STATE OF MAINE

MAINE SUPREME JUDICIAL COURT

SITTING AS THE LAW COURT

DOCKET NO. LIN-24-209

JEREMIAH HOGAN, *et al*.,

Appellants

v.

LINCOLN MEDICAL PARTNERS, *et al*.,

Appellees

ON APPEAL FROM LINCOLN COUNTY SUPERIOR COURT

BRIEF OF APPELLEES LINCOLN MEDICAL PARTNERS, *et al*.

Confidential/Non-Public

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INTRODUCTION

In this appeal, this Court is asked to determine whether a federal statute—the *Public Readiness and Emergency Preparedness Act*, or "PREP Act"—means what it unambiguously says: that 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). More specifically, this Court is asked to determine whether the Superior Court (Lincoln County, *Billings, J.*) correctly interpreted and applied the PREP Act to Appellants' Notice of Claim, which asserts multiple "claims for loss" arising out of the administration of the Pfizer-BioNTech mRNA COVID-19 vaccine to Appellants' minor child, and, in turn, whether the trial court correctly determined that the Notice of Claim failed to state claims upon which relief could be granted.

For all the reasons below, this Court should affirm the trial court's dismissal of Appellants' Notice of Claim pursuant to Fed. R. Civ. P. 12(b)(6). Each of the Appellees are "covered" or "qualified" persons who are alleged to have caused harm to Appellants through the administration of the Pfizer-BioNTech mRNA COVID-19 vaccine. As a result, Appellees are immune from suit and liability for Appellants' claims arising out of or resulting from the administration of the vaccine.

FACTS AND PROCEDURAL HISTORY

In this action for professional negligence under the Maine Health Security Act, Appellants filed a Notice of Claim on May 3, 2023, which Notice arose out of Appellees' alleged administration of the Pfizer-BioNTech mRNA COVID-19 vaccine to Appellants' minor child on or about November 12, 2021. *See* 24 M.R.S. § 2853(1). (A. 3, 17-35) In their Notice of Claim, Appellants assert the following allegations, which this Court views as if they were admitted for purposes of this appeal. *See 20 Thames St. LLC v. Ocean State Job Lot of Maine 2017 LLC*, 2021 ME 33, ¶ 2, 252 A.3d 516; *Davric Maine Corp. v. Bangor Historic Track, Inc*., 2000 ME 102, ¶ 6, 751 A.2d 1024.

Appellants Jeremiah Hogan and Siara Jean Harrington are the parents of a minor child, J.H. (A. 18, ¶¶ 5-7.) Appellee Andrew Russ, M.D. ("Dr. Russ") is a physician and health care practitioner licensed to practice medicine in Maine. (A. 18, ¶ 8.) Dr. Russ is employed by Appellee Lincoln Medical Partners ("Lincoln Health"), which is a health care entity. (A. 18, ¶ 8.) Lincoln Health operates under the umbrella of Appellee MaineHealth, which is a Maine nonprofit corporation and health care entity. (A. 19, ¶¶ 9-10.)

During October 2021, Appellees planned a vaccine clinic to be operated at a school in Waldoboro on November 12, 2021. (A. 17, 20, ¶¶ 2, 16.) Prior to the November 12 vaccine clinic, Appellees transmitted letters about the vaccine clinic

and consent forms to parents of students at the school, including to Mr. Hogan and Ms. Harrington. (A. 20, ¶¶ 16-18.) According to the Notice of Claim, neither Mr. Hogan nor Ms. Harrington completed or signed a registration form or a consent form for their minor child's participation in the November 12, 2021, vaccine clinic. (A. 20, ¶ 19.) On November 12, 2021, Appellees operated a COVID-19 vaccine clinic at the school. (A. 17, ¶ 2.) Appellants allege that Dr. Russ administered the Pfizer-BioNTech mRNA COVID-19 vaccine to their minor child at the November 12 vaccine clinic without first obtaining the informed consent of Mr. Hogan or Ms. Harrington. (A. 21, ¶ 21.) On November 12, Appellants' minor child returned home after school with a band-aid on his arm and was irritable and emotionally unstable. (A. 22, ¶ 23.)

Based on these allegations, Appellants asserted eight tort claims against Appellees, seeking to hold MaineHealth and Lincoln Health vicariously liable for the acts of their agents and employees, including Dr. Russ. (A. 19, 23-30, ¶¶ 11-13 and Counts I-VIII.)[1]

On August 31, 2023, Appellees filed a Motion to Dismiss, which sought dismissal of the Notice of Claim pursuant to M.R. Civ. P. 12(b)(1) and (6) based upon the statutory protections afforded under the federal PREP Act. (A. 35-55.) On

[1] Appellant's Notice of Claim asserts the following claims: (I) professional negligence (II) professional negligence (systemic) (III) Battery (IV) False Imprisonment (V) Intentional Infliction of Emotional Distress (VI) Negligent Infliction of Emotional Distress (VII) Tortious Interference with Parental Rights and (VIII) Negligent Supervision.

September 4, 2023, the Panel Chair referred Appellee's Motion to Dismiss to the Superior Court. *See* M.R. Civ. P. 80M(e). (A. 93.) On April 16, 2024, following additional briefing from the parties (A. 56-82, 83-92), the Superior Court (Lincoln County, *Billings, J.*) granted Appellees' Motion and dismissed Appellants' Notice of Claim. (A. 7-16.)

ISSUES PRESENTED FOR REVIEW

I. Whether the trial court erred in its interpretation and application of the plain language of the PREP Act to provide immunity to Appellees with respect to all claims for loss causally related to the administration of a covered countermeasure.

II. Whether the plain language of the PREP Act conflicts with the federal "Emergency Use Authorization" statute.

III. Whether the PREP Act preempts state law claims against persons immune from liability.

IV. Whether the trial court erred in its application of the doctrine of constitutional avoidance.

STANDARD OF REVIEW

Pursuant to Rule 12 of the Maine Rules of Civil Procedure, a party may move to dismiss a claim for a party's "failure to state a claim upon which relief can be granted." M.R. Civ. P. 12(b)(6). In reviewing a trial court's decision on a motion

to dismiss pursuant to M.R. Civ. P. 12(b)(6), this Court "view[s] the facts alleged in the complaint as if they were admitted." *Andrews v. Sheepscot Island Co*., 2016 ME 68, ¶ 8, 138 A.3d 1197 (quotation marks omitted). This Court can consider "official public documents, documents that are central to the plaintiff's claim, and documents referred to in the complaint" as part of its review under Rule 12(b)(6), "when the authenticity of such documents is not challenged." *Moody v. State Liquor & Lottery Comm'n,* 2004 ME 20, ¶ 11, 843 A.2d 43. Thus, this Court "review[s] the legal sufficiency of the complaint de novo and view[s] the complaint in the light most favorable to the plaintiff to determine whether it sets forth elements of a cause of action or alleges facts that would entitle the plaintiff to relief pursuant to some legal theory." *Andrews*, 2016 ME 68, ¶ 8, 138 A.3d 1197 (quotation marks omitted) Dismissal of a claim is proper "when it appears beyond doubt that a plaintiff is entitled to no relief under any set of facts that he might prove in support of his claim." *Argereow v. Weisberg*, 2018 ME 140, ¶12, 195 A.3d 1210 (quotation marks omitted).

The interpretation of a statute is a legal issue that this Court reviews *de novo*. *See Thurston v. Galvin*, 2014 ME 76, ¶ 13, 94 A.3d 16. This Court's "primary purpose in interpreting a statute is to give effect to the intent of the Legislature." *Dickey v. Vermette*, 2008 ME 179, ¶ 5, 960 A.2d 1178 (quotation marks omitted). To do so, the Court "first look[s] to the statute's plain meaning and construe[s] the

language to avoid absurd, illogical, or inconsistent results." *Savage v. Maine Pretrial Servs., Inc*., 2013 ME 9, ¶ 7, 58 A.3d 1138 (quotation marks omitted). "If the plain language of a statute is ambiguous, only then will [this Court] look beyond that language to examine other indicia of legislative intent, such as legislative history." *Wuori v. Otis*, 2020 ME 27, ¶ 7, 226 A.3d 771A.3d 223 (quotation marks omitted); *see Savage*, 2013 ME 9, ¶ 8, 58 A.3d 1138 (recognizing that this Court will consider a statute's "underlying policy" or certain "rules of construction" only when a statute is ambiguous (quotation marks omitted)). "Statutory language is considered ambiguous if it is reasonably susceptible to different interpretations." *Wuori*, 2020 ME 27, ¶ 7, 226 A.3d 771A.3d 223 (quotation marks omitted). Moreover, this Court's 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 v. Riendeau*, 2000 ME 198, ¶ 14, 761 A.2d 291 (quotation marks and alteration omitted).

SUMMARY OF THE ARGUMENT

Appellees respectfully request that this Court affirm the dismissal with prejudice of Appellants' Notice of Claim pursuant to M.R. Civ. P. 12(b)(6) because the plain language of the PREP Act provides immunity to Appellees for the "claims for loss" asserted in the trial court and, in turn, preempts the claims asserted in this

forum. In their Notice of Claim, Appellants assert "claims for professional negligence" under the Maine Health Security Act, all of which seek compensation for claims for loss causally related to the alleged administration of the COVID-19 vaccine. (A. 17-30, ¶ 2, 31, 34, 38, 41, 45, 51, 56, 60.) Accordingly, because each Appellee is a "covered" or "qualified" person under the PREP Act who are alleged to have administered a "covered countermeasure," *i.e.*, the COVID-19 vaccine, during the effective period of a PREP Act declaration, Appellees are immune from suit for any claims for loss allegedly suffered by Appellants.

The plain language of the PREP Act has been interpreted and applied uniformly by courts in other jurisdictions to uphold the PREP Act's immunity provision, including for claims involving alleged lack of informed consent. Moreover, contrary to Appellants' contentions, other federal statutes do not create any implicit exceptions to the PREP Act's clear and direct immunity language. Additionally, the PREP Act is not unconstitutional, as applied to the circumstances of this case. The Act provides for specific avenues of redress to provide compensation to persons seeking relief for claims resulting from the use or administration of a "covered countermeasure." In this case, Appellants have not sought relief, first, through these other available avenues.

For the reasons below, and for those reasons articulated by the trial court, the Appellants' Notice of Claim should be dismissed.

ARGUMENT

I. The trial court correctly interpreted and applied the plain language of the PREP Act to provide immunity to Appellees with respect to all claims for loss causally related to the administration of a covered countermeasure.

A. The PREP Act

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). "The 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 the pandemic." *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)

(emphasis added); *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. § 247d-6d(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*. § 247d-6d(a)(2)(B) (emphasis added).

Like any comprehensive federal law, the PREP Act provides numerous statutory definitions. As 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); *see Gerber v. Forest View Ctr*., No. 21-CV-05359KAMJRC, 2022 WL 3586477, at *3 (E.D.N.Y. Aug. 22, 2022) (recognizing that a "qualified person" includes "hospitals, nursing homes and other entities."). 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 ones asserted in Appellants' Notice of Claim, 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). This federal administrative 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) (emphasis

added). "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). 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).

B. The Secretary's COVID-19 Declarations

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*. 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).

Here, at the onset of the COVID-19 pandemic, the Secretary first issued a PREP Act Declaration on March 17, 2020. *See* 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] (*See* A. 50-55) 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. Thus, upon issuance of the March 2020 Declaration, the immunity provision of the PREP Act became effective. *See* March 2020 Declaration, § IV; 42 U.S.C. § § 247d-6d(a)(1).

As declared by the Secretary, the "Recommended Activities" subject to protection under the PREP Act during the COVID-19 pandemic included "the

[2] After the initial March 2020 COVID-19 Declaration, the Secretary issued 11 amended Declarations, which are compiled, for ease of reference, at the Health and Human Services website. *See* https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx. 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 Appellants' 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).

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.

In subsequent amended Declarations, the Secretary has expanded the definitions of other statutory terms. *See, e.g.*, Third Amendment to Declaration Under the PREP Act, § V (adding pharmacists to list of designated "covered" persons); Fifth Amendment to Declaration Under the PREP Act, § V (adding inactive physicians and registered nurses to list of designated "covered" persons); Seventh Amendment to Declaration Under the PREP Act, § V (adding, among others, midwives, dentists, and optometrists to list of designated "covered" persons). Other amendments have clarified the term "covered countermeasure." *See, e.g.*, Second Amendment to Declaration Under the PREP Act, § VI (clarifying that a countermeasure includes "any vaccine used . . . to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or

a virus mutating therefrom"); Fourth Amendment to Declaration Under the PREP Act, § VI (clarifying that section VI includes all qualified pandemic and epidemic products under the PREP Act).

C. The plain language of the PREP Act provides immunity to Appellees for claims for loss resulting from administration of the Pfizer-BioNTech mRNA COVID-19 to Appellants' minor child.

In light of the PREP Act's plain language and the subsequent Declarations issued by the Secretary, this Court must affirm the trial court's dismissal of Appellants' Notice of Claim. As "covered" or "qualified" persons who are alleged to have caused harm to Appellants through the administration of the Pfizer-BioNTech mRNA COVID-19 vaccine, Appellees are immune from suit and liability for all claims arising out of or caused by the administration of the vaccine.

The PREP Act's immunity provision became effective upon the Secretary's issuance of the March 2020 Declaration. In accordance with the Declaration, the "distribution, administration, and use of . . . Covered Countermeasures" were designated as "Recommended Activities" subject to immunity under the PREP Act. March 2020 Declaration, §§ III-IV; *see* 42 U.S.C. § 247d-6d(a)(1). Clearly, the Pfizer-BioNTech mRNA COVID-19 vaccine is a "covered countermeasure" or "qualified pandemic or epidemic product" under the PREP Act and March 2020 Declaration. 42 U.S.C. § 247d-6d(i)(1), (7); *see* March 2020 Declaration, § VI (including as a countermeasure "any vaccine used to treat, diagnose, cure, prevent,

or mitigate COVID–19, or the transmission of SARS-CoV–2 or a virus mutating therefrom"). Moreover, Appellants, as "covered person[s]" who "prescribed, administered, or dispensed" the COVID-19 vaccine and as "qualified person[s]" who were "authorized to prescribe, administer, or dispense" the COVID-19 vaccine, are clearly within the scope of "person[s]" shielded from immunity under the PREP Act. 42 U.S.C. § 247d-6d(i)(2), (5), (8); March 2020 Declaration, §§ IV-VI. And, to the extent that the Notice of Claim alleges that some or all of the Appellees "planned" the November 12, 2021, vaccine clinic (A. 20, ¶ 16), Appellants also are "program planners" for purposes of the PREP Act. *See* 42 U.S.C. § § 247d-6d(i)(2), (6) (stating that a program planner is a "covered person" and defining a "program planner" as a "person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of . . . a qualified pandemic or epidemic product").

Accordingly, the alleged administration of the COVID-19 vaccine to Appellants' minor child, and the alleged harm to Appellants resulting therefrom, fall squarely within the PREP Act's immunity. All "claims for loss" asserted in the Notice of Claim are for mental or physical injuries alleged to be "caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure"—that is, the claims and alleged injuries arise out of the Pfizer-BioNTech mRNA COVID-19 vaccine allegedly administered to Appellants'

minor child on November 12, 2021. 42 U.S.C. § 247d-6d(a)(1); *see id.* § 247d-6d(a)(2)(A)-(B); *Hampton v. California*, 83 F.4th 754, 764 (9th Cir. 2023) (noting that "[a]t the very least," PREP Act immunity will apply when "the underlying use or administration of a covered countermeasure . . . played some role in bringing about or contributing to the plaintiff's injury."). (A. 17-30, ¶ 2, 31, 34, 38, 41, 45, 51, 56, 60.) Thus, the claims arise out of the "physical provision of" the Pfizer-BioNTech mRNA COVID-19 vaccine to Appellants' minor child. March 2020 Declaration, § IX. Moreover, the Notice of Claim does not assert any claim for "willful misconduct," as defined by the PREP Act, and does not allege that Appellants pursued administrative relief through the Covered Countermeasure Process Fund. *See* 42 U.S.C. § 247d-6d(d)(1), § 247d-6e. Under the PREP Act, Appellees are "immune from suit and liability under Federal and State law" with respect to the claims for loss asserted in the Notice of Claim. 42 U.S.C. § 247d-6d(a)(1).

To reinforce the trial court's application of the PREP Act to Appellants' Notice of Claim, and to guide this Court in its own interpretation and application of the PREP Act, numerous cases from other jurisdictions are illustrative. In New York, for example, a county public health department held a vaccination clinic at a local school for administration of the 2009 H1N1 influenza vaccine during a public health emergency. *Parker v. St. Lawrence Cnty. Pub. Health Dep't*, 954 N.Y.S.2d 259, 261

(N.Y. App. Div. 2012). At the vaccine clinic, a nurse administered the influenza vaccine to a kindergartner *without the parent's consent*. *Id*. However, based on the protections provided by the PREP Act, the court concluded that the plaintiff's "state law claims for negligence and battery are preempted by the PREP Act and, inasmuch as the exclusive remedy under the statute is a federal cause of action to be brought in federal court, the complaint must be dismissed." *Id*. at 263. Similarly, in Kansas, a mother brought suit against Walmart and one of its pharmacists for administering the COVID-19 vaccine to her minor child *without the mother's consent*, asserting claims for, among other things, negligence, battery, and interference with parental rights. *M.T. as next friend of M.K. v. Walmart Stores, Inc*., 528 P.3d 1067, 1071 (Kan. Ct. App. 2023). There, the appellate court concluded that "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." *Id*. at 1084. As a result, the court remanded the matter with instructions to dismiss all claims asserted by the mother. *Id*. In applying the PREP Act to similar claims arising out of the administration of the COVID-19 vaccine, other courts have reached analogous conclusions regarding the PREP Act's broad reach and its grant of immunity. *See, e.g*., *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).

Notably, in the time since the filing of Appellees' Motion to Dismiss, other jurisdictions have continued to interpret the plain language of the PREP Act to provide immunity for asserted claims for loss resulting from the administration of a COVID-19 vaccine, including for claims involving informed consent. Most recently, the Vermont Supreme Court affirmed a trial court's dismissal of a complaint based on PREP Act immunity. *Politella v. Windham Southeast Sch. Dist*., 2024 VT 43, ¶ 22, --- A.3d ---.[3] There, parents of six-year-old child asserted eight state law claims against a school district, among others, after the child was administered a COVID-19 vaccine without the parents' consent and after the child "verbally protested" receiving the vaccine. *Id*., 2024 VT 43, ¶¶ 3-5, --- A.3d ---. 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*., 2024 VT 43, ¶¶

[3] Here, in the trial court's order dismissing Appellants' Notice of Claim, the court relied on the Vermont trial court's decision in *Politella* to support dismissal in this matter. *See Politella v. Windham Southeast School Dist*., No. 22-CV-01707, 2022 WL 18143866, at *1, 3 (Vt. Super. Ct. Dec. 28, 2022). (A. 13-14) As noted above, the Vermont Supreme Court has since affirmed the Vermont trial court's decision.

19, 22, --- A.3d ---. 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*., 2024 VT 43, ¶¶ 9, 22, --- A.3d ---.

Numerous other courts have recently reached similar conclusions. *See, e.g.*, *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); *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); *Happel v. Guilford Cnty. Bd. of Educ*., 899 S.E.2d 387, 393 (N.C. Ct. App. 2024) (holding that "broad scope of immunity provided by the PREP Act" required dismissal of claims against school for alleged vaccination of child without parental consent).

Accordingly, given the plain language of the PREP Act and the uniform interpretations of the Act in the cases cited above, all claims asserted in the Notice of Claim are "claims for loss" alleged to be "caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure"—again, the claims arise out of and relate to the Pfizer-BioNTech mRNA COVID-19 vaccine allegedly administered to Appellants' minor child on November 12, 2021. 42 U.S.C. § 247d-6d(a)(1). (A. 17-30, ¶ 2, 31, 34, 38, 41, 45, 51, 56, 60.).)

Therefore, under the plain language of the PREP Act, Appellees are "immune from suit and liability under Federal and State law" with respect to the claims asserted against them in the Notice of Claim. 42 U.S.C. § 247d-6d(a)(1); *see Politella*, 2024 VT 43, ¶¶ 9, 22, --- A.3d ---; *M.T.*, 528 P.3d at 1084; *Parker*, 954 N.Y.S.2d at 263. As such, Appellants are not entitled to "relief under any set of facts that [they] might prove in support of [their] claim." *Argereow*, 2018 ME 140, ¶12, 195 A.3d 1210 (quotation marks omitted).

II. The plain language of the PREP Act does not conflict with the federal "Emergency Use Authorization" statute.

In an attempt to diminish the plain, unambiguous language of the PREP Act, and the broad immunity that the Act expressly provides, Appellants contend that the Act must be "harmonized" with other federal statutes relating to "emergency use authorization" ("EUA") of certain drugs, arguing that one statute in particular, 21

U.S.C. § 360bbb-3, "clearly protects the right to refuse the medical intervention that is subject to the EUA." (Blue Brief, p. 6-13) In effect, Appellants argue that the PREP Act's reference to Section 360bbb-3 creates an exception to the PREP Act's clear directive that certain persons are immunized "from suit and liability under Federal and State law with respect to all claims for loss" during the pendency of a declaration issued by the Secretary during a public health emergency. 42 U.S.C. § 247d 6d(a)(1).

Appellants' statutory interpretation argument is misguided for a variety of reasons. First, Appellants rely on a portion of the federal EUA statute, 21 U.S.C. § 360bbb-3(e), to argue that "the obligation to obtain consent" is somehow excluded from the grant of immunity expressly included under the PREP Act. However, the the statutory language relied upon by Appellants does not support their argument. Section 360bbb-3(e), entitled "Conditions of authorization," provides, in relevant part, as follows:

> With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:
>
> (i) Appropriate conditions designed to ensure that health care professionals administering the product are informed--
>
> (I) that the Secretary has authorized the emergency use of the product;
>
> (II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

> (III) of the alternatives to the product that are available, and of their benefits and risks.
>
> (ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed--
>
> (I) that the Secretary has authorized the emergency use of the product;
>
> (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
>
> (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.
>
> (iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.
>
> (iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

21 U.S.C. § 360bbb-3(e)(1)(A) (emphasis added).

As is evident from this statutory language, the EUA statute does not create any implicit exception to the plain language of the PREP Act. Rather, Section 360bbb-3(e) imposes on the *Secretary* an obligation to establish conditions, "to the extent practicable," that individuals be informed about certain conditions when administered with an "emergency use" product. *See Children's Health Defense, Inc. v. Rutgers, the State Univ. of New Jersey*, 93 F.4th 66, 75 (3d Cir.), *cert. denied sub nom. Children's Health Def. v. Rutgers, the State Univ. of New Jersey*, 144 S. Ct. 2688 (2024) ("[Section] 360bbb-3(e)(1)(A) obligates only the Secretary of Health and Human Services to act, by establishing 'conditions designed to ensure' informed

consent." (emphasis added)). Simply put, this Section does not "create[] an incoherent conflict with" the PREP Act's immunity provision. (Blue Brief, at 11.)

In effect, Appellants contend that because "consent" is mentioned in Section 360bbb-3, it is therefore excluded from the PREP Act's immunity provision. According to Appellants' reading of the two federal statutes, injuries resulting from any known "risks" of an EUA product would also be excluded from PREP Act immunity because the term "risks" is similarly mentioned in Section 360bbb-3. *See* 21 U.S.C.A. § 360bbb-3(e)(1)(A)(ii)(II) (establishing conditions that individuals are informed of the "risks" of use). In Appellants' interpretation of, and attempt to "harmonize," the two federal statutes, Appellants ask this Court to create an implicit exception to the PREP Act's express immunity under "Federal and State law with respect to all claims for loss," 42 U.S.C. § 247d-6d(a)(1), and replace it with an exception that would narrow the scope of immunity plainly intended for by Congress. Thus, Appellants ask this Court to read into the PREP Act additional exceptions that are not included under the Act.

Appellants' argument also ignores the plain language of the PREP Act. 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) (emphasis added). By

attempting to read additional exceptions into the Act, including by looking to other federal statutes, Appellants attempt to override the clear directive of Congress in drafting the PREP Act language as it did. If Congress had intended for other exceptions to apply to the immunity granted under, Congress certainly could have included such exceptions within the PREP Act. *See, e.g.*, *In re Haas*, 48 F.3d 1153, 1156 (11th Cir. 1995) ("Where Congress knows how to say something but chooses not to, its silence is controlling." (citing *BFP v. Resolution Trust Corp*., 511 U.S. 531, 537 (1994)

Moreover, to this point, Appellants' arguments conflate the issue of a general right to accept or refuse medication with the negligence and intentional tort claims asserted in the Notice of Claim, for which Appellants seek compensation for their alleged mental and physical loss or injury. (*See* A. 17-31, ¶¶ 2, 31, 34, 38, 41, 45, 51, 56, 60.) The claims and relief sought in the Notice of Claim are barred by the PREP Act and the Secretary's subsequent Declaration, even under any conditions the Secretary may establish pursuant to Section 360bbb-3(e). In short, the PREP Act does not abolish a person's right to consent to medical treatment. It does, however, provide immunity to certain persons during declared public health emergencies for a person's "claims for loss" arising out of the administrative of a vaccine, including claims that result from alleged negligent or tortious conduct related to informed consent. 42 U.S.C. § 247d-6d(a)(1).

Appellants also contend that the trial court's interpretation of the plain language of the PREP Act would lead to absurd results, suggesting a variety of hypothetical situations that could arise. (Blue Brief, at 13-15.) This Court need not issue an advisory opinion about future, hypothetical cases. Again, Appellants' Motion to Dismiss required the trial court, and now this Court, to analyze whether the Notice of Claim "sets forth elements of a cause of action or alleges facts that would entitle the [Appellants] to relief pursuant to some legal theory," not whether the examples set forth in the Appellants' Brief may lead a prospective plaintiff to some other form of relief, including for potential willful conduct. *Argereow*, 2018 ME 140, ¶12, 195 A.3d 1210 (quotation marks omitted).

Lastly, whether the Pfizer-BioNTech mRNA COVID-19 vaccine allegedly administered to Appellants' minor child is considered "intrinsically experimental," whether the vaccine was developed at "warp speed," and whether the "federal government harvested vast amounts of data" in developing the vaccine are all tangential issues that are irrelevant in this matter. *See M.T.*, 528 P.3d at 1074 ("Application of the PREP Act does not turn on the effectiveness of the countermeasure"); *see also Politella*, 2024 VT 43, ¶¶ 20, --- A.3d --- (citing *M.T.* and rejecting plaintiff's claim that Pfizer BioNTech COVID-19 vaccine was "experimental"). (Blue Brief, at 15-18) As noted above, the vaccine allegedly administered to Appellants' minor child was a "covered countermeasure" under the

PREP Act and, therefore, is subject to the PREP Act's immunity provision, notwithstanding assertions about its effectiveness or experimental nature. *See* 42 U.S.C. § 247d-6d(a)(1).

In short, Appellants' statutory interpretation argument misses the mark. The Court need look only at the plain language of the PREP Act to determine that the PREP Act means what Congress plainly intended it to mean: 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 COVID-19 vaccine. 42 U.S.C. § 247d-6d(a)(1). The PREP Act provides a "sole exception" to this express immunity, for actions involving "willful misconduct." The EUA statute does not alter or weaken the PREP Act's clear language and does not establish any new exception under the Act.

III. The PREP Act preempts state law claims against persons immune from liability.

Appellants argue that the trial court erred in its preemption analysis. (Blue Brief, at 22-26) Although Appellees' Motion to Dismiss raised the issue of preemption and sought dismissal under Rule 12(b)(1), the trial court did not address this argument and based its dismissal of the Notice of Claim on Rule 12(b)(6). (A. 7-16) In any event, to the extent that this Court reviews whether Appellants' Notice of Claim should be dismissed pursuant to Rule 12(b)(1), the PREP Act

preempts Appellants' asserted claims in this forum.

Under the PREP Act, a State may not "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 [42 U.S.C. § 247d-6d]," or that "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]." 42 U.S.C. § 247d-6d(b)(8). Notably, as the Supreme Court has "repeatedly recognized" in regards to other similar statutory language, "the phrase 'relate to' in a preemption clause expresses a broad pre-emptive purpose" and is a term "notably expansive in sweep." *Coventry Health Care of Missouri, Inc. v. Nevils*, 581 U.S. 87, 95–96 (2017) (quotation marks and alterations omitted).

Here, Appellants' asserted claims are inherently "different from" and "in conflict with" the PREP Act's immunity and exclusive remedy provisions, 42 U.S.C. § 247d-6d(b)(8), and therefore are completely preempted by the Act. *See, e.g.*, *Parker*, 954 N.Y.S.2d at 263; *see also Gieser*, 2024 WL 3077100, at *5 (concluding that PREP Act's preemption clause "provides a federal defense to state law claims") As noted above, the PREP Act provides "two avenues of recourse" for claims resulting from the administration of a covered countermeasure. *Goins*, No. 2022 WL 17413570, at *4. Thus, Appellants could have sought relief through the Covered

Countermeasure Process Fund or, alternatively, through a civil action for "willful misconduct" filed in the US District Court for the District of Columbia. 42 U.S.C. §§ 247d-6d(c)-(e), 247d-6e. However, as the trial court determined, "there are no allegations in the Notice of Claim that [Appellants' minor child] has suffered death or serious injury as defined by the [PREP Act] or that [the child's] vaccination was the product of willful misconduct." (A. 12) Accordingly, as the Vermont Supreme Court has concluded, "when the federal PREP Act immunizes a defendant, the PREP Act bars all state-law claims against that defendant as a matter of law." *Politella*, 2024 VT 43, ¶ 9, --- A.3d ---.

Therefore, to the extent that this Court reviews whether Appellants' Notice of Claim should be dismissed pursuant to Rule 12(b)(1), the PREP Act preempts Appellants' asserted claims in this forum.

IV. The trial court correctly applied the doctrine of constitutional avoidance.

Appellants also contend that the trial court erred in not addressing constitutional concerns raised in their Opposition to Appellees' Motion to Dismiss (*see* A. 56), arguing that the trial court should have evaluated whether the PREP Act infringes upon certain property rights or substantive due process rights of the Appellants.[4] (Blue Brief, at 26-36).

[4] The only court that appears to have raised a constitutional question regarding the PREP Act was a district court in Kansas. *See Tonkinson v. Walmart, Inc*., No. 21CV05493, 2022 WL 1266666, at *2 (Kan. Dist. Ct.

"When constitutional rights are implicated in the application of a statute," this Court "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*, 2012 ME 57, ¶ 19, 41 A.3d 551 (abrogated on other grounds) (citing *Rideout v. Riendeau*, 2000 ME 198, ¶ 14, 761 A.2d 291). The Court's 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*, 2000 ME 198, ¶ 14, 761 A.2d 291 (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*, 2015 ME 50, ¶ 8, 115 A.3d 92 (quotation marks omitted). Moreover, the Court's "role in reviewing the constitutionality of a statute must necessarily be limited by the facts in the case before [it]" and the Court "may not reach beyond those facts to decide the constitutionality of matters not yet presented." *Rideout*, 2000 ME 198, ¶ 15, 761 A.2d 291. "Thus, when there is a reasonable interpretation of a statute that will satisfy constitutional requirements, [this Court] will adopt that interpretation, notwithstanding other possible interpretations of the statute that

Apr. 26, 2022). Even there, that ruling was ultimately overturned on appeal. *See M.T. as next friend of M.K. v. Walmart Stores*, Inc., 528 P.3d 1067, 1084 (Kan. Ct. App. 2023), cited *supra*.

could violate the Constitution." *Nader*, 2012 ME 57, ¶ 19, 41 A.3d 551 (citations omitted).

Here, Appellants asserted eight tort claims in their Notice of Claim, seeking compensation for mental and physical injuries resulting from the alleged administration of a vaccine. (A. 17-31, ¶¶ 2, 31, 34, 38, 41, 45, 51, 56, 60.) In light of these asserted claims, the Court need not resort to any constitutionality argument because there are constructions and interpretations of the entire PREP ACT that are "reasonable" and in conformity with Congress' clear intent to provide immunity to covered persons during declared public health emergencies, including immunity for the claims asserted by Appellants.

Appellants argue that the PREP Act, as applied to the facts of this case, would infringe upon Appellants' constitutional rights because the Act does not "provide any avenue for redress." (Blue Brief, at 31, 35.) 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."). Appellants 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 US 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 is made in the Notice of Claim that Appellants exhausted or otherwise pursued these administrative remedies prior to filing suit in the trial court. Thus, to the extent that Appellants attempt to assert a violation of constitutionally protected rights, Appellants have not alleged that they first sought to remedy their alleged harms through the specific provisions provided for under the PREP Act. Their failure to do so rebuts any argument that the PREP Act is unconstitutional or otherwise fails to "provide any avenue for redress."

Appellants likewise argue that applying the PREP Act to the tort claims alleged in the Notice of Claim Appellants would violate Appellants' substantive due process rights. In support of their argument, Appellants cite to numerous cases outlining parental rights and a right to bodily integrity, all of which deal with "state action." (Blue Br, at 31-36) In this case, the Notice of Claim does not allege any "state action." Moreover, Count VII of the Notice of Claim asserts a claim for "Tortious Interference with Parental Rights" and cites many of the same "state action" cases. (A. 29-30) However, such a claim is not a cognizable claim under Maine law.[5] (A. 29-30) Even if it were a cognizable tort claim, it would nonetheless

[5] Appellants rely upon a Virginia case involving an unauthorized adoption, *Wyatt v. McDermott*, 725 S.E.2d 555 (Va. 2012), to support their tort claim in Count VII. (A. 29-30)

be subject to the PREP Act's immunity provision, as such a claim would clearly be a "claim[] for loss." *See* 42 U.S.C. § 247d-6d(a)(1).

To be sure, Appellants' arguments related to property interests and constitutional rights arise out of the immunity afforded under the PREP Act, which, according to Appellants, allows tortious conduct to occur "consequence-free." (Blue Brief, at 36.) However, PREP Act immunity is no different than the numerous Maine statutes providing tort immunity to persons in various circumstances. For example, 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." Based on Appellants' argument, this Maine statute would also be unconstitutional because the person rendering aid could provide medical treatment to another person or child, without obtaining consent.

In short, the trial court did not err in declining to address the constitutional arguments raised by Appellants. There are "reasonable interpretation[s]" of the PREP Act that "satisfy constitutional requirements . . . notwithstanding other possible interpretations of the statute that could violate the Constitution." *Nader*, 2012 ME 57, ¶ 19, 41 A.3d 551 (citations omitted). As numerous other jurisdictions have concluded, the plain language of the PREP Act can be applied and interpreted

in such a way that comports with constitutional protections. *See supra*, p. 18-21. And, as shown above, the PREP Act provides for specific avenues of redress, through the Covered Countermeasure Process Fund or, for cases of willful misconduct, through filing suit in the District of Columbia, that provide compensation for alleged tortious conduct. In this case, Appellants either were not aware of or did not otherwise pursue these avenues of redress. Without doing so, Appellants are without relief in this Court because, under the PREP Act, Appellants are "immune from suit and liability under Federal and State law with respect to all claims for loss" resulting from the alleged administration of the Pfizer-BioNTech mRNA COVID-19 vaccine.

In short, the PREP Act does not abolish a person's or a parent's right to consent to medical treatment. It does, however, provide immunity to certain persons during declared public health emergencies for asserted "claims for loss" arising out of the administrative of a vaccine, including claims that result from alleged tortious conduct. 42 U.S.C. § 247d-6d(a)(1). Again, Appellants conflate the issue of a right to accept or refuse medical treatment, which the PREP Act does not address, with the negligence and intentional tort claims asserted in the Notice of Claim, for which the PREP Act provides immunity during declared public health emergencies. (*See* A. 17-31, ¶¶ 2, 31, 34, 38, 41, 45, 51, 56, 60 (seeking compensation for physical and mental injury)

CONCLUSION

For the foregoing reasons, the Appellees respectfully request that this Court affirm the trial court's dismissal of Appellants' Notice of Claim. The Notice of Claim seeks compensation for mental and physical injuries "caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure"—the Pfizer-BioNTech mRNA COVID-19 vaccine allegedly administered to Appellants' minor child on November 12, 2021. 42 U.S.C. § 247d-6d(a)(1). (Notice of Claim, ¶¶ 2, 31, 34, 38, 41, 45, 51, 56, 60.) Accordingly, Appellees urge this Court to interpret and apply the PREP Act consistent with its plain language and in the same manner as the trial court and the courts from other jurisdictions.

Dated at Portland, Maine this 19th day of September, 2024.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Joseph M. Mavodones, Esq., Attorney for Respondents-Appellees Lincoln Medical Partners, *et al.*, hereby certify that I have served two copies of the Brief of Appellees, via email and by depositing same in the United States Mail, postage prepaid, upon counsel for Appellants as follows:

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