MAINE SUPREME JUDICIAL COURT

SITTING AS THE LAW COURT

Docket No. Lin-24-209

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Jeremiah Hogan et al.,

Appellants

v.

Lincoln Medical Partners, et al.,

Appellees

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ON APPEAL FROM THE SUPERIOR COURT

(LINCOLN COUNTY)

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# BRIEF OF APPELLANTS

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## INTRODUCTION

This is an appeal from the grant of a Motion to Dismiss Appellants' Notice of Claim filed pursuant to the Maine Health Security Act, 24 M.R.S. §§ 2501-2988 (LEXIS July 24, 2024) ("Maine Health Security Act").

## STATEMENT OF FACTS

Appellant J.H. is a minor and the biological son of Appellants Siara Harrington and Jeremiah Hogan. App. 18. Appellees are a physician and health care practitioner licensed in Maine, and two Maine health care corporations that employ him. App. 18-19. Appellees planned, and then operated on November 12, 2021, a COVID-19 pediatric "vaccine clinic" at the pre-K through 6th-grade Miller School in Waldoboro, where J.H. was a student. App. 20-21. Appellees promoted the vaccine clinic through letters and text messages sent to parents, including Appellants Harrington and Hogan. App. 20. Appellee LincolnHealth Partners, Inc. ("Lincoln Health") sent a "Dear Parent or Guardian" letter to Appellants announcing the clinic, stressing that COVID-19 vaccination was optional, and attaching both a registration form and a vaccination consent form designed by Appellee MaineHealth, Inc. ("Maine Health") stating "**most important this must be signed by a parent**." (Emphasis in original.) App. 20, 33-35.

On November 9, 2021, a few days before the vaccine clinic was to be held, Appellees transmitted the October 2021 letter and its two attachments to Appellants Harrington and Hogan a second time, by text message. App. 20. The parents made a conscious decision against vaccination, accordingly neither completed, signed or delivered the consent form or registration form, and neither of them ever provided any consent of any kind, verbally or in writing, to J.H.'s participation in the vaccine clinic or to J.H. being injected with any COVID-19 vaccine. *Id.* Notwithstanding Appellees' failure to obtain consent, during the course of the clinic on November 12, 2021, Appellee Andrew Russ injected J.H. with a Pfizer COVID-19 vaccine. App. 21. Dr. Russ had served as J.H.'s pediatrician since birth, and had previously offered an mRNA COVID-19 vaccination to Appellant Harrington, who unequivocally rejected it. App. 22.

On May 4, 2023, Appellants filed a Notice of Claim with the Lincoln County Superior Court pursuant to the Maine Health Security Act. App. 3. On May 12, 2023, the Chair of the Medical Malpractice Screening Panel commenced the screening process and on July 5, 2023, she issued a Scheduling Order that included a plan of discovery. App. 4. Before producing any discovery to Appellants, Appellees filed on September 1, 2023 a Motion to Dismiss based on the Public Readiness and Emergency

Preparedness Act ("PREP Act"), 42 U.S.C. § 247d et seq, and the motion was granted by Order dated April 16, 2024. App. 4-5. Appellants filed a Notice of Appeal to the Maine Supreme Judicial Court on May 7, 2024 App. 6.

## ISSUE PRESENTED FOR REVIEW

Whether the Superior Court erred in determining that the PREP Act provides immunity against and preempts Appellants' state law claims.

## SUMMARY OF ARGUMENT

Properly construed, the PREP Act does not provide immunity to Appellees or preempt Appellants' claims, and even if it were construed to provide immunity and preempt Appellants' claims, the PREP Act would be unconstitutional as applied to the facts of this case.

## STANDARD OF REVIEW

Appellees moved to dismiss for lack of subject matter jurisdiction under M. R. Civ.P. 12(b)(1), and for failure to state a claim under M. R. Civ.P. 12(b)(6). App. 36. The Superior Court framed its dismissal in terms of M. R. Civ.P. 12(b)(6). App. 8.

In an appeal from an order granting a motion to dismiss under Rule 12 (b)(6), the Law Court reviews *de novo* the legal sufficiency of a complaint 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." *Calnan v. Hurley*, 2024 ME 30, ¶ 7, ___A.3d___, quoting *Doe v. Bd. of Osteopathic Licensure*, 2020 ME 134, ¶ 6, 242 A.3d 182 (quotation marks omitted).

Dismissal of a complaint is proper only when the complaint fails to state a claim for which relief may be granted. See M.R. Civ. P. 12(b)(6). "A motion to dismiss tests the legal sufficiency of the complaint." *Livonia v. Town of Rome*, 1998 ME 39, ¶ 5, 707 A.2d 83, 85 (citing *Richards v. Soucy*, 610 A.2d 268, 270 (Me. 1992)). For the purposes of a motion made pursuant to Rule 12(b)(6), "the material allegations of the complaint must be taken as admitted." *Livonia*, 1998 ME 39, P5, 707 A.2d at 85 (citing *Larrabee v. Penobscot Frozen Foods, Inc.*, 486 A.2d 97, 98 (Me. 1984)). When reviewing a dismissal, the court examines 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. *Livonia*, 1998 ME at P5, 707 A.2d at 85. "A dismissal should only occur when it appears 'beyond doubt that [the] plaintiff[s] [are] entitled to no relief under any set of facts that [they] might prove in support of [their] claim.'" *McAfee v. Cole*, 637 A.2d 463,

465 (Me. 1994) (quoting *Hall v. Board of Envtl. Protection*, 498 A.2d 260, 266 (Me. 1985)).

The Law Court reviews the interpretation of a statute *de novo* for errors of law. *In re Wage Payment Litig. v. Wal-Mart Stores, Inc.*, 2000 ME 162, P4, 759 A.2d 217. In conducting its review, "[it] seek[s] to give effect to the legislative intent by examining the plain meaning of the statutory language. If the plain meaning of the text does not resolve an interpretative issue raised, [it] then consider[s] the statute's history, underlying policy, and other extrinsic factors to ascertain legislative intent. In ascertaining legislative intent, [it] interprets the section of the statute in the context of the statutory scheme in which it is found." *Id.* (internal citations omitted).

## ARGUMENT

### I. The Superior Court Erred in Determining that the PREP Act Immunizes Appellees from Liability for Non-Consensual Medical Interventions

In 2005, Congress enacted the Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. § 247d *et seq.*, "to encourage the expeditious development and deployment of medical countermeasures during a public health emergency...." *Cannon v. Watermark Ret.*

*Communities, Inc.*, 45 F.4th 137, 139 (D.C. Cir. 2022) (quotation marks omitted). App. 38.

The immunity provision of the PREP Act states in relevant part:

> *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…*

42 U.S.C. § 247d-6d(a)(1). Appellees assert that they are "covered person[s]", that the substance injected into Appellant J.H. was a "covered countermeasure" and that consequently they are immune. App. [ ].

## A. The PREP Act Must be Harmonized with the Emergency Use Authorization Statutes

There are only two paths through which medical products can gain access to the U.S. market: following ordinary "approval" by the Food and Drug Administration ("FDA"), or subject to an Emergency Use Authorization ("EUA") issued by the FDA Commissioner during a declared emergency. App. 58. Ordinary FDA approval requires submission of an Investigational New Drug Application ("IND") requesting authorization to proceed with human clinical trials. Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a). App. 58-59. The IND is based on already obtained animal experiment data, toxicity data, manufacturing information, clinical protocols, data from prior human research and information about the developer. App. 58. If the FDA approves the IND, then human clinical

trials may proceed in four phases. *Id.* The overall length of a Phase 3 trial alone is between two and ten years. *Id.* Upon completion of the Phase 3 trial, the developer may submit a New Drug Application ("NOA"), including data from the human trial and pre-clinical animal trials. App. 58-59. The FDA then reviews the NDA for "substantial evidence" from years' long well-controlled clinical trials that the drug is "safe and effective for [its] particular intended use, indication, and patient population" and that the benefits of the drug outweigh the risks, before granting approval. 21 U.S.C. § 355(b). App. 59.

By contrast, EUA products enter the market unapproved by the FDA, escaping the years' long FDA approval process and the safeguards it provides. *Id.* Specific and detailed EUA procedures were first introduced in the aftermath of the 9-11 terrorist attacks by the Project Bioshield Act of 2004, 108 P.L. 276 (Jul. 21, 2004), and are codified at 21 U.S.C. § 360bbb-3 et seq. *Id.* Whereas a developer must demonstrate that a drug is safe and effective in order to obtain ordinary FDA approval, it need only show that it "may be effective" to obtain an EUA. 21 U.S.C. § 360bbb-3(c). *Id.* And whereas a developer must present "substantial evidence" of safety and efficacy in accordance with 21 U.S.C. § 355(d), including data from completed Phase 3 human clinical trials, in order to obtain ordinary FDA

approval, an EUA is granted merely on the basis of the FDA Commissioner's determination that it is "reasonable to believe" that the product "may be effective," and no data from human clinical trials is required. 21 U.S.C. § 360bbb-3(c)(2) and (k). *Id.* The FDA Commissioner typically decides whether to issue an EUA within weeks. *Id.* Thus commentators have characterized EUA products as "experimental". App. 59-60.

Appellees describe the COVID-19 vaccine injected into J.H. as a "covered countermeasure" for the purposes of the PREP Act. App. 38-40. They settle on the definition of that term found in 42 U.S.C. § 247d-6d(i)(l)(A), as a "qualified pandemic or epidemic product." App. 40. Then they cite to the further definition of qualified pandemic or epidemic product" found in § 247d-6d(i)(7). *Id.* That section sets forth a two-part definition, but Appellees cite to only the first half of the definition found in § 247d- 6d(i)(7), the part located in subsection (A), and suppress the second half of the definition located in sub-section (B), which states that in order to be a "qualified pandemic or epidemic product" the product in question must also be:

> *(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 351 et seq.] or licensed under section 351 of this title [42 USCS § 262];*

> *(ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(i) or 360j(g)]; or*
> *(iii)* ***authorized for emergency use*** *in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 USCS § 360bbb-3, 360bbb-3a, or 360bbb-3b].*

*Id.* at § 247d-6d(i)(7)(B) (emphasis added).

Only three COVID-19 vaccines were circulating in the U.S. market on November 12, 2021, the date on which Appellees injected J.H.: the Pfizer-BioNTech COVID- 9 vaccine, the Moderna COVID-19 vaccine and the Johnson & Johnson (Janssen) COVID-19 vaccine. App. 60. None of these vaccines had been approved or licensed by the FDA as provided in § 247d-6d(i)(7)(B)(i), and none of them were subject to exemption as provided in § 247d-6d(i)(7)(B)(ii). App. 60-61. All of them were circulating in the market under an EUA issued pursuant to 21 U.S.C. § 360bbb-3, as provided in 42 U.S.C. § 247d-6d(i)(7)(B)(iii). App. 61. According to the vaccination card they created, Appellees injected J. H. with a Pfizer-BioNTech COVID-19 vaccine, and the Pfizer-BioNTech EUA was first issued under § 360bbb-3 on December 11, 2020. App. 61. The Pfizer-BioNTech EUA has been reissued on numerous occasions since then, at the time of briefing at the Superior Court level most recently on September 11, 2023. App. 61. Thus, at the time of briefing below the Pfizer-BioNTech COVID-19 vaccine still

lacked FDA approval or licensure, and still circulated pursuant to an EUA issued under § 360bbb-3.

Why do Appellees prefer to read the PREP Act in isolation, separate from the EUA statutes to which it refers and that form its statutory context? The problem for Appellees is that § 360bbb-3 very clearly protects the right to refuse the medical intervention that is subject to the EUA. The statute lists certain "[r]equired conditions" for the issuance of the EUA, among them:

> *(ii) Appropriate conditions designed to ensure that individuals lo 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*
> *(Ill)* ***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.*

Id. at § 360bbb-3(e)(l)(A)(ii) (emphasis added).

The grant of immunity in the PREP Act must be construed in light of 21 U.S.C. § 360bbb-3, to which it expressly refers. The EUA statutes at § 360bbb-3 et seq. and the PREP Act are part of a single, post-911 statutory scheme. App. 62. This Court must "consider the whole statutory scheme for the section at issue in seeking to obtain a harmonious result." *Preti Flaherty Beliveau & Pachios LLP v. State Tax Assessor*, 2014 ME 6, ¶ 11, 86

A.3d 30. The "[r]equired conditions" in § 360bbb-3(e)(l)(A) are distinct from other conditions set forth in § 360bbb-3(e)(l)(B), which are *not* said to be required. This makes sense, since, as discussed *infra*, the right to reject medical interventions, or stated differently, the obligation to obtain consent prior to conducting medical interventions, is entrenched in the common law of tort, constitutional law and international law. Congress could have used language in § 360bbb-3 that expressly abolishes consent, but it chose not to. Instead, under § 360bbb-3(e)(l)(A), the Secretary may have some discretion with respect to the way he promotes the right to accept or refuse, but it is clear that the right exists and must be protected. The PREP Act itself does not purport to amend § 360bbb-3(e)(l)(A)(ii)(III), nor does it use language expressly abolishing consent. Construing the immunity language in 42 U.S.C. § 247d-6d(a)(l) so broadly that it applies even to claims for violations of the bare right to accept or refuse medical interventions creates an incoherent conflict with § 360bbb-3(e)(1)(A)(ii)(III), and violates the harmonious-reading canon.

Claims that arise from violations of the fundamental right "to accept or refuse" a COVID-19 vaccine, are different from claims arising from "the administration to or the use by an individual" of a COVID-19 vaccine, and are not intended to be extinguished by § 247d-6d(a)(l). The statutory text

makes this obvious, since obtaining or failing to obtain consent is not included in the exclusive list of items specifically identified in § 247d-6d(a)(2)(B) as being within the scope of § 247d-6d(a)(l) immunity. Section 247d-6d defines the scope of § 247d-6d(a)(l) immunity by listing those things that have "a causal relationship with the administration to or us by an individual of a covered countermeasure":

> ***including*** *a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.*

42 U.S.C. § 247d-6d(a)(2)(B) (emphasis added). This phrasing – "including" - *but not* "including without limitation" - suggests that the list is exhaustive and not open-ended. The list does not include consent, the act of obtaining consent, or procedures for obtaining consent. The *expressio unis est exclusio alterius* canon presumptively excludes consent from the list (*see also* discussion in section I.D *infra*).

The application of two additional canons reinforces this conclusion. First, "specific statutes prevail over general ones when the two are inconsistent." *Houlton Water Co. v. PUC*, 2016 ME 168, ¶ 21, 150 A.3d 1284 (quoting *Fleet Nat'l Bank v. Liberty*, 2004 ME 36, ¶ 10, 845 A.2d 1183 and 2B Singer & Singer, *Sutherland Statutory Construction* § 51:2 at 215 (7th

ed. 2012) ("If an irreconcilable conflict does exist between two statutes, the more specific statute controls over the more general one....")). 21 U.S.C. § 360bbb-3 is a highly specific statutory provision dealing exclusively with the EUA process, products and environment. 42 U.S.C. § 247d-6d, enacted later in time, is a generalized statute that applies to a range of medical products, including inter alia those that have full FDA approval. Secondly, 21 U.S.C. § 360bbb-3 and 42 U.S.C. § 247d-6d ought not be interpreted in a manner that renders § 360bbb-3(e)(l)(A)(ii)(III) "surplusage". *In re Jillian T.*, 2020 ME 54, ¶ 7, 230 A.3d 937.

### B. The PREP Act Must be Construed in a Manner that Avoids Absurd, Illogical or Inconsistent Results

"In reviewing the plain language of a statute, we examine the statute in the context of the entire statutory scheme and will construe it so as 'to avoid absurd, illogical or inconsistent results.'" *Convery v. Town of Wells*, 2022 ME 35, ¶ 10, 276 A.3d 504 (quoting *Urrutia v. Interstate Brands Int'l*, 2018 ME 24, ¶ 12, 179 A.3d 312). Appellees' proposed broad construction of the immunity conferred by § 247d-6d(a)(l) works absurd, illogical and inconsistent results. For example, if their interpretation is correct, then:

- "Covered persons" can willfully, knowingly and intentionally physically force others over their objections to be injected with COVID-19 vaccines, and provided no serious physical injury or

death can be proven, they cannot be sued, and their grievous wrongs cannot even form the basis for a claim submitted to the Covered Countermeasure Process Fund ("CCPF") which limits "covered injur[ies]" to "serious physical injury and death". 42 U.S.C. § 247d-6e(e)(3). App. 64.

- "Covered persons" can willfully, knowingly and intentionally deceive others into being injected with COVID-19 vaccines (perhaps by misrepresenting them as other vaccines or treatments), and provided no serious physical injury or death can be proven, they cannot be sued, and their grievous wrongs cannot even form the basis for a claim submitted to the CCPF.
- "Covered persons" can arbitrarily, and even with a discriminatory motive, elect to inject men with a full dose of COVID-19 vaccines, and women with only a fractional dose, defective dose or no dose; or elect to inject only Christians with a full dose of COVID-19 vaccines, and Jews with only a fractional dose, defective dose or no dose; or elect to inject only Caucasians with a full dose of COVID-19 vaccines, and African Americans with only a fractional dose, defective dose or no dose; and provided no serious physical injury or death can be

proven, they cannot be sued, and their grievous wrongs cannot even form the basis for a claim submitted to the CCPF.

- If, during the school vaccine clinic on November 12, 2021, Appellees, without consent, injected J.H. with both (1) a standard measles, mumps and rubella vaccine, and (2) the Pfizer-BioNTech COVID-19 vaccine, then they could be sued under state common law of tort for the former injection, but not for the latter injection simultaneously administered in the same circumstances.

The arguments that Appellees advance to shelter from liability for their non-consensual vaccination of J.H., a 5-year-old child with a learning disability, are the same arguments that lead to these absurd and inconsistent results. Construing the PREP Act in the manner proposed by Claimants, on the other hand, leads to no absurd or inconsistent results. It is neither absurd nor inconsistent to honor and preserve the right to refuse injection with intrinsically experimental medical products, and allow claims based on a failure to obtain the type of minimal, basic consent described in 21 U.S.C. § 360bbb-3(e)(l)(A)(ii)(III) ("the option to accept or refuse"), when settled common law, constitutional law and international law demand even more fulsome "informed consent" as discussed *infra*.

### C. The Prep Act Must be Construed in a Manner that Does Not Violate the Customary International Law Norm Prohibiting Non-Consensual Human Medical Experimentation

Customary international law prohibits non-consensual human medical experimentation. *Abdullahi v. Pfizer*, 562 F.3d 163, 178 (2nd Cir. 2009) ("The history of the norm in United States law demonstrates it has been firmly embedded for more than 45 years and - except for our dissenting colleague - its validity has never been seriously questioned by any court."). The *Abdullahi* court cites numerous sources of the norm, among them the Nuremberg Code as a primary source. *Id.* at 178-179. The First Principle of the Nuremberg Code is that "[t]he voluntary consent of the human subject is absolutely essential." *United States v. Brandt*, 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. I 0, 179 (1949). The Nuremberg Code elaborates on this Principle as follows:

> *This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.*

*Id.*

The COVID-19 vaccines are EUA products, and as EUA products they are intrinsically experimental, entering the market without FDA approval

or any of the safeguards afforded by the traditional FDA approval pathway. App. 59. Moreover, COVID-19 is the result of a novel coronavirus, SARS-CoV-2. App. 66. When it emerged as a pandemic in March 2020, no known alternative vaccine or treatment existed for this novel disease. *Id.* The COVID-19 vaccines were developed and presented for approval at "warp speed," within months of the federal declaration of emergency. *Id.* The federal government harvested vast amounts of data regarding the uptake, safety, efficacy and adverse events caused by the experimental COVID-19 vaccines following their release into the market, through multiple reporting mechanisms. App. 66-67. Accordingly, to the extent that the PREP Act abrogates the legal requirement of consent prior to injection with a COVID-19 vaccine, it violates the *jus cogens* norm prohibiting non-consensual human medical experimentation.

"It has been a maxim of statutory construction since the decision in *Murray v. The Charming Betsy*, 2 Cranch 64, 118 (1804), that 'an act of congress sought never to be construed to violate the law of nations, if any other possible construction remains ....'" *Weinberger v. Rossi*, 456 U.S. 25, 32 (1982). This Court can reject the construction of the PREP Act urged by Appellees, and choose another, one that respects and does not violate

international law. Applying the *Charming Betsy* canon, since this Court *can* adopt an alternate construction, it *should*.

### D. The Prep Act Must be Construed in a Manner that Does Not Derogate from the Common Law

The Supreme Court has observed:

> *The informed consent doctrine has become firmly entrenched in American tort law. The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment.*

*Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 270 (1990) (internal citations omitted). The Law Court has long recognized the doctrine of informed consent as an actionable species of medical negligence. In *In re Gardner*, the leading "right to die" case in Maine (decided before *Cruzan*) the Law Court noted that "Maine's law of informed consent supports the right of an individual to decline medical care" and that "[t]he personal right to refuse life-sustaining treatment is now firmly anchored in the common law doctrine of informed consent, which requires the patient's informed consent to the administration of any medical care." *In re Gardner*, 534 A.2d 947, 951 (Me. 1987) (emphasis added). In *Downer v. Veilleux*, the Law Court had held that "[E]very competent adult has the right to forego treatment, or even cure, if it entails what for him are intolerable consequences or risks, however unwise his sense of values may be to

others." *Downer v. Veilleux*, 322 A.2d 82, 90-91 (Me. 1974) (emphasis added).

When analyzing the interplay between 42 U.S.C. § 247d-6d and the common law, the Court must:

> *look to 'the well-established rule of statutory construction that the common law is not to be changed by doubtful implication [or] be overturned except by* ***clear and unambiguous*** *language, and that a statute in derogation of it will not effect a change thereof beyond that* ***clearly indicated*** *either by express terms or by necessary implication.'*

*Wilmington Sav. Fund Soc'y v. Needham,* 2019 ME 42, ¶ 16, 204 A.3d 1277 (quoting *Batchelder v. Realty Res. Hosp., LLC*, 2007 ME 17, ¶ 23, 914 A.2d 1116) (emphasis added). As previously discussed, Section 247d-6d defines the scope of § 247d-6d(a)(l) immunity by exhaustively listing those things that have "a causal relationship with the administration to or us by an individual of a covered countermeasure" and consent is not on the list (*see supra* section I.A).

At best, the scope of § 247d-6d(a)(l) immunity is ambiguous, not "clear and unambiguous." Further, the reference to 21 U.S.C. § 360bbb-3 that appears in 42 U.S.C. § 247d-6d(i)(l)(B)(iii) removes any possibility that it is "clearly indicated" by express terms that Congress intended to abolish the doctrine of consent. Nor is it a necessary implication. In addition to claims for willful misconduct, death and serious physical injury, Congress

permitted a range of other claims to escape § 247d-6d(a)(l), which does not provide immunity against federal enforcement actions brought by the federal government, civil, criminal or administrative; suit and liability for claims under federal law for equitable relief; or claims brought in non-U.S. tribunals or under non-U.S. law. Why, then, is it necessarily the case that claims based on a complete failure to obtain consent are barred?

### E. The Prep Act Must be Construed in a Manner that Does Not Violate the Constitution

In Section III of their Opposition below, Appellants have shown that the PREP Act is "reasonably susceptible to a construction that renders it unconstitutional." *Smith v. Hawthorne*, 2007 ME 72, ¶ 28, 924 A.2d I051; App. [ ]. "When a statute is challenged as unconstitutional, trial courts "must construe a statute to preserve its constitutionality, or to avoid an unconstitutional application of the statute, if at all possible." *State v. Ingalls*, 2020 Me. Super. LEXIS 60, *7-8 (quoting *Nader v. Me. Democratic Party*, 2012 ME 57, ¶ 19, 41 A.3d 551). Further, "[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress." *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988). Appellees have produced no

evidence that the legislators and legislative committees responsible for the PREP Act intended to abolish the pre-existing constitutional right to reject medical interventions, especially those that are experimental medical products that are not FDA approved.

### F. Appellees' Caselaw Does Not Compel a Decision in their Favor

The cases cited by Appellees in Section B of their Motion to Dismiss emanate from New York, Kansas, Oklahoma, New Mexico and Vermont, not Maine, and none are binding on this Court. Further, none of them address the specific statutory and constitutional arguments articulated by Claimants in their Opposition below or in this appeal.

For example, the facts in *Parker v. St. Lawrence Cnty. Pub. Health Dept.*, 954 N.Y.S.2d 259 (N.Y. App. Div. 2012) are most analogous to the facts of this case, and *Parker* does reach the erroneous conclusion that actions based on a lack of consent are barred. However, it is a cursory opinion, and it rests on a citation to Sotomayor J.'s *dicta* in her dissent in *Bruesewitz v. Wyeth LLC*, 562 US 223,253, 131 S. Ct. 1068, 1088, 179 L Ed 2d 1 (2011). which involves the National Childhood Vaccine Injury Act of 1986, not the PREP Act. The dissent includes only a "by way of example" discussion of the PREP Act in the context of a claim based not on lack of consent, but on product "design" – which, unlike consent, is one of the

matters expressly listed in 42 U.S.C. § 247d-6d(a)(2)(8) as being within the scope of § 247d-6d(a)(l) immunity.

"The person asserting the affirmative defense of immunity bears the burden of proof." *Hilderbrand v. Wash. Cty. Comm'rs*, 2011 ME 132, ¶ 7, 33 A.3d 425; *see also McCandless v. Ramsey, 2019 ME 111, ¶¶ 12-13, 211 A.3d 1157.* The PREP Act does not contain language shifting this burden. For all of the foregoing reasons, Appellees have not met their burden of establishing immunity.

## II. The Superior Court Erred in Determining that the PREP Act Pre-empts Appellants' Claims

The preemption provision of the PREP Act states in relevant part:

> *no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that - (A) is different from, or is in conflict with, any requirement applicable under this section; and (B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing or administration by qualified persons of the covered countermeasure…*

42 U.S.C. § 247d-6d(b)(8).

Broad federal preemption of state law is highly disfavored. As the U.S. Supreme Court has emphasized, "[W]e have never assumed lightly that Congress has derogated state regulation, but instead have addressed claims

of pre-emption with the starting presumption that Congress does not intend to supplant state law." *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers, Ins.*, 514 U.S. 645, 654 (1995) (citations omitted) (emphasis added). Thus, "[i]f a federal law contains an express pre-emption clause, it does not immediately end the inquiry because **the question of the substance and scope of Congress' displacement of state law still remains**." *Altria Group, Inc. v. Good*, 555 U.S. 70, 76 (2008) (emphasis added).

In determining whether a state law is preempted, courts "wor[k] on the assumption that the historic police powers of the States [a]re not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *California Div. of Labor Standards Enforcement v. Dillingham Constr., N. A., Inc.*, 519 U.S. 316, 325, (1997) (internal quotation marks and citation omitted); *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) ("In all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.") (cleaned up and citations omitted); *Me. Forest Prods. Council v. Cormier*, 51 F.4th 1 (1st Cir. 2022).

Maine "in its fullest exercise of sovereignty has the inherent power to pass regulations designed to promote the public health, safety and welfare." *Me. Med. Ctr. v. Cote*, 577 A.2d 1173, 1176 (Me. 1990). "[R]egulation of health, medicine, and the medical profession are areas in which the States have traditionally exercised authority." *Genbiopro, Inc. v. Sorsaia*, No. 3:23-0058, 2023 U.S. Dist. LEXIS 149195, at *40 (S.D. W. Va. Aug. 24, 2023). In the legitimate exercise of its police power, Maine has permitted common law tort claims to proceed against healthcare professionals who fail or refuse to obtain patient consent prior to a medical intervention, subject to certain tort reform limitations including *inter alia* the interposition of medical malpractice screening panels. See Maine Health Security Act, 24 M.R.S. §§ 2501-2851. The regulation of its medical profession and of the claims that can be asserted against medical professionals is a field traditionally occupied by Maine. Thus the presumption against pre-emption applies.

Further, the Supreme Court has cautioned against strictly literal interpretations of the "related to" term in pre-emption clauses. Courts are not to read pre-emption clauses "to the furthest stretch of [their] indeterminacy." *Travelers Ins. Co.*, 514 U.S. at 655. As Justice Scalia warned, "everything is related to everything else." *Cal. Div. of Labor*

*Standards Enf't v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 335 (1997) ("[A]pplying the 'relate to' provision according to its terms was a project doomed to failure, since, as many a curbstone philosopher has observed, everything is related to everything else."). Instead, courts must look to Congress's statutory objectives to limit the scope of such clauses. *Travelers Ins. Co.* at 656 ("We simply must…look instead to the objectives of the…statute as a guide to the scope of the state law that Congress understood would survive.").

The PREP Act pre-emption clause defines the scope of its pre-emption with alist of matters subject to pre-emption, and consent is *not on the list*. 42 U.S.C. § 247d-6d(b)(8)(B). Further, it is not on the closed-ended list of matters within the scope of immunity set forth in another section of this statutory scheme, 42 U.S.C. § 247d-6d(b)(8)(B). The doctrine of consent is fundamental and entrenched in our law. If abolishing consent were among the critical objectives of the statute, surely that goal would have been expressly included in these lists by Congress.

The Superior Court, though, did not begin with (or even reference) this presumption against federal preemption in areas of traditional state concern. In addition to the regulation of health, medicine, and the medical profession, protections of the familial relationship and parental rights are

historically and traditionally within the realm of state law. *Cf., e.g., Sosna v. Iowa*, 419 U.S. 393, 404 (1975) (explaining that "regulation of domestic relations" is "an area that has long been regarded as a virtually exclusive province of the States") (*see also* discussion in section III.C *infra*). The U.S. Supreme Court has "consistently recognized that the whole subject of the domestic relations of husband and wife, parent and child, belongs to the laws of the States and not to the laws of the United States." *Rose v. Rose*, 481 U.S. 619, 625 (1987) (cleaned up, citations omitted, and emphasis added). Therefore, "[b]efore a state law governing domestic relations will be overridden, it must do major damage to clear and substantial federal interests." *Id.* (cleaned up, citations omitted, and emphasis added); *see Row v. Row*, 185 N.C. App. 450, 456, 650 S.E.2d 1, 4 (2007) (quoting *Rose v. Rose*). Rather than read the PREP Act to avoid friction between a federal statute and the longstanding protection of fundamental parental liberties by a state—as the U.S. Supreme Court has repeatedly instructed—the Superior Court here has brought state and federal law into direct conflict and resolved that dispute against the most sacred of constitutionally protected liberty interests.

## III. The Superior Court Erred in its Application of the Doctrine of Constitutional Avoidance

The Superior Court appears to have understood the canon as an instruction to avoid considering constitutional questions, and has suggested that it should not consider those questions unless articulated in the Notice of Claim. App. 16.

However, the U.S. Supreme Court has explained that the canon of constitutional avoidance is not an instruction to courts to avoid taking up constitutional questions, as the Superior Court appears to believe, rather it "is a tool for choosing between competing plausible interpretations of a statutory text, resting on the reasonable presumption that Congress did not intend the alternative which raises serious constitutional doubts." *Clark v. Martinez*, 543 U.S. 371, 377-378 (2005). Further, "when deciding which of two plausible statutory constructions to adopt, a court must consider the necessary consequences of its choice. If one of them would raise a multitude of constitutional problems, the other should prevail - - whether or not those constitutional problems pertain to the particular litigant before the court." *Id.* at 380-381.

### A. PREP Act Immunity Deprives Claimants of their Property Right in their Claims and their Right to Procedural Due Process

Legal claims - choses in action - are constitutionally protected property rights. *See, e.g., Tulsa Professional Collection Services. v. Pope*,

485 U.S. 478, 485 (1988) ("Little doubt remains that [a cause of action] is property protected by the Fourteenth Amendment."); *Adams v. Palmer*, 51 Me. 480, 493 (1863) ("A right to reduce a chose in action to possession, is one thing, and a right to the property which is the result of the process by which the chose in action has been reduced to possession, is another and different thing. But they are both equally vested rights."). This is so before the legal claim has been crystallized in a judgment, and even before it has been filed with a court. *Pritchard v. Norton*, 106 U.S. 124, 132 (1882). Preclusion law, class action law and bankruptcy law recognize and protect rights in legal claims that have not been liquidated, even ones that ultimately may prove to be without merit and result in no compensation. *See, e.g.*, *Taylor v. Sturgell*, 553 U.S. 880, 892 (2008) (preclusion); *Phillips Petroleum Co. v. Shutts*, 472 U.S. at 797, 808 (1985) (class actions); 11 U.S.C. § 54l(a)(l) (2012); *Parker v. Goodman*, 499 F.3d 616, 624-25 (6th Cir. 2007) (bankruptcy).

Since Appellants have not alleged "willful misconduct" or that their injuries constitute "serious physical injury or death", the limited alternative *fora* provided by Congress in 42 U.S.C. §§ 247d-6d(d) and (e) (suit on a federal cause of action in the United States District Court for the District of Columbia, provided that plaintiff can establish "willful misconduct" by clear

and convincing evidence and "serious physical injury or death") and § 247d-6e (a claim before the CCPF for "serious physical injury or death") are foreclosed. Appellants cannot sue in federal court, and they are ineligible to file a claim with the CCPF. App. 82 (demonstrative chart). Therefore, a PREP Act construction that confers immunity on Appellees or pre-empts Appellants' claims works an unconstitutional taking of Appellants' property interests in their claims.

The Due Process Clauses of the Maine and Federal Constitutions guarantee due process before depriving a citizen of a property right, *Balian v. Bd of Licensure in Med.*, 1999 ME 8, ¶¶ 10-11, 722 A.2d 364, and there has been none here.

While Congress has the power to limit the jurisdiction of courts, it cannot determine what cases courts may hear in a way that violates other constitutional provisions. Many scholars have agreed that the Constitution provides limitations on the power to restrict court jurisdiction. *See, e.g.*, Lawrence Gene Sager, *Foreword: Constitutional Limitations on Congress' Authority to Regulate the Jurisdiction of the Federal Courts*, 95 Harv. L. Rev. 17, 42 (1981) ("Congress can substantively restrict the jurisdiction of the Supreme Court and of the lower federal courts. When it does so, however, it is fully bound by the constraints of the Constitution.");

Theodore Eisenberg, *Congressional Authority to Restrict Lower Federal Court Jurisdiction*, 83 Yale L.J. 498, 514 (1974) ("While Congress does not have unfettered control over lower court jurisdiction such that it could in effect abolish the courts by obliterating their jurisdiction, it is also clear that some degree of congressional control, consistent with the Constitution, is valid.").

In *Battaglia v. Gen. Motors Corp.*, the Second Circuit examined the Portal-to-Portal Act of 1947, 24 Pub. L. No. 49, ch. 52, § 2(d), 61 Stat. 84, 86 (1947) (codified at 29 U.S.C. § 252(d)) (2012), which stripped all state and federal courts of jurisdiction to entertain due process challenges to the substantive provisions of the statute, which in turn defined compensable working time for purposes of the Fair Labor Standards Act in a way that arguably disturbed vested rights under earlier judicial decisions. 169 F.2d 254, 255- 256 (2d Cir. 1948). In a widely cited opinion, the court held that the jurisdiction-stripping provision would be invalid if the underlying substantive provision violated due process:

> *We think, however, that the exercise of Congress of its control over jurisdiction is subject to compliance with at least the requirements of the Fifth Amendment. That is to say, while Congress has the undoubted power to give, withhold, and restrict the jurisdiction of courts other than the Supreme Court, it must not so exercise that power as to deprive any person of life, liberty, or property without due process of law or to take private property without just compensation.*

169 F.2d at 257.

Much more recently, the Supreme Court narrowly construed a federal statute granting discretion to the director of the Central Intelligence Agency in making certain employment decisions, "in part to avoid the 'serious constitutional question' that would arise if a federal statute were construed to deny any judicial forum for a colorable constitutional claim." *Webster v. Doe*, 486 U.S. 592, 603 (1988). Commenting on this decision, one commentator noted that "[t]]here is a strong argument that due process would be violated if the effect of the jurisdictional restriction is that no court, state or federal, could hear a constitutional claim." Erwin Chemerinsky, FEDERAL JURISDICTION § 3.3 at 201, 210 (6th ed. 2012). And speaking more generally, the same commentator pointed out that "on several occasions the Supreme Court went out of its way to narrowly construe federal statutes that appeared to preclude all judicial review."

### B. PREP Act Immunity Infringes upon the Constitutional Right of Appellant J.H. to Bodily Integrity

If the PREP Act were construed to permit Defendants to inject J.H. with a COVID-19 vaccine without consent and without providing any avenue for legal redress, the statute would violate his substantive due process right to bodily integrity under the Fifth Amendment. *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997) ("the 'liberty' protected by the Due

Process Clause [of the Fourteenth Amendment] includes the right[ ] ... to bodily integrity").

In *Cruzan v. Dir., Mo. Dep't of Health*, 491 U.S. 261 (1990), the Supreme Court found that the right to reject unwanted medical treatment is an aspect of the fundamental right to bodily integrity. Chief Justice Rehnquist observed:

> *This notion of bodily integrity has been embodied in the requirement that in-formed consent is generally required for medical treatment...The informed consent doctrine has become firmly entrenched in American tort law...The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment....[T]he common law doctrine of informed consent is viewed as generally encompassing the right of a competent individual to refuse medical treatment....The principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions.*

*Id.* at 269-278 (internal citations and quotations omitted). In the words of Justice O'Connor, "the liberty guaranteed by the Due Process Clause must protect, if it protects anything, an individual's decision to reject medical treatment...." *Id.* at 289. *Cruzan* also specifically noted that "'(t]he forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty.'" *Id.* at 278 (emphasis added) (quoting a case decided during the same term, *Washington v. Harper*, 494 U.S. 210, 221-222 (1990)).

The First Circuit has recognized the "intuitively obvious proposition" that "a person has a constitutionally protected interest in being left free by the state to decide for himself whether to submit to the serious and potentially harmful medical treatment that is represented by the administration of antipsychotic drugs." *Rogers v. Okin*, 634 F.2d 650, 653-654 (1st Cir. 1980).

The Law Court has come to the same conclusion (*see* discussion at section I.D *supra*).

This right to be free from unwanted medical intervention, including vaccination, must therefore be categorized as a fundamental liberty interest. It satisfies the test for classification as such an interest articulated by the U.S. Supreme Court in *Glucksberg* since it is "objectively, deeply rooted in this Nation's history and tradition" and is carefully described. 521 U.S. at 720-721.

As noted in *Glucksberg*, the infringement of a fundamental liberty interest normally calls for strict scrutiny, requiring the infringement to be narrowly tailored to serve a compelling state interest. *Id.* However, as the Appellees and their caselaw remind us, the provisions of the PREP Act have been universally described as "sweeping" and "broad", and thus cannot possibly survive heightened review.

In *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), the U.S. Supreme Court reviewed a Massachusetts statute requiring smallpox vaccination. Commentators frequently cite to *Jacobson* for the proposition that vaccine mandates are subject to "rational basis" review, but that term did not exist in 1905, and the *Jacobson* court did not describe its analysis using that term. Further, though *Jacobson* predates the Supreme Court's twentieth century development of substantive due process law in cases like *Cruzan*, the Court nevertheless scrutinized the medico-scientific understanding of the smallpox epidemic and the vaccines then in use. *Id.* at 24. It is very doubtful that Appellees' construction of the PREP Act would survive even *Jacobson* review. Smallpox threatened public health more directly and substantially than COVID-19, since during the smallpox era the fatality rate among the unvaccinated was approximately 30%, whereas the overall COVID-19 case fatality rate in the United States is just 1.1%. App. 77. By 1905, smallpox vaccines had been in use for nearly a century, *Id.*, but as discussed *infra* the COVID-19 vaccines are fairly described as new and experimental. Finally, rather than immunizing vaccine administrators for non-consensual vaccination, the Massachusetts law preserved informed consent. It required residents either to obtain free vaccination or

revaccination against smallpox, or to pay a fine of $5 (approximately $150 in today's dollars) for non-compliance. *Id.*

### C. PREP Act Immunity Infringes upon the Parental Rights of Appellants Siara Jean Harrington and Jeremiah Hogan

If the PREP Act were construed to permit Defendants to inject J.H. with a COVID-19 vaccine without consent and without providing any avenue for legal redress, the statute would violate the substantive due process right of J.H.'s biological parents to make decisions concerning the care, custody and control of J.H. under the Fifth Amendment.

In 2000, the U.S. Supreme Court stated that the interest of parents in the care, custody and control of their children is "perhaps the oldest of the fundamental liberty interests" recognized by the Court. *Troxel v. Granville*, 530 U.S. 57, 65-66 (2000). *Troxel* followed at least two earlier decisions protecting parental rights. *See Stanley v. Illinois*, 405 U.S. 645, 651(1972) (the rights to conceive and to raise one's children are "essential," "basic civil rights of man" and "far more precious … than property rights"); *Wisconsin v. Yoder*, 406 U.S. 205, 232 (1972) ("The history and culture of Western civilization reflect a strong tradition of parental concern for the nurture and upbringing of their children. This primary role of the parents in the upbringing of their children is now established beyond debate as an enduring American tradition."). The Supreme Court's jurisprudence

"historically has reflected Western civilization concepts of the family as a unit with broad parental authority over minor children." *Troxel,* 530 U.S. at 65-66 (citing *Santosky v. Kramer*, 455 U.S. 745, 753 (1982)). Making medical decisions for minor children is obviously an important component of that broad parental authority.

The constitutionally protected right of parents in the care, custody and control of their children has been recognized repeatedly by the Law Court, most recently in *In re Child of Ryan F.*, 2020 ME 21, ¶ 19, 224 A.3d 1051 ("It is well established that parents have a fundamental liberty interest to make decisions concerning the care, custody, and control of their children, and that such a fundamental and important right to raise one's children is protected by the due process clause of both the United States Constitution and the Maine Constitution.").

Again, *Glucksberg*'s requirement of a "careful description" of the asserted fundamental liberty interest is easily met in this case. As parents, Appellants Siara Harrington and Jeremiah Hogan have the right to decide which medical treatments their minor child receives and which treatments their minor child does not receive. J.H. received a medical treatment -- an injection with a COVID-19 vaccine -- without their consent. App. 21-22. If the PREP Act is construed to allow this to occur consequence-free, the

statute is unconstitutional as applied to the facts of this case. And as with the infringement upon J.H.'s own liberty rights, there is no legitimate governmental interest, let alone a compelling one, in facilitating or allowing parents to be deprived of their constitutional rights in this way, whether or not a "public health emergency" has been declared.

## CONCLUSION

For all of the foregoing reasons, the order dismissing the Notice of Claim should be vacated and this case should be remanded to the Superior Court for further proceedings pursuant to the Maine Health Security Act.

Dated at Portland, Maine, this 1st day of August, 2024

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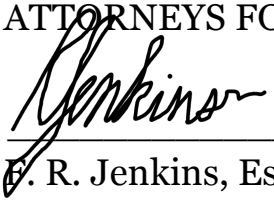

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**CERTIFICATE OF SERVICE**

I hereby certify that on August 1, 2024, I caused two copies of the Brief of Appellants to be served upon the following counsel of record via hand delivery, and one electronic copy via e-mail:

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