises an issue of constitutional magnitude, which if meritorious, could substantially affect the rights of [others].

Patriot Portfolio v. Patriot Portfolio v. Weinstein (in Re Weinstein), 164 F.3d 677, 685 (1st Cir. 1999). See also *United States v. Brunner*, 726 F.3d 299, 304 (2d Cir. 2013); *Readco, Inc. v. Marine Midland Bank*, 81 F.3d 295, 302 (2d Cir. 1996); *In re Aquilino*, 135 F.4th 119, 130 n. 7 (3d Cir. 2025) (court “will reach ‘a pure question of law even if not raised below where refusal to reach the issue would result in a miscarriage of justice or where the issue’s resolution is of public importance’”); *Stewart v. Hall*, 770 F.2d 1267, 1271 (4th Cir. 1985); *Federal Election Comm'n v. Lance*, 635 F.2d 1132, 1136 (5th Cir. 1981); *City*

Mgmt Corp. v. U.S. Chem. Co., 43 F.3d 244, 255 (6th Cir. 1994); *Universal Title Ins. Co. v. United States*, 942 F.2d 1311, 1314 (8th Cir. 1991); *United States v. Echavarria-Escobar*, 270 F.3d 1265, 1268 (9th Cir. 2001); *In re Daikin Miami Overseas, Inc.*, 868 F.2d 1201, 1207 (11th Cir. 1989).

In the State trial court and on appeal, Petitioners argued that § 247d-6d and § 247d-6e were unconstitutional. But even if no constitutional issue was stated below, Petitioners’ claim raises an issue of constitutional magnitude which, if meritorious, substantially affects the fundamental right to have access to the courts for remedy.

B. The Maine court failed to protect the constitutional right of its citizens to remedy by due course of law.

Respondents admit that the PREP Act provides specific avenues to redress claims for loss “caused by a covered countermeasure, including the COVID-19 vaccine.” (Br. Opp. 17).² Despite admitting that only injuries “directly caused”³ by the countermeasure itself may be redressed via the Covered Countermeasure Process Fund, Respondents insist that Petitioners’ failure to pursue such redress “rebuts any argument that the PREP Act is unconstitutional.” (Br. Opp. 17–18). This contention is wholly frivolous.

The PREP Act contains no administrative exhaustion requirement before the filing of State claims for professional negligence, interference with

² They also admit that “the PREP Act … does not abolish a person’s or a parent’s right to consent to medical treatment.” (Br. Opp. 19).

³ 42 U.S.C. § 247d-6e(a) and (b)(1).

parental rights, kidnapping or battery. Victims of a countermeasure product may bring an administrative claim only when a countermeasure product caused “serious physical injury” or death. Petitioners have never asserted a product liability tort claim.

Respondents further contend that the PREP Act’s immunity provision does not violate Petitioners’ parental and bodily integrity rights because parental rights “are not absolute”⁴ when the federal government has a compelling interest in legislating to address public health concerns, citing *Roman Cath. Diocese of Brooklyn v. Cuomo*, 592 U.S. 14, 18 (2020).

This argument erroneously assumes that Congress has power to preempt Petitioners’ right of access to State courts for common law torts, as well as power to violate fundamental rights by immunizing persons like Dr. Russ in favor of a “compelling federal interest” in a public health emergency.

Maine’s constitution guarantees right of redress (and due process) in Art. I, § 19: “Every person, for an injury inflicted on the person or the person’s reputation, property or immunities, shall have remedy by due course of law; and right and justice shall be administered freely and without sale, completely and without denial.”

⁴ Citing *Door v. Woodard*, 140 A.3d 467 (Me. 2016), determining parental rights where the law allows grandparents to sue for visitation. The Supreme Judicial Court of Maine concluded that grandparents do not have any fundamental right to visit their grandchildren: “the relationship that a grandparent has with his or her grandchild is a decision to be made by a fit parent, not the courts, unless the record presents a compelling reason for the State to intervene.”

Congress has *no power* to legislate public health laws for the States or to preempt the State’s judicial power with respect to harms caused by medical professionals. It is well established that such power is reserved to the States as a police power, *see Pet.* at 21–23. If the PREP Act is interpreted as regulating the States’ police power, then it unquestionably exceeds the powers of Congress. Similarly, Congress has no power to selectively destroy State court jurisdiction over product liability torts against medical products.

Respondents misrepresent *Roman Cath. Diocese of Brooklyn* as concerned with federal power, when it was entirely concerned with the State of New York’s power to promulgate emergency public health measures derogating the religious freedom guaranteed by the First Amendment. This Court concluded that “Government is not free to disregard the First Amendment in times of crisis.” *Id.*, at 21 (J. Gorsuch, concurring). This is true for all constitutionally guaranteed rights.⁵ Because “even in a pandemic, the Constitution cannot be put away and forgotten.” *Id.*, at 19.

C. The abnormal adoption of the PREP Act underscores the need for scrutiny by this Court as to its constitutionality.

The question presented by Petitioners concerns the constitutionality of 42 U.S.C. § 247d-6d as interpreted. The rules in both the Senate and House of Representatives prohibit enacting legislation in the manner by which the PREP Act was adopted.

⁵ There is one enumerated exception; *see Art. I, § 9*, allowing the Writ of Habeas Corpus to be suspended in times of rebellion or invasion.

Since no congressional review or debate was had concerning the meaning and constitutional import of the language employed or the provisions therein, it is reasonable to expect that controversies over its constitutionality will arise. Further, the PREP Act enacts novel federal preemptions of the jurisdiction of State legislatures and courts, and has erroneously been interpreted to preempt many State claims.

Respondents complain that it is unnecessary to suggest that the legislative history of the PREP Act warrants careful scrutiny of the PREP Act provisions by this Court, because the PREP Act contains “unambiguous” text. Instead, the novel preemptions, passed without any review in Congress, emphasize that this Court’s review of the statutory language for constitutionality is essential in protecting the American people from Congressional overreach.

D. If Respondents were acting under color of State law, as they now propose, could the PREP Act provide immunity for their violations of fundamental liberty?

Assuming Petitioners’ arguments are correct, Respondents urge this Court to deny *certiorari* anyway.

Respondents may not be immune under the PREP Act, they say, but they *are* immune from suit for “any and all tort claims” under the Maine Tort Claims Act (MTCA) as “government employees.” 14 M.R.S. § 8101 *et seq*, so if this case is remanded to the Maine courts, Petitioners will lose.

Contrary to Respondents’ claim, a “government employee” within the scope of the MTCA “does not mean a person or other legal entity acting in the capacity of an independent contractor under contract

to the governmental entity.”¹⁴ M.R.S. § 8102(1). MTCA immunity is extended to private contractors only when their actions are undertaken on behalf of a governmental entity and they perform a governmental function, not where a doctor’s services at a temporary vaccine clinic are offered on a public school campus. *See, e.g., Hamilton v. Woodsum*, 223 A.3d 904, 910 (Me. 2020).

But all discussion of potential immunity under the MTCA is purely theoretical. Petitioners never invoked the MTCA below; Respondents never raised any defense pursuant to the MTCA below. No facts in the record support any assertion that Respondents are covered by the MTCA.

Moreover, any consideration of trial outcomes upon remand is irrelevant, speculative and improper. Respondents raise this red herring to distract from the critical issue which requires resolution by this Court — does the PREP Act preempt State law and immunize common law tortfeasors?

Respondents’ unavailing claim that they *may* be State actors highlights the urgent need for this Court’s resolution of the issues presented.

Under 42 U.S.C. § 1983, persons violating constitutional rights while acting under color of State law may be sued. Can Congress pass a law which instead *immunizes* persons who violate fundamental rights? Such a law would itself violate the Fifth and Fourteenth Amendments.

E. A widening split in the State courts has resulted from an improper extension of PREP Act immunity.

The split in State courts, and a corresponding split in federal courts, is caused by the proper

analysis, on the one hand, that the PREP Act provides immunity only for product liability torts, and the misreading, on the other hand, of the PREP Act’s provisions to extend into common law torts sounding in battery, false imprisonment, etc., or constitutional torts claiming violations of bodily integrity, informed consent, and parental rights.

Simply stated, the PREP Act regulates only *product liability torts* when harm is caused by any medical product designated a “covered countermeasure.” This is apparent in the descriptive title affixed by Congress to 42 U.S.C. §247d–6d: “Targeted liability protections for … products and … countermeasures.”

The *sine qua non* of product liability is that an injury must first be caused by the product itself. Where no harm is attributable to the product, no claim exists. This is why the PREP Act addresses only “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 [the product].” § 247d–6d(a)(1).

While the scope of loss is broadly defined, it must still be caused by the product. Since many persons or organizations along the manufacturing and supply chain can potentially be held liable for product defects, the PREP Act extends immunity to any “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.” § 247d–6d(a)(2)(B).

Only State laws “with respect to a covered countermeasure” are preempted, that is, laws which

would allow claims concerning defective medical products.

Thus, where no *product liability tort* is asserted with respect to losses caused by a countermeasure, *no immunity from tort claims exists either.*

Respondents' listing of various decisions it contends are "unanimous" with respect to the application of the PREP Act to torts other than product liability claims is unavailing. Included in the list are cases rejected because they asserted product liability tort claims re COVID-19 vaccines; if the PREP Act is constitutional, then these claims were properly barred.

Petitioners set forth many federal cases which conclude that there is no immunity for tort claims outside of the product liability category. (Pet. 17–19). The Supreme Court of North Carolina recognized that constitutional claims are not immunized by the PREP Act in *Happel v. Guildford Cnty. Bd. of Educ.*, 913 S.E.2d 174 (N.C. 2025).⁶ The Connecticut Supreme Court in *Mills v. Hartford Healthcare Corp.*, 347 Conn. 524, 576 (2023) recognized that "tortious conduct that constituted a distinct and independent cause of the plaintiff's injuries that itself has no causal relationship to the countermeasure" was not immunized under the PREP Act.

Those decisions conflict with the decisions of the Maine Supreme Judicial Court here, the Nevada Supreme Court decision in *De Becker v. UHS of Delaware, Inc.*, 555 P.3d 1192 (Nev. 2024), and the Vermont Supreme Court decision in *Politella v. Windham Se. Schl. Dist.*, 325 A.3d 88 (Vt. 2024).⁷

⁶ Overturning a lower court case upon which both the Maine and Vermont courts had relied.

⁷ This Court denied *certiorari* in *De Becker* and *Politella*, but the

Thus, the PREP Act’s limitation of immunity to product liability torts has been recognized by some State courts and disregarded by others. This split is deepening and widening. When a COVID countermeasure is tangentially involved but not the *cause* of the losses claimed, some States allow their citizens due process and access to jury trials for remedy of torts, but many others do not.

F. The PREP Act may perpetually destroy the right to State jury trials of common law torts.

Respondents are correct that the COVID-19 public health emergency (PHE) which precipitated the March 17, 2020 declaration of liability protection for COVID-19 countermeasures, expired as of May 11, 2023. The “emergency” lasted three and a half years.

According to Respondents, because the immunity provision “arises only in time” of declared PHEs, the “ fleeting nature” of a such PHEs would render a decision in this case advisory and “without any immediate impact.” (Br. Opp. 32).

Respondents are dead wrong. The ending of the COVID-19 PHE *did not end* immunity for its countermeasure products. Instead, the HHS Secretary continuously reauthorized the PREP Act declaration; the 12th amendment now provides liability immunity through December 31, 2029, because “COVID-19 continues to present a credible risk of a future public health emergency.” Covered Countermeasures are COVID-19 vaccines and tests, and seasonal influenza vaccines. 89 Fed. Reg. 99875.

split is deepening, and this issue’s national impact requires resolution by this Court.

Ten years is not a fleeting moment of time.

Because the authority to issue such declaration is *not* dependent upon a PHE declaration, but upon a determination “that … there is a credible risk that [a] disease … *may in the future constitute* such [PHE]” (emphasis added), the HHS Secretary may declare immunity from many medical product liability torts in perpetuity. *See* 42 U.S.C. § 247d-6d(b)(1).

Respondents suggest that the issue of the scope and constitutionality of the PREP Act’s immunity provision is unlikely to recur in the near term, when it is actually ongoing. They urge this Court to allow this issue to evade review so that the next time (and the next time) a declaration of countermeasure immunity is issued, the unchecked abuses of constitutional rights and the federal invasion into the jurisdiction of the States will become entrenched.

The federal question presented here directly affects the rights and obligations of parties subject to or affected by the PREP Act’s provisions, making this a justiciable controversy, not a request for advisory guidance.

CONCLUSION

The petition for a writ of *certiorari* should be granted.

Respectfully submitted,

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October 13, 2025