APPENDIX

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APPENDIX A

MAINE SUPREME JUDICIAL COURT

Decision: 2025 ME 22
Docket: Lin-24-209
Argued: November 12, 2024
Decided: March 4,2025

Panel: STANFILL, C.J., and MEAD, HORTON, CONNORS, LAWRENCE, AND DOUGLAS, JJ.

JEREMIAH HOGAN et al.
v.
LINCOLN MEDICAL PARTNERS et al.

HORTON, J.

[¶1] Jeremiah Hogan, Siara Jean Harrington, and their child (collectively, Hogan) appeal from a judgment of the Superior Court (Lincoln County, *Billings, J.*) dismissing—based on federal statutory immunity—a notice of claim alleging that Lincoln Medical Partners; MaineHealth, Inc.; and Andrew Russ, M.D. (collectively, Lincoln Medical) committed various torts when Russ administered a COVID-19 vaccine to the child at a school clinic without parental consent. Because we agree with the trial court that federal law confers immunity on Lincoln Medical and preempts state law that would otherwise allow Hogan to sue, we affirm the judgment.

I. BACKGROUND

[¶2] We draw the facts from Hogan's notice of claim, viewed in the light most favorable to Hogan. *See Dutil v. Burns*, 674 A.2d 910, 911 (Me. 1996). At a school clinic held in November 2021, Lincoln Medical administered the Pfizer-BioNTech mRNA COVID-19 vaccine to Jeremiah Hogan and Siara Jean Harrington's five-year-old child without having obtained parental consent to the vaccination.

[¶3] On May 4, 2023, Hogan filed a notice of claim pursuant to the Maine Health Security Act, *see* 24 M.R.S. § 2853 (2024), in the Superior Court against the doctor who administered the vaccine (Russ), the corporation for which the doctor worked (Lincoln Medical Partners), and that corporation's parent company (MaineHealth, Inc.). Framed as a multi-count civil complaint for medical malpractice, Hogan's notice alleged claims against all defendants on behalf of the child for professional negligence, systemic professional negligence, battery, and false imprisonment. The notice alleged three additional tort claims against all defendants on behalf of the parents: intentional infliction of emotional distress, negligent infliction of emotional distress, and tortious interference with parental rights. Finally, the notice alleged negligent supervision against the corporate defendants on behalf of the child and parents.

[¶4] After the court (*Mullen, C.J.*) appointed a chair for the prelitigation screening panel, Lincoln Medical moved to dismiss the notice of claim, arguing that it was immune from suit under the Federal Public Readiness and Emergency Preparedness (PREP) Act; see 42 U.S.C.A. §§ 247-6d, 247-6e (Westlaw through Pub. L. No. 118-158). The screening panel chair ordered that the matter be

referred to the Superior Court for consideration of the motion.

[¶5] After receiving an opposing memorandum from Hogan and a reply memorandum from Lincoln Medical, the court (*Billings, J.*) entered a judgment on April 18, 2024, granting Lincoln Medical's motion to dismiss. The court interpreted the federal statute to provide immunity to each named defendant, with no applicable exceptions.

[¶6] Hogan timely appealed. *See* 14 M.R.S. § 1851 (2024); M.R.App.P.2B(c)(1).

II. DISCUSSION

[¶7] We begin by summarizing the federal statutes at issue. The PREP Act provides for immunity as follows:

> Subject to the other provisions of this section, 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.A. § 247d-6d(a)(1).[1] "The immunity ... applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure ..." *Id.* §

[1] The term "loss" includes "any type of loss," including emotional injury and the fear of injury. 42 U.S.C.A. § 247d-6d(a)(2)(A) (Westlaw through Pub. L. No. 118-158).

247d-6d(a)(2)(B). One "covered countermeasure" is a drug or biological product "authorized for emergency use" under specified statutes, including 21 U.S.C.A. § 360bbb-3 (Westlaw through Pub. L. No. 118-158) (codification of section 564 of the Federal Food, Drug and Cosmetics Act, added by Pub. L. No. 108-136 (Nov. 24, 2003)). 42 U.S.C.A. § 247d-6d(i)(1)(C). One type of "covered person" is "a qualified person who prescribed, administered, or dispensed such countermeasure." *Id.* 42 U.S.C.A. § 247d-6d(i)(2)(B)(iv). "[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" is a "qualified person" under the statute. *Id.* § 247d-6d(i)(8)(A). The statute's definition of "person" includes both individuals and corporations. *Id.* § 247d-6d(i)(5).

[¶8] For immunity to apply, the countermeasure must have been administered to a member of the population specified in a declaration issued by the Secretary of Health and Human Services to address the category of disease specified in the declaration. *Id.* § 247d-6d(a)(3)(B), (a)(3)(C)(i), (b). It must also have been administered during the declaration's effective period and in a location covered by the declaration. § 247d-6d(a)(3)(A), (a)(3)(C)(ii).

[¶9] As an exception to the immunity conferred in § 247d-6d(a)(1), Congress has authorized "an exclusive Federal cause of action against a covered person *for death or serious physical injury proximately caused by willful misconduct* ... by such covered person." *Id.* § 247d-6d(d)(1)(emphasis added). For purposes of the statute, a "serious physical injury" is one that

> **(A)** is life threatening;
> **(B)** results in permanent impairment of a body function or permanent damage to a body structure; or
> **(C)** 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). "[W]illful misconduct" under the statute is an act or ommission that is 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).

[¶10] The plaintiff has the "burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury." Id. § 247d-6d(c)(3). If a person suffers serious physical injury or death, suit may generally not be commenced until after the plaintiff has pursued recovery from a "Covered Countermeasure Process Fund," which is designed to compensate those who have encountered adverse effects from countermeasures. *Id.* § 247d-6e(a), (b)(1), (5)(A), (d)(1), (e)(3).

[¶11] The provision in the PREP Act conferring immunity on "covered persons" includes a provision preempting conflicting state law:

> **Preemption of State law**
>
> During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that-
>
> > **(A)** is different from, or is in conflict with, any requirement applicable under this section; and
> >
> > **(B)** relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act.

Id. § 247d-6d(b)(8).

[¶12] Hogan does not dispute either that the Secretary issued a declaration or that the vaccine was administered by a qualified person as a countermeasure during the time and in a location covered by the declaration. See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (Mar. 10, 2020). Having filed

the claims in state court, Hogan cannot and does not contend that the claims fall within the sole exception to the immunity conferred in § 247d-6d(a)(1)—the authorized "exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct ... by such covered person." *Id.* § 247d-6d(d)(1). The issue is therefore limited to whether the federal immunity statute immunizes Lincoln Medical against Hogan's claims and preempts state law that would otherwise allow a lawsuit.

[¶13] In general, "the construction of federal regulations or policies [is a] matter[] of federal rather than state law." *Littlefield v. State, Dep't of Hum. Servs.*, 480 A.2d 731, 736 (Me. 1984). Thus, in determining whether the federal immunity provision constrains state actions, we interpret the statute with the goal "to effectuate the legislative intent and purposes of the United States Congress." *Id.*

[¶14] The starting point in discerning congressional intent is the existing statutory text. ... It is well established that when the statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms." *Lamie v. U.S. Tr.,* 540 U.S. 526, 534 (2005) (quotation marks omitted); *see also Wisconsin Cent. Ltd. v. United States,* 585 U.S. 274, 284 (2018) ("[W]ords generally should be interpreted as taking their ordinary, contemporary, common meaning ... at the time Congress enacted the statute." (quotation marks omitted)). "The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a

whole." *Robinson v. Shell Oil Co.,* 519 U.S. 337, 341 (1997).

A. Immunity

[¶15] The language at issue here is plain, broad, and unambiguous with respect to immunity from tort liability. A covered person is immune from suit and liability under state law "with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration" of the emergency-authorized countermeasure—here, the vaccine. 42 U.S.C.A. § 247d-6d(a)(1); *see id.* § 247d-6d(i)(1)(C). The immunity "applies to any claim for loss that has a causal relationship with the administration to ... an individual of" the vaccine. *Id.* § 247d-6d(a)(2)(B).

[¶16] Hogan alleges only injuries that were caused by the administration of the vaccine. Even construed strictly because it is in derogation of the common law, the immunity statute is clearly broad in scope. *See Jamison v. Encarnacion*, 281 U.S. 635, 640 (1930) ("The rule that statutes in derogation of the common law are to be strictly construed does not require such an adherence to the letter as would defeat an obvious legislative purpose or lessen the scope plainly intended to be given to the measure."); *Johnson v. S. Pac. Co.*, 196 U.S. 1, 17 (1904) ("[C]onceding that statutes in derogation of the common law are to be construed strictly, [t]hey are also to be construed sensibly, and with a view to the object aimed at by the legislature." (quotation marks omitted)). We interpret the PREP Act's immunity provision bassed on its plain language and conclude that all defendants are immune from Hogan's "claims for loss caused by, arising out of, relating to, or resulting from the administration" of the vaccine to

the child. 42 U.S.C.A § 247d-6d(a)(1). This interpresentation is consistent with other state appellate courts' construction of the immunity provision when parents alleged torts arising from a lack of consent to vaccinate children. *See Parker v. St. Lawrence Cnty. Pub. Health Dep't,* 954 N.Y.S.2d 259, 260–261, 263 (N.Y. App. Div. 2012); *M.T. v. Walmart Stores, Inc.*, 528 P.3d 1067, 1071, 1080–81 (Kan. Ct. App. 2023); *deBecker v. UHS of Del., Inc.*, 555 P.3d 1192, 1203 (Nev. 2024); *Happel v. Guilford Cnty. Bd. of Educ.*, 899 S.E.2d 387, 389–90, 393–94 (N.C. Ct. App. 2024); *Politella v. Windham Se. Sch. Dist.,* 325 A.3d 88, 91–92, 98 (Vt. 2024).

[¶17] Hogan argues that this interpretation of federal law fails to harmonize the statute with the Emergency Use Authorization (EUA) statutes allowing the use of otherwise unapproved drugs or biological products that it is reasonable to believe may be effective during a public health emergency declared by the Secretary. *See* 21 U.S.C.A. § 360bbb-3(c). The PREP Act references the EUA statute for purposes of explicitly including, within the scope of the term "covered countermeasure," a countermeasure authorized for emergency use.[2] 42 U.S.C.A. § 247d-6d(i)(1)(C); 21 U.S.C.A. § 360bbb-3. Accepting the allegations of the notice of claim as true, the provider's failure to obtain parental consent in this

[2] The statute allowing EUAs requires the Secretary of Health and Human Services to establish conditions on the authorization, to the extent practicable, "to ensure that individuals to whom the product is administered are informed ... of the option to accept or refuse administration of the product." 21 U.S.C.A. § 360bbb-3(e)(1)(A)(ii)(III) (Westlaw through Pub. L. No. 118-158). Although the statute imposes a burden on the Secretary, it does not create a cause of action to enforce that obligation, and in any event, Hogan has not sued the Secretary of Health and Human Services.

individual instance does not make the administered vaccine—approved for emergency use under § 360bbb-3—any less of a "covered countermeasure" under § 247d-6d(i)(1)(C).

[¶18] The PREP Act also does not, as Hogan asserts, violate international law prohibiting non-consensual human medical experimentation. The administration of a vaccine approved for emergency use is not an experiment but an authorization to use a countermeasure that has been approved to combat a public health emergency. See 21 U.S.C.A. § 360bbb-3. The notice of claim alleges no facts, such as the subsequent monitoring or testing of the child, that would suggest medical experimentation.[3]

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[3] Although Hogan also contends that the immunity provision is, as applied, inconsistent with constitutional principles of due process, the fundamental rights of parents to make decisions regarding the care and management of their children, *see Troxel v. Granville*, 530 U.S. 67, 66 (2000) are not absolute, *see Dorr v. Woodard*, 2016 ME 79, ¶ 13, 140 A.3d 467, and the federal government has a compelling interest in legislating to address public health emergencies, *see Roman Cath. Diocese of Brooklyn v. Cuomo*, 592 U.S. 14, 18 (2020) ("Stemming the spread of COVID-19 is unquestionably a compelling interest ..."). We reach the same conclusion whether the statute is subject to rational-basis or strict-scrutiny review. *See Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905) (applying a rational-basis analysis to determine whether a state vaccine requirement was constitutional); *Pitts v. Moore*, 2014 ME 59, ¶ 12 & n.3, 90 A.3d 1159 (setting forth the strict scrutiny standard requiring a compelling government interest for the government to interfere with the fundamental right to parent). As to Hogan's assertion that the immunity provision violates the child's constitutional right of bodily integrity, "[i]n the context of COVID-19, courts across the country have concluded that *Jacobson* established that there is no fundamental right to refuse vaccination." *Williams v. Brown*, 567 F. Supp. 3d 1213, 1226 (D. Or. 2021); *see also Norris v. Stanley*, 567 F. Supp. 3d 818, 821 (W.D. Mich. 2021) ("Plaintiff is absolutely correct that

B. Federal Preemption

[¶19] Hogan argues that the federal immunity statue has not preempted state common law. "A conflict warranting preemption may be direct in that the state regulation obviously contradicts federal regulation, or it may arise from congressional intent; either express or implied, to occupy a particular area." *State v. Lauriat*, 561 A.2d 496, 496–97 (Me. 1989) (quotation marks omitted). "Preemption, however, is not a favored concept, and federal regulation will be deemed to be preemptive of state regulatory powers only if grounded in persuasive reasons—either the nature of the regulated subject matter permits no other conclusion or that Congress has unmistakably so ordained." *Id.* (quotation marks omitted).

[¶20] "In determining whether a federal law preempts a state law cause of action, the determinative inquiry is 'Congress' intent in enacting the federal statute at issue.'" *Parker*, 954 N.Y.S.2d at 261 (quoting *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983)). "Where, as here, a federal law contains an express preemption clause, "[t]he 'focus [is] on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent.'" *Id.* (quoting *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 594 (2011)).

[¶21] The statute at issue here plainly provides that no state may "enforce" or "continue in effect" laws that "relate[] to" the administration of covered countermeasures by qualified persons and differ from or conflict with the federal statute. 42 U.S.C.A. §

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she possesses those rights [to privacy and bodily integrity], but there is no fundamental right to decline a vaccination.")

247d-6d(b)(8). The Supreme Court has recognized that "the phrase 'relate to' in a preemption clause 'express[es] a broad pre-emptive purpose.'" *Coventry Health Care of Mo., Inc. v. Nevils*, 581 U.S. 87, 95–96 (2017) (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992)). Although Hogan is correct that there are limits on the extent to which a state law will be regarded as "relat[ing] to" a specific federal measure, see *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655–56 (1995) (quotation marks omitted), Maine's common law torts clearly fall within the PREP Act's prohibition to the extent that they allow recovery for claims against defendants administering vaccines who, under the federal statute, are immune from suit or liability, see 42 U.S.C.A. § 247d-6d(a)(1), (b)(8).

The entry is:

Judgment affirmed.

F.R. Jenkins, Esq. (orally), Meridian 361 International Law Group, PLLC, Portland, and David E. Bauer, Esq., Portland, for appellants Jeremiah Hogan, Siara Jean Harrington, and their child.

Devin W. Deane, Esq., Noah D. Wuesthoff, Esq., and Joseph M. Movodones, Esq. (orally), Norman, Hanson & DeTroy, LLC, Portland, for appellees Lincoln Medical partners, MaineHealth, Inc., and Andrew Russ.

APPENDIX B

STATE OF MAINE LINCOLN, ss.	SUPEROR COURT CIVIL ACTION DOCKET NO. CV 23-13
SIARA JEAN HARRINGTON, et al., Claimants, v. ANDREW RUSS, M.D., et al., Respondents.	**ORDER ON RESPONDENTS' MOTION TO DISMISS**

INTRODUCTION

The matter before the court is Respondents Andrew Russ, M.D., Lincoln Health Medical Partners, Inc. ("Lincoln Health"), and MaineHealth, Inc.'s joint Motion to Dismiss Siara Jean Harrington, Jeremiah Hogan, and J.H.'s Notice of Claim pursuant to the Maine Health Security Act, 24 M.R.S. §§ 2501–2988, and Maine Rule of Civil Procedure 80M(b)(1). For the following reasons, the motion is granted.

BACKGROUND

This case involves the administration of a COVID-19 vaccine to a minor without parental consent. On November 12, 2021, the Miller School in Waldoboro held a COVID-19 vaccine clinic. (Notice of Claim ¶ 16.) The clinic was planned and promoted by Respondents, who sent out letters containing consent

forms and registration forms by mail and by text message. (*Id.* ¶¶ 16–18.) Ms. Harrington and Mr. Hogan declined to complete, sign, or deliver either form for their minor child, J.H. (*Id.* ¶ 19.) Despite the withholding of consent, on the day of the vaccine clinic, Respondent Russ administered to J.H. a Pfizer COVID-19 vaccine (*Id.* ¶ 21).)

On May 3, 2023, Claimants filed a Notice of Claim with Maine's Medical Malpractice Screening Panel, alleging four counts on behalf of J.H.: (I) Professional Negligence; (II) Professional Negligence (Systemic); (III) Battery; and (IV) False Imprisonment; three counts on behalf of Ms. Harrington and Mr. Hogan: (V) Intentional Infliction of Emotional Distress; (VI) Negligent Infliction of Emotional Distress; and (VII) Tortious Interference with Parental Rights; and one count on behalf of all Claimants: (VII) Negligent Supervision. Respondents' Motion to Dismiss was received by the Court on September 1, 2023.

STANDARD OF REVIEW

When ruling on a motion to dismiss for failure to state a claim pursuant to M.R. Civ. P. 12(b)(6), the court views the "facts alleged in the complaint as if they were admitted." *Nadeau v. Frydrych*, 2014 ME 154, ¶ 5, 108 A.3d 1254 (per curiam) (quotation marks omitted). A compliant must set forth the "elements of a cause of action or allege[] facts that would entitle the plaintiff to relief pursuant to some legal theory." *Id.* Facts are read in the light most favorable to the plaintiff. *Id.* "Dismissal is warranted only 'when it appears beyond a doubt that the plaintiff is not entitled to relief under any set of facts' that might be proved in support of the claim." *Halco*

v. Davey, 2007 ME 48, ¶ 6, 919 A.2d 626 (quoting *Johanson v. Dunnington*, 2001 ME 169, ¶ 5, 785 A.2d 1244). On the other hand, "a party may not ... proceed on a cause of action if that party's complaint has failed to allege facts that, if proved, would satisfy the element of the cause of action." *Burns v. Architectural Doors and Windows*, 2011 ME 61, ¶ 17, 19 A.3d 823.

Rule 8 requires: "a short and plain statement of the claim showing that the pleader is entitled to relief." M.R. Civ. P. 8(a). "Notice pleading requirements are forgiving; the plaintiff need only give fair notice of the cause of action by providing a short and plain statement of the claim showing that the pleader is entitled to relief." *Desjardins v. Reynolds*, 2017 ME 99, ¶ 17, 162 A.3d 228 (quotation marks omitted).

DISCUSSION

The Motion seeks dismissal on the basis that Respondents are immune from suit under the Public Readiness and Emergency Preparedness Act (the "PREP Act").[1] The PREP Act was enacted by

[1] As an initial matter, Claimants argue that the Motion is premature and that they should be entitled to limited discovery through the Panel proceedings prior to the Court's involvement. This argument has no merit. The Panel Chair has no jurisdiction to decide the defenses raised by Respondents. See M.R. Civ. P. 80M(e); *Frame v. Millinocket Reg'l Hosp.*, 2013 ME 104, ¶ 3, 82 A.3d 137 (absent agreement of the parties, the panel lacks jurisdiction to hear dispositive legal defenses); *Gafner v. Down E. Cmty. Hosp.*, 1999 ME 130, ¶ 30, 735 A.2d 969 ("if the claimant could not, under any set of facts make out a cause of action against the respondent, it would be senseless for the panel, the parties, and the court to go through the motions of adjudicating the claim."). Nor are Claimants entitled

Congress in December 2005 to encourage swift medical responses to public health emergencies by limiting liablity for losses related to those responses. *See Cannon v. Watermark Ret. Cmtys., Inc.,* 45 F.4th 137, 139 (D.C. 2022). In March 2020, the Secretary of the Department of Health and Human Services (the "Secretary") declared the COVID-19 pandemic to be a public health emergency under the PREP Act. *See* Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (March 17, 2020).

Under 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." 42 U.S.C. § 247d-6d(a)(1). "Loss" is defined broadly as "any type of loss" and includes "physical, mental, or emotional injury, illness, disability, or condition." *Id.* § 247d-6d(a)(2)(A). Immunity applies to all claims for loss that have "a causal relationship with the administration to or use by an individual of a covered countermeasure." *Id.* § 247d-6d(a)(2)(B). Here, Claimants allege the following types of loss: physical injury and severe emotional distress to J.H., (Notice of Claim ¶¶ 31, 34, 38, 41, 60), and severe emotional distress to Ms. Harrington and Mr. Hogan, (Notice of Claim ¶¶ 45, 51, 56, 60). These losses fall within the parameters of the statute, which provides immunity for both physical and emotional injury.

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to discovery on claims barred by the PREP Act. *See Bird v. State*, 2023 WY 102, ¶ 19, 537 P.3d 332, 337 (2023) (affirming trial court's decision to deny limited discovery to the plaintiffs based on PREP Act immunity).

"Covered countermeasure" is defined, in relevant part, as "a qualified pandemic or epidemic product," which include drugs and biological products used "to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic" or "to limit the harm such pandemic or epidemic might otherwise cause." 42 U.S.C. § 247d-6d(i)(1), (7). In June 2020, the Secretary issued an amendment clarifying that "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" constitutes a covered countermeasure. Second Amendment to Declaration Under the PREP Act, 85 Fed. Reg. 35100 (June 8, 2020). Claimants allege that J.H. was administered the Pfizer COVID-19 vaccine. That vaccine is a covered countermeasure. *Id.; see also M.T. ex rel. M.K. v. Walmart Stores, Inc.,* 528 P.3d 1067, 1075 (Kan. Ct. App. 2023) (finding that the Pfizer COVID-19 vaccine is a covered countermeasure).

"Covered person" is defined, in relevant part, as "a qualified person who prescribed, administered, or dispensed" a countermeasure. 423 U.S.C. § 247d-6d(i)(2)(B)(iv). A "person" can be "an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department." *Id.* § 247d-6d(i)(5). A "qualified person" is "a licensed health professional or other individual who is authorized to prescribe administer, or dispense" a countermeasure. *Id.* § 247d-6d(i)(8).

Dr. Russ, as a licensed health professional who administered a COVID-19 vaccine, is a covered person. Lincoln Health and MaineHealth are also covered persons, as entities authorized to prescribe, administer, or dispense vaccines. *Id.; see also Gerber*

v. Forest View Ctr., No. 21-cv-05359(KAM)(JRC), 2022 WL 3586477, at *3 (E.D.N.Y. Aug. 22, 2022) ("qualified person" includes "hospitals, nursing homes, and other entities"). Moreover, as the Notice of Claim alleges that all three Respondents were involved in planning the vaccine clinic (Notice of Claim ¶ 16), they are also all covered persons by way of being "program planners." 42 U.S.C. § 247d-6d(i)(2)(B)(iii); *see also Happel v. Guilford County*, __S.E.2d__, No. COA23-487, 2024 WL 925471, at *4 (N.C. Ct. App. Mar. 5, 2024) (finding that defendant medical society "is a covered person as a program planner that administered a vaccine clinic").

The only exception to immunity under the PREP Act is reserved for cases of death or serious physical injury caused by willful misconduct.[2] 42 U.S.C. § 247d-6d(d)(1). "Serious physical injury" is defined as 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." *Id.* § 247d-6d(i)(10). "Willful misconduct" is defined as an act or omission taken "intentionally to achieve a wrongful purpose," "knowingly without legal or factual justification," and "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*. § 274d-6d(c)(1)(A). Here, there are no allegations in the Notice of Claim that J.H. has suffered death or serious physical injury as defined by the statute or

[2] There is also an emergency fund, the "Covered Countermeasure Process Fund," through which individuals may obtain payments by engaging in an administrative process. *See id*. § 247d-6e. Willful misconduct is not required, but the claim for loss must still include death or serious physical injury. *Id.*

that his vaccination was the product of willful misconduct. Further, even if there were such allegations, any claim for relief under this exception must be brought exclusively in the United States District Court for the District of Columbia. *Id.* § 247d-6d(e)(1).

Courts in other jurisdictions have determined, under substantially similar circumstances, that the PREP Act provides immunity for the administration of vaccines without consent. M.T., 528 P.3d at 1070 (immunity under PREP Act for defendant on all claims related to the administration of a COVID-19 vaccine to a minor without parental consent); *Happel*, 2024 WL 925471, at *6 (same); *Politella v. Windham S.E. Sch. Dist.*, No. 22-CV-01707, 2022 WL 18143866, at *1, 3 (Vt. Super Ct. Dec. 28, 2022) (same); *Parker v. St. Lawrence Cnty. Pub. Health Dep't,* 102 A.D.3d 140, 141–42, 954 N.Y.S.2d 259 (N.Y. App. Div. 2012) (immunity under PREP Act for public health department on all claims related to the administration of the H1N1 influenza vaccine to a minor without parental consent); *Bird*, 537 P.3d at 336 (immunity under PREP Act for prison that injected incarcerated persons with the Janssen COVID-19 vaccine when the consent form stated that they would receive either Moderna or Pfizer); *Cowen v. Walgreen Co.*, No. 22-CV-157-TCK-JFJ, 2022 WL 17640208, at *2 (N.D. Okla. Dec. 13, 2022) (immunity under PREP Act for Walgreens on all claims related to the administration of a Moderna COVID-19 vaccine to a patient who was actually seeking a flu vaccine).

In *Politella*, plaintiff parents alleged that their six-year-old child was administered a COVID-19 vaccine without their consent during a state-sponsored vaccine clinic at the minor's school. 2022

WL 18143866, at *1. The school acknowledged the mistake and published an apology in the local newspaper. *Id.* The plaintiffs filed an eight-count complaint against the State of Vermont and the school district, alleging, in relevant part, violation of state healthcare laws, negligence, battery, and NIED. *Id.* at *2. The court found that the PREP Act was "patently applicable" to the plaintiffs' claims and dismissed the complaint. *Id.* at *3.

In *Happel*, plaintiff mother alleged that her 14-year-old son was administered a COVID-19 vaccine without her consent at a dual testing and vaccination facility at the minor's school. 2024 WL 925471, at *1. The minor was brought to the facility to receive a COVID-19 test and allegedly did not want the vaccine. *Id.* The mother filed a complaint against the board of education and the medical society, alleging battery and violations of state and federal constitutional rights. *Id.* The Court of Appeals of North Carolina determined that "the broad scope of immunity provided by the PREP Act ... shields Defendants ... from Plaintiffs' claims relating to the administration of the COVID-19 vaccine." *Id.* at *6.

In *M.T.,* plaintiff mother alleged that her 15-year-old daughter was administered a COVID-19 vaccine without the mother's consent at a Walmart pharmacy. 528 P.3d at 1071. The minor had gone to the pharmacy wth her older brother, purposefully seeking a COVID-19 vaccine. *Id.* The pharmacist allegedly told the minor that she could re ceive a vaccine without parental consent based on a mistaken understanding that 15 was the age of consent, rather than the correct age of 16. *Id.* The mother filed a complaint against Walmart and the pharmacist, alleging, in relevant part, battery and negligence. *Id.* The court held that the PREP Act

applied to all claims, including those based on the failure to secure parental consent: "The Act applies to all claims causally related to the administration by a covered person of a covered countermeasure." Id. at 1084.

The Court finds the reasoning of the decisions cited above persuasive. Respondents are covered persons who administered a covered countermeasure and are thus immune from liability as to Claimants' claims for loss. The fact that Claimants allege a failure to obtain consent does not vitiate that immunity.[3] This finding is supported by the plain languge of the PREP Act.[4] The Notice of Claim does

[3] Claimants argue that the grant of immunity in the PREP Act must be construed in light of the Emergency Use Authorization ("EUA") statue, 21 U.S.C. § 360bbb-3, to which it refers. See 42 U.S.C. § 247d-6d(i)(7)(B)(iii) (providing that the term "qualified pandemic product" includes drugs and biological products authorized under the EUA statute). Specifically, Claimants point to language in the EUA statute which requires the Secretary, "to the extent practicable," to establish conditions to ensure, among other tings, that individuals are informed "of the option to accept or refuse administration of the product." 21 U.S.C. § 360bbb-3(e)(1)(A). Claimants argue that, if the PREP Act provides liability for the administration of vaccines without informed consent, it is inconsistent with the EUA.

The two statutes are not in conflict. The PREP Act does not deprive individuals of their right to refuse vaccines, it simply limits their right to seek compensation for losses related to vaccination to those instances where death or serious bodily injury has occurred. Claimants' argument as to the PREP Act's inconsistency with the EUA is misguided. Further, because the PREP Act does not, as Claimants contend, "abolish the doctrine of consent" (Opp. at 14), Claimants' related arguments that the PREP Act violates international and common law principles of informed consent similarly fail.

[4] Claimants have not cited any cases supporting the opposite conclusion, and the Court is aware of only one. See *Tonkinson v. Walmart, Inc.,* 2022 WL 1266666 (Kan. Dist. Ct. Apr. 26, 2022) (determining that the PREP Act did not shield defendant from liability for vaccinating a child for COVID-19 without parental consent pimarily on the basis that the word

not allege facts sufficient to find relief under the sole exception to immunity, for death or serious physical injury. Moreover, even if it the Notice of Claim did allege that J.H. suffered death or serious physical injury as a result of vaccination, this Court would not be the proper venue to hear that claim.

Finally, Claimants make a number of arguments related to the constitutionality of the PREP Act and its application both in this case and in other hypothetical cases invented by Claimants. Because this case can be decided on the plain language of the PREP Act and because the Notice of Claim solely contains tort claims, the Court declines to address those arguments. See *State v. Athayde*, 2022 ME 41, ¶ 21, 277 A.3d 387 (exercising judicial restraint to avoid issuing an unnecessary opinion on the constitution); *M.T.,* 528 P.3d at 1084 ("Finally, we need not address the district court's unbidden constitutional concerns about the PREP Act. Because this case can be decided on the text of the Act and [the plaintiff] never advanced any constitutional claim, we adhere to the long-standing doctrine of judicial self-restraint known as constitutional avoidance.").

CONCLUSION

It is hereby ORDERED:

Respondents Andrew Russ, Lincoln Health, and MaineHealth's Motion to Dismiss is Granted.

"consent" does not appear in the statute). In that case, the district court's decision to allow the plaintiff to proceed on her consent-related claims was vacated by the appellate court, leading to a dismissal of all of the plaintiff's claims. *M.T.,* 528 P.3d at 1067.

DATED: April 16, 2024.

s/Daniel Billings
Daniel I. Billings, Justice
Maine Superior Court

APPENDIX C

Federal Statutes

42 U.S.C. §247d–6d. Targeted liability protections for pandemic and epidemic products and security countermeasures

(a) Liability protections

(1) In general

Subject to the other provisions of this section, 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.

(2) Scope of claims for loss

(A) Loss

For purposes of this section, the term "loss" means any type of loss, including-

(i) death;

(ii) physical, mental, or emotional injury, illness, disability, or condition;

(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

(B) Scope

The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the

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

(3) Certain conditions

Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if-

(A) the countermeasure was administered or used during the effective period of the declaration that was issued under subsection (b) with respect to the countermeasure;

(B) the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration; and

(C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the administration or use of the countermeasure, the countermeasure was administered to or used by an individual who-

(i) was in a population specified by the declaration; and

(ii) was at the time of administration physically present in a geographic area specified by the declaration or had a connection to such area specified in the declaration.

(4) Applicability of certain conditions

With respect to immunity under paragraph (1) and subject to the other provisions of this section:

(A) In the case of a covered person who is a manufacturer or distributor of the covered countermeasure involved, the immunity applies

without regard to whether such countermeasure was administered to or used by an individual in accordance with the conditions described in paragraph (3)(C).

(B) In the case of a covered person who is a program planner or qualified person with respect to the administration or use of the covered countermeasure, the scope of immunity includes circumstances in which the countermeasure was administered to or used by an individual in circumstances in which the covered person reasonably could have believed that the countermeasure was administered or used in accordance with the conditions described in paragraph (3)(C).

(5) Effect of distribution method

The provisions of this section apply to a covered countermeasure regardless of whether such countermeasure is obtained by donation, commercial sale, or any other means of distribution, except to the extent that, under paragraph (2)(E) of subsection (b), the declaration under such subsection provides that subsection (a) applies only to covered countermeasures obtained through a particular means of distribution.

(6) Rebuttable presumption

For purposes of paragraph (1), there shall be a rebuttable presumption that any administration or use, during the effective period of the emergency declaration by the Secretary under subsection (b), of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued.

(b) Declaration by Secretary

(1) Authority to issue declaration

Subject to paragraph (2), if the Secretary makes a determination 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, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

(2) Contents

In issuing a declaration under paragraph (1), the Secretary shall identify, for each covered countermeasure specified in the declaration-

(A) the category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure;

(B) the period or periods during which, including as modified by paragraph (3), subsection (a) is in effect, which period or periods may be designated by dates, or by milestones or other description of events, including factors specified in paragraph (6);

(C) the population or populations of individuals for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation to all individuals);

(D) the geographic area or areas for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation), including, with respect to

individuals in the populations identified under subparagraph (C), a specification, as determined appropriate by the Secretary, of whether the declaration applies only to individuals physically present in such areas or whether in addition the declaration applies to individuals who have a connection to such areas, which connection is described in the declaration; and

(E) whether subsection (a) is effective only to a particular means of distribution as provided in subsection (a)(5) for obtaining the countermeasure, and if so, the particular means to which such subsection is effective.

(3) Effective period of declaration

(A) Flexibility of period

The Secretary may, in describing periods under paragraph (2)(B), have different periods for different covered persons to address different logistical, practical or other differences in responsibilities.

(B) Additional time to be specified

In each declaration under paragraph (1), the Secretary, after consulting, to the extent the Secretary deems appropriate, with the manufacturer of the covered countermeasure, shall also specify a date that is after the ending date specified under paragraph (2)(B) and that allows what the Secretary determines is-

(i) a reasonable period for the manufacturer to arrange for disposition of the covered countermeasure, including the return of such product to the manufacturer; and

(ii) a reasonable period for covered persons to take such other actions as may be appropriate to limit administration or use of the covered countermeasure.

(C) Additional period for certain strategic national stockpile countermeasures

With respect to a covered countermeasure that is in the stockpile under section 247d–6b of this title, if such countermeasure was the subject of a declaration under paragraph (1) at the time that it was obtained for the stockpile, the effective period of such declaration shall include a period when the countermeasure is administered or used pursuant to a distribution or release from the stockpile.

(4) Amendments to declaration

The Secretary may through publication in the Federal Register amend any portion of a declaration under paragraph (1). Such an amendment shall not retroactively limit the applicability of subsection (a) with respect to the administration or use of the covered countermeasure involved.

(5) Certain disclosures

In publishing a declaration under paragraph (1) in the Federal Register, the Secretary is not required to disclose any matter described in section 552(b) of title 5.

(6) Factors to be considered

In deciding whether and under what circumstances or conditions to issue a declaration under paragraph (1) with respect to a covered countermeasure, the Secretary shall consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasure.

(7) Judicial review

No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.

(8) Preemption of State law

During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that-

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(9) Report to Congress

Within 30 days after making a declaration under paragraph (1), the Secretary shall submit to the appropriate committees of the Congress a report that provides an explanation of the reasons for issuing the declaration and the reasons underlying the determinations of the Secretary with respect to paragraph (2). Within 30 days after making an amendment under paragraph (4), the Secretary shall submit to such committees a report that provides the reasons underlying the determination of the Secretary to make the amendment.

(c) Definition of willful misconduct

(1) Definition

(A) In general

Except as the meaning of such term is further restricted pursuant to paragraph (2), the term "willful misconduct" shall, for purposes of subsection (d), denote an act or omission that is 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.

(B) Rule of construction

The criterion stated in subparagraph (A) shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.

(2) Authority to promulgate regulatory definition

(A) In general

The Secretary, in consultation with the Attorney General, shall promulgate regulations, which may be promulgated through interim final rules, that further restrict the scope of actions or omissions by a covered person that may qualify as "willful misconduct" for purposes of subsection (d).

(B) Factors to be considered

In promulgating the regulations under this paragraph, the Secretary, in consultation with the Attorney General, shall consider the need to define the scope of permissible civil actions under subsection (d) in a way that will not adversely affect the public health.

(C) Temporal scope of regulations

The regulations under this paragraph may specify the temporal effect that they shall be given for purposes of subsection (d).

(D) Initial rulemaking

Within 180 days after December 30, 2005, the Secretary, in consultation with the Attorney General, shall commence and complete an initial rulemaking process under this paragraph.

(3) Proof of willful misconduct

In an action under subsection (d), the plaintiff shall have the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury.

(4) Defense for acts or omissions taken pursuant to Secretary's declaration

Notwithstanding any other provision of law, a program planner or qualified person shall not have engaged in "willful misconduct" as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in the declaration under subsection (b), provided either the Secretary, or a State or local health authority, was provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff's alleged loss within 7 days of the actual discovery of such information by such program planner or qualified person.

(5) Exclusion for regulated activity of manufacturer or distributor

(A) In general

If an act or omission by a manufacturer or distributor with respect to a covered countermeasure, which act or omission is alleged under subsection (e)(3)(A) to constitute willful misconduct, is subject to regulation by this chapter or by the Federal Food, Drug, and

Cosmetic Act [21 U.S.C. 301 et seq.], such act or omission shall not constitute "willful misconduct" for purposes of subsection (d) if-

(i) neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission; or

(ii) such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy.

Any action or proceeding under subsection (d) shall be stayed during the pendency of such an enforcement action.

(B) Definitions

For purposes of this paragraph, the following terms have the following meanings:

(i) Enforcement action

The term "enforcement action" means a criminal prosecution, an action seeking an injunction, a seizure action, a civil monetary proceeding based on willful misconduct, a mandatory recall of a product because voluntary recall was refused, a proceeding to compel repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i), 360j(g)], a debarment proceeding, an investigator disqualification proceeding where an investigator is an employee or agent of the manufacturer, a revocation, based on willful misconduct, of an authorization under section 564 of such Act [21 U.S.C. 360bbb–3], or a suspension or withdrawal, based on willful misconduct, of an approval or clearance under chapter V of such Act [21 U.S.C. 351 et seq.] or of a licensure under section 262 of this title.

(ii) Covered remedy

The term "covered remedy" means an outcome-

(I) that is a criminal conviction, an injunction, or a condemnation, a civil monetary payment, a product recall, a repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i), 360j(g)], a debarment, an investigator disqualification, a revocation of an authorization under section 564 of such Act [21 U.S.C. 360bbb–3], or a suspension or withdrawal of an approval or clearance under chapter 5 [1] of such Act or of a licensure under section 262 of this title; and

(II) that results from a final determination by a court or from a final agency action.

(iii) Final

The terms "final" and "finally"-

(I) with respect to a court determination, or to a final resolution of an enforcement action that is a court determination, mean a judgment from which an appeal of right cannot be taken or a voluntary or stipulated dismissal; and

(II) with respect to an agency action, or to a final resolution of an enforcement action that is an agency action, mean an order that is not subject to further review within the agency and that has not been reversed, vacated, enjoined, or otherwise nullified by a final court determination or a voluntary or stipulated dismissal.

(C) Rules of construction

(i) In general

Nothing in this paragraph shall be construed-

(I) to affect the interpretation of any provision of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], of this chapter, or of any other applicable statute or regulation; or

(II) to impair, delay, alter, or affect the authority, including the enforcement discretion, of the United States, of the Secretary, of the Attorney General, or of any other official with respect to any administrative or court proceeding under this chapter, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], under title 18, or under any other applicable statute or regulation.

(ii) Mandatory recalls

A mandatory recall called for in the declaration is not a Food and Drug Administration enforcement action.

(d) Exception to immunity of covered persons

(1) In general

Subject to subsection (f), the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person. For purposes of section 2679(b)(2)(B) of title 28, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized.

(2) Persons who can sue

An action under this subsection may be brought for wrongful death or serious physical injury by any person who suffers such injury or by any representative of such a person.

(e) Procedures for suit

(1) Exclusive Federal jurisdiction

Any action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia.

(2) Governing law

The substantive law for decision in an action under

subsection (d) shall be derived from the law, including choice of law principles, of the State in which the alleged willful misconduct occurred, unless such law is inconsistent with or preempted by Federal law, including provisions of this section.

(3) Pleading with particularity

In an action under subsection (d), the complaint shall plead with particularity each element of the plaintiff's claim, including-

(A) each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure administered to or used by the person on whose behalf the complaint was filed;

(B) facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed; and

(C) facts supporting the allegation that the person on whose behalf the complaint was filed suffered death or serious physical injury.

(4) Verification, certification, and medical records

(A) In general

In an action under subsection (d), the plaintiff shall verify the complaint in the manner stated in subparagraph (B) and shall file with the complaint the materials described in subparagraph (C). A complaint that does not substantially comply with subparagraphs (B) and (C) shall not be accepted for filing and shall not stop the running of the statute of limitations.

(B) Verification requirement

(i) In general

The complaint shall include a verification, made by affidavit of the plaintiff under oath, stating that the pleading is true to the knowledge of the deponent,

except as to matters specifically identified as being alleged on information and belief, and that as to those matters the plaintiff believes it to be true.

(ii) Identification of matters alleged upon information and belief

Any matter that is not specifically identified as being alleged upon the information and belief of the plaintiff, shall be regarded for all purposes, including a criminal prosecution, as having been made upon the knowledge of the plaintiff.

(C) Materials required

In an action under subsection (d), the plaintiff shall file with the complaint-

(i) an affidavit, by a physician who did not treat the person on whose behalf the complaint was filed, certifying, and explaining the basis for such physician's belief, that such person suffered the serious physical injury or death alleged in the complaint and that such injury or death was proximately caused by the administration or use of a covered countermeasure; and

(ii) certified medical records documenting such injury or death and such proximate causal connection.

(5) Three-judge court

Any action under subsection (d) shall be assigned initially to a panel of three judges. Such panel shall have jurisdiction over such action for purposes of considering motions to dismiss, motions for summary judgment, and matters related thereto. If such panel has denied such motions, or if the time for filing such motions has expired, such panel shall refer the action to the chief judge for assignment for further proceedings, including any trial. Section 1253 of title 28 and paragraph (3) of subsection (b) of section 2284

of title 28 shall not apply to actions under subsection (d).

(6) Civil discovery

(A) Timing

In an action under subsection (d), no discovery shall be allowed-

(i) before each covered person sued has had a reasonable opportunity to file a motion to dismiss;

(ii) in the event such a motion is filed, before the court has ruled on such motion; and

(iii) in the event a covered person files an interlocutory appeal from the denial of such a motion, before the court of appeals has ruled on such appeal.

(B) Standard

Notwithstanding any other provision of law, the court in an action under subsection (d) shall permit discovery only with respect to matters directly related to material issues contested in such action, and the court shall compel a response to a discovery request (including a request for admission, an interrogatory, a request for production of documents, or any other form of discovery request) under Rule 37, Federal Rules of Civil Procedure, only if the court finds that the requesting party needs the information sought to prove or defend as to a material issue contested in such action and that the likely benefits of a response to such request equal or exceed the burden or cost for the responding party of providing such response.

(7) Reduction in award of damages for collateral source benefits

(A) In general

In an action under subsection (d), the amount of an award of damages that would otherwise be made to a

plaintiff shall be reduced by the amount of collateral source benefits to such plaintiff.

(B) Provider of collateral source benefits not to have lien or subrogation

No provider of collateral source benefits shall recover any amount against the plaintiff or receive any lien or credit against the plaintiff's recovery or be equitably or legally subrogated to the right of the plaintiff in an action under subsection (d).

(C) Collateral source benefit defined

For purposes of this paragraph, the term "collateral source benefit" means any amount paid or to be paid in the future to or on behalf of the plaintiff, or any service, product, or other benefit provided or to be provided in the future to or on behalf of the plaintiff, as a result of the injury or wrongful death, pursuant to-

(i) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(ii) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(iii) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; or

(iv) any other publicly or privately funded program.

(8) Noneconomic damages

In an action under subsection (d), any noneconomic damages may be awarded only in an amount directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff. For purposes of this paragraph, the term "noneconomic damages" means damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of

life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses.

(9) Rule 11 sanctions

Whenever a district court of the United States determines that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure in an action under subsection (d), the court shall impose upon the attorney, law firm, or parties that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which may include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorney's fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

(10) Interlocutory appeal

The United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction of an interlocutory appeal by a covered person taken within 30 days of an order denying a motion to dismiss or a motion for summary judgment based on an assertion of the immunity from suit conferred by subsection (a) or based on an assertion of the exclusion under subsection (c)(5).

(f) Actions by and against the United States

Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or

employees under any other law, including any provision of chapter 171 of title 28 (relating to tort claims procedure).

(g) Severability

If any provision of this section, or the application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of this section and the application of such remainder to any person or circumstance shall not be affected thereby.

(h) Rule of construction concerning National Vaccine Injury Compensation Program

Nothing in this section, or any amendment made by the Public Readiness and Emergency Preparedness Act, shall be construed to affect the National Vaccine Injury Compensation Program under subchapter XIX of this chapter.

(i) Definitions

In this section:

(1) Covered countermeasure

The term "covered countermeasure" means-

(A) a qualified pandemic or epidemic product (as defined in paragraph (7));

(B) a security countermeasure (as defined in section 247d–6b(c)(1)(B) of this title);

(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b]; or

(D) a respiratory protective device that is approved by the National Institute for Occupational Safety and

Health under part 84 of title 42, Code of Federal Regulations (or any successor regulations), and that the Secretary determines to be a priority for use during a public health emergency declared under section 247d of this title.

(2) Covered person

The term "covered person", when used with respect to the administration or use of a covered countermeasure, means-

(A) the United States; or

(B) a person or entity that is-

(i) a manufacturer of such countermeasure;

(ii) a distributor of such countermeasure;

(iii) a program planner of such countermeasure;

(iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or

(v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

(3) Distributor

The term "distributor" means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

(4) Manufacturer

The term "manufacturer" includes-

(A) a contractor or subcontractor of a manufacturer;

(B) a supplier or licenser of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a covered countermeasure; and

(C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

(5) Person

The term "person" includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.

(6) Program planner

The term "program planner" means a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

(7) Qualified pandemic or epidemic product

The term "qualified pandemic or epidemic product" means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)),[2] biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) [2] that is-

(A)(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); and
(B)(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 262 of this title;
(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), 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 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b].

(8) Qualified person

The term "qualified person", when used with respect to the administration or use of a covered countermeasure, means-
(A) 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
(B) a person within a category of persons so identified in a declaration by the Secretary under subsection (b).

(9) Security countermeasure

The term "security countermeasure" has the meaning given such term in section 247d–6b(c)(1)(B) of this title.

(10) Serious physical injury
The term "serious physical injury" means an injury that-
(A) is life threatening;
(B) results in permanent impairment of a body function or permanent damage to a body structure; or
(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

42 U.S.C. §247d–6e. Covered countermeasure process

(a) Establishment of Fund
Upon the issuance by the Secretary of a declaration under section 247d–6d(b) of this title, there is hereby established in the Treasury an emergency fund designated as the "Covered Countermeasure Process Fund" for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration, which Fund shall consist of such amounts designated as emergency appropriations under section 402 of H. Con. Res. 95 of the 109th Congress, this emergency designation shall remain in effect through October 1, 2006.
(b) Payment of compensation
(1) In general
If the Secretary issues a declaration under 247d–6d(b) of this title, the Secretary shall, after amounts have by law been provided for the Fund under subsection (a), provide compensation to an eligible individual for a covered injury directly caused by the

administration or use of a covered countermeasure pursuant to such declaration.

(2) Elements of compensation

The compensation that shall be provided pursuant to paragraph (1) shall have the same elements, and be in the same amount, as is prescribed by sections 239c, 239d, and 239e of this title in the case of certain individuals injured as a result of administration of certain countermeasures against smallpox, except that section 239e(a)(2)(B) of this title shall not apply.

(3) Rule of construction

Neither reasonable and necessary medical benefits nor lifetime total benefits for lost employment income due to permanent and total disability shall be limited by section 239e of this title.

(4) Determination of eligibility and compensation

Except as provided in this section, the procedures for determining, and for reviewing a determination of, whether an individual is an eligible individual, whether such individual has sustained a covered injury, whether compensation may be available under this section, and the amount of such compensation shall be those stated in section 239a of this title (other than in subsection (d)(2) of such section), in regulations issued pursuant to that section, and in such additional or alternate regulations as the Secretary may promulgate for purposes of this section. In making determinations under this section, other than those described in paragraph (5)(A) as to the direct causation of a covered injury, the Secretary may only make such determination based on compelling, reliable, valid, medical and scientific evidence.

(5) Covered countermeasure injury table

(A) In general

The Secretary shall by regulation establish a table identifying covered injuries that shall be presumed to be directly caused by the administration or use of a covered countermeasure and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply. The Secretary may only identify such covered injuries, for purpose of inclusion on the table, where the Secretary determines, based on compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury.

(B) Amendments

The provisions of section 239b of this title (other than a provision of subsection (a)(2) of such section that relates to accidental vaccinia inoculation) shall apply to the table established under this section.

(C) Judicial review

No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this paragraph.

(6) Meanings of terms

In applying sections 239a, 239b, 239c, 239d, and 239e of this title for purposes of this section-

(A) the terms "vaccine" and "smallpox vaccine" shall be deemed to mean a covered countermeasure;

(B) the terms "smallpox vaccine injury table" and "table established under section 239b of this title" shall be deemed to refer to the table established under paragraph (4); and

(C) other terms used in those sections shall have the meanings given to such terms by this section.

(c) Voluntary program

The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any declaration under 247d–6d of this title and any applicable guidelines of the Centers for Disease Control and Prevention and that potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part.

(d) Exhaustion; exclusivity; election

(1) Exhaustion

Subject to paragraph (5), a covered individual may not bring a civil action under section 247d–6d(d) of this title against a covered person (as such term is defined in section 247d–6d(i)(2) of this title) unless such individual has exhausted such remedies as are available under subsection (a), except that if amounts have not by law been provided for the Fund under subsection (a), or if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of this section within 240 days after such request was filed, the individual may seek any remedy that may be available under section 247d–6d(d) of this title.

(2) Tolling of statute of limitations

The time limit for filing a civil action under section 247d–6d(d) of this title for an injury or death shall be tolled during the pendency of a claim for compensation under subsection (a).

(3) Rule of construction

This section shall not be construed as superseding or otherwise affecting the application of a requirement,

under chapter 171 of title 28, to exhaust administrative remedies.

(4) Exclusivity

The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses, except for a proceeding under section 247d–6d of this title.

(5) Election

If under subsection (a) the Secretary determines that a covered individual qualifies for compensation, the individual has an election to accept the compensation or to bring an action under section 247d–6d(d) of this title. If such individual elects to accept the compensation, the individual may not bring such an action.

(e) Definitions

For purposes of this section, the following terms shall have the following meanings:

(1) Covered countermeasure

The term "covered countermeasure" has the meaning given such term in section 247d–6d of this title.

(2) Covered individual

The term "covered individual", with respect to administration or use of a covered countermeasure pursuant to a declaration, means an individual-

(A) who is in a population specified in such declaration, and with respect to whom the administration or use of the covered countermeasure satisfies the other specifications of such declaration; or

(B) who uses the covered countermeasure, or to whom the covered countermeasure is administered, in a good faith belief that the individual is in the category described by subparagraph (A).

(3) Covered injury

The term "covered injury" means serious physical injury or death.

(4) Declaration

The term "declaration" means a declaration under section 247d–6d(b) of this title.

(5) Eligible individual

The term "eligible individual" means an individual who is determined, in accordance with subsection (b), to be a covered individual who sustains a covered injury.