STATE OF MAINE
LINCOLN, ss.

SUPERIOR COURT
CIVIL ACTION
Docket No. CV-23-13

Claimants

v.

Respondents

RESPONDENTS' MOTION TO DISMISS CLAIMANTS' NOTICE OF CLAIM

Respondents

, by and through undersigned counsel, hereby move to dismiss Claimants' Notice of Claim pursuant to M.R. Civ. P. 12(b)(1), (6) and 80M(e). Because the Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. § 247d *et seq.*, provides immunity to Respondents and preempts the claims asserted by Claimants, Respondents respectfully request that this Court dismiss Claimants' Notice of Claim with prejudice. In support, Respondents state as follows.

BACKGROUND

Claimants filed a Notice of Claim on May 3, 2023, commencing an action for professional negligence against Respondents. *See* 24 M.R.S. § 2853(1). Claimants' Notice of Claim arises out of Respondents' alleged administration of the Pfizer-BioNTech mRNA COVID-19 vaccine to Claimant on or about November 2021. In their Notice of Claim, Claimants assert the following allegations, which are viewed as if they were admitted for purposes of this Motion. *See 20 Thames St. LLC v. Ocean State Job Lot of Maine 2017 LLC*, 2021 ME 33, ¶ 2, 252 A.3d 516; *Davric Maine Corp. v. Bangor Historic Track, Inc.*, 2000 ME 102, ¶ 6, 751 A.2d 1024.

Claimants are the parents of Claimant , a minor. (Notice of Claim, ¶¶ 5-7.) Respondent , MD is a physician and health care practitioner licensed to practice medicine in Maine. (*Id.* ¶ 8.) is employed by Respondent , which is a health care entity. (*Id.* ¶ 8.) operates under the umbrella of Respondent , which is a Maine nonprofit corporation and health care entity. (*Id.* ¶¶ 9-10.)

During October 2021, Respondents planned a vaccine clinic to be operated at the School in on November , 2021. (*Id.* ¶¶ 2, 16.) Prior to the November vaccine clinic, Respondents transmitted letters about the vaccine clinic and consent forms to parents of students at the School, including to Claimants. (*Id.* ¶¶ 16-18.) According to the Notice of Claim, neither nor completed or signed a registration form or a consent form for 's participation in the November , 2021, vaccine clinic. (*Id.* ¶ 19.) On November , 2021, Respondents operated a COVID-19 vaccine clinic at the School. (*Id.* ¶ 2.) Claimants allege that Dr. administered the Pfizer-BioNTech mRNA COVID-19 vaccine to at the November vaccine clinic without first obtaining the informed consent of Claimants. (*Id.* ¶ 21.) On November returned home after school with a band-aid on his arm and was irritable and emotionally unstable. (*Id.* ¶ 23.)

Based on these allegations, Claimants assert eight tort claims against Respondents, seeking to hold and vicariously liable for the acts of their agents and employees, including Dr. . (*See Id.*, ¶¶ 11-13 and Counts I-VIII.)

ARGUMENT

Respondents respectfully request that the Court dismiss Claimants' Notice of Claim with prejudice because the federal PREP Act provides immunity to Respondents and preempts the

claims asserted in this forum. In 2005, Congress enacted the PREP Act "to encourage the expeditious development and deployment of medical countermeasures during a public health emergency by allowing the [Health and Human Services] Secretary to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines." *Cannon v. Watermark Ret. Communities, Inc.*, 45 F.4th 137, 139 (D.C. Cir. 2022) (quotation marks and alteration omitted). Thus, upon the issuance of a "declaration" by the Secretary of the U.S. Department of Health and Human Services, the PREP Act mandates that "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 use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(1) (emphasis added); *see Garcia v. Welltower OpCo Grp., LLC*, 2023 WL 2612605, at *3 (C.D. Cal. Mar. 23, 2023) (recognizing that the PREP Act "provides sweeping immunity"). Accordingly, because Respondents are "covered" or "qualified" persons under the PREP Act who are alleged to have administered a "covered countermeasure," *i.e.*, the COVID-19 vaccine, during the effective period of a PREP Act declaration, Respondents are immune from suit for any claims for loss allegedly suffered by Claimants.

A. Legal Standards & Statutory Framework

1. Rule 12(b) Legal Standard

Pursuant to Maine Rule of Civil Procedure 12(b), a party may move to dismiss a claim for a court's "lack of jurisdiction over the subject matter" and for a party's "failure to state a claim upon which relief can be granted." M.R. Civ. P. 12(b)(1), (6). A Rule 12(b)(6) motion to dismiss "tests the legal sufficiency of the allegations in a complaint, rather than the sufficiency of the evidence that a plaintiff is able to present." *Lawson v. Willis*, 2019 ME 36, ¶ 15, 204 A.3d 133.

Thus, the Court must determine whether a complaint "sets forth elements of a cause of action or alleges facts that would entitle the plaintiff to relief pursuant to some legal theory." *Argereow v. Weisberg*, 2018 ME 140, ¶12, 195 A.3d 1210 (quotation marks omitted). Dismissal of a claim is proper "when it appears beyond doubt that a plaintiff is entitled to no relief under any set of facts that he might prove in support of his claim." *Id.* "When a motion to dismiss is based on the court's lack of subject matter jurisdiction, [a court] make[s] no favorable inferences in favor of the plaintiff such as [a court does] when reviewing a motion to dismiss for failure to state a claim upon which relief can be granted." *Tomer v. Maine Hum. Rts. Comm'n*, 2008 ME 190, ¶ 9, 962 A.2d 335. Moreover, in reviewing subject matter jurisdiction, a court may review "material outside the pleadings submitted by the pleader and the movant." *Moyant v. Petit*, 2021 ME 13, ¶ 2, 247 A.3d 326 (quotation marks omitted); *see also State v. Dana*, 404 A.2d 551, 563 (Me. 1979) (taking judicial notice of matters published in the Federal Register).

2. The PREP Act, 42 U.S.C. § 247d *et seq*

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 if a declaration under subsection (b) has been issued with respect to such countermeasure." 42 U.S.C. § 247d-6d(a)(1) (emphasis added); *see Solomon v. St. Joseph Hosp.*, 62 F.4th 54, 58 (2d Cir. 2023) (section 247d-6d(a)(1) provides "broad immunity"). "The purpose of the Act's immunity provision is to insulate covered individuals and entities from liability for their administration or use of countermeasures, such as vaccines . . . that are designed to combat the pandemic." *Ruiz v. ConAgra Foods Packaged Foods, LLC*, No. 21-CV-387-SCD, 2021 WL 3056275, at *2 (E.D. Wis. July 20, 2021). For purposes of the phrase "claims for loss," the term "loss" is defined, in

part, as "any type of loss, including . . . physical, mental, or emotional injury, illness, disability, or condition" or the "fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring." *Id.* § 247d-6d(a)(2)(A). Moreover, the immunity provided under the PREP Act "applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the . . . distribution . . . marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." *Id.* § 247d-6d(a)(2)(B).[1]

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

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

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[1] The "sole" statutory exception to the immunity provided by the PREP Act is "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." 42 U.S.C. § 247d-6d(d)(1). "Willful misconduct" is defined as an act or omission taken (i) "intentionally to achieve a wrongful purpose," (ii) "knowingly without legal or factual justification," and (iii) "in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." *Id.* § 247d-6d(c)(1)(A). "Serious physical injury" means an injury that is "life threatening," "results in permanent impairment of a body function or permanent damage to a body structure," or "necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure." *Id.* § 247d-6d(i)(10).

Here, the Notice of Claim does not allege any act or omission that constitutes "willful misconduct" or "serious physical injury," as those terms are defined by the PREP Act. However, even if the Notice of Claim did make such allegations, the only forum with jurisdiction to hear such a claim is the US District Court for the District of Columbia, which is required to appoint a three-judge panel to conduct an initial review of any complaint asserting a "willful misconduct" claim. *Id.* § 247d-6d(e)(1), (5).

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

Id. § 247d-6d(i)(7). A "covered person," as that term is used "with respect to the administration or use of a covered countermeasure" is defined as "a person or entity that is . . . a qualified person who prescribed, administered, or dispensed such countermeasure; or . . . an official, agent, or employee of a person or entity." *Id.* § 247d-6d(i)(2). A "qualified person" means "a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or . . . a person within a category of persons so identified in a declaration by the Secretary." *Id.* § 247d-6d(i)(8); *see Gerber v. Forest View Ctr.*, No. 21-CV-05359KAMJRC, 2022 WL 3586477, at *3 (E.D.N.Y. Aug. 22, 2022) (recognizing that a "qualified person" includes "hospitals, nursing homes and other entities."). Moreover, a "person" broadly includes "an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department." *Id.* § 247d-6d(i)(5).

Because of this broad immunity provided under the PREP Act, the Act requires individuals to seek relief for claims, like the ones asserted in Claimants' Notice of Claim, through the "Covered Countermeasure Process Fund," which provides "timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to [a] declaration." *Id.* § 247d-6e(a). This federal administrative remedy

"shall be exclusive of any other civil action or proceeding for any claim or suit." *Id.* § 247d-6e(d).[2] To begin the process of seeking compensation from the Fund, an individual must file a "Request Form" or letter of intent "within one year of the date of the administration or use of a covered countermeasure that is alleged to have caused the injury." 42 C.F.R. § 110.42(a). For any individual who "qualifies for compensation" under the Fund, "the individual has an election to accept the compensation or to bring an action" for "willful misconduct" pursuant to section 247d-6d(d). *Id.* § 247d-6e(d)(5); *see supra* n.1. However, if an "individual elects to accept the compensation, the individual may not" bring a claim for willful misconduct. *Id.*

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

3. The Secretary's COVID-19 Declarations

As noted, the broad immunity afforded by the PREP Act arises once "a declaration" is issued by the Secretary of the Department of Health and Human Services ("Secretary"). *Id.* § 247d-6d(a)(1). Under subsection (b) of the PREP Act, the Secretary "may make a declaration,

[2] Again, the only exception to the requirement that an individual pursue injury claims through the Covered Countermeasure Process Fund is the exception for claims resulting from "willful misconduct." 42 U.S.C. § 247d-6e(d)(4); *see* 42 U.S.C. § 247d-6d(c)-(d) (discussing willful misconduct).

through publication in the Federal Register" if the Secretary determines "that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency." *Id.* § 247d-6d(b)(1). In a declaration, the Secretary may recommend "the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stat[e] that subsection (a) is in effect with respect to the activities so recommended." *Id.* During the effective period of any declaration issued by the Secretary, "no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that--

> (A) is different from, or is in conflict with, any requirement applicable under [42 U.S.C. § 247d-6d]; and
>
> (B) relates to the . . . prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under [42 U.S.C. § 247d-6d] or any other provision of this chapter.

Id. § 247d-6d(b)(8).

Here, at the onset of the COVID-19 pandemic, the Secretary issued a PREP Act Declaration on March 17, 2020. *See* Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020) ("March 2020 Declaration").[3] A copy of the March 2020 COVID-19 Declaration is attached hereto as Exhibit A. At that time, the Secretary "determined that the spread of SARS-CoV–2 or a virus mutating therefrom and the resulting disease COVID–19 constitutes a public

[3] After the initial March 2020 COVID-19 Declaration, the Secretary issued 11 amended Declarations, which are compiled, for ease of reference, at the Health and Human Services website. *See* https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx. As relevant to this matter, the 9th Amended Declaration became effective on September 14, 2021, and was in effect during the relevant time period alleged in the Plaintiffs' Notice of Claim. As discussed below, these amendments have primarily expanded the category of "covered persons" subject to immunity under the PREP Act.

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

As declared by the Secretary, the "Recommended Activities" subject to protection under the PREP Act during the COVID-19 pandemic included "the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures." March 2020 Declaration, §§ III-IV. As the term is used in both the PREP Act and the March 2020 Declaration, the "administration" of a covered countermeasure is defined, in part, as the "physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures." March 2020 Declaration, § IX.

In subsequent amended Declarations, the Secretary has expanded the definitions of other statutory terms. *See* Third Amendment to Declaration Under the PREP Act, § V (adding pharmacists to list of designated "covered" persons); Fifth Amendment to Declaration Under the PREP Act, § V (adding inactive physicians and registered nurses to list of designated "covered" persons); Seventh Amendment to Declaration Under the PREP Act, § V (adding "[a]ny midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist or veterinarian" to list of designated "covered" persons). Other amendments have clarified the term "covered countermeasure." *See* Second Amendment to Declaration Under the PREP Act, § VI (clarifying that a countermeasure includes "any vaccine used . . . to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom"); Fourth Amendment to

Declaration Under the PREP Act, § VI (clarifying that section VI includes all qualified pandemic and epidemic products under the PREP Act).

B. Respondents are immune from suit and liability for any claim for loss caused by or arising out of the administration of the COVID-19 vaccine.

Given the PREP Act's statutory framework and the subsequent Declarations issued by the Secretary, Claimants' Notice of Claim must be dismissed. As "covered" or "qualified" persons who are alleged to have caused harm to Claimants through the administration of the Pfizer-BioNTech mRNA COVID-19 vaccine, Respondents are immune from suit and liability for Claimants' claims arising out of or caused by the administration of the vaccine.

The PREP Act's immunity provision became effective upon the Secretary's issuance of the March 2020 Declaration. In accordance with the Declaration, the "distribution, administration, and use of . . . Covered Countermeasures" were designated as "Recommended Activities" subject to immunity under the PREP Act. March 2020 Declaration, §§ III-IV; *see* 42 U.S.C. § 247d-6d(a)(1). Clearly, the Pfizer-BioNTech mRNA COVID-19 vaccine is a "covered countermeasure" or "qualified pandemic or epidemic product" under the PREP Act and March 2020 Declaration. 42 U.S.C. § 247d-6d(i)(1), (7); *see* March 2020 Declaration, § VI (including as a countermeasure "any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS-CoV–2 or a virus mutating therefrom"). Moreover, Respondents, as "covered person[s]" who "prescribed, administered, or dispensed" the COVID-19 vaccine and as "qualified person[s]" who were "authorized to prescribe, administer, or dispense" the COVID-19 vaccine, are clearly within the scope of "person[s]" shielded from immunity under the PREP Act.[4] 42 U.S.C.

[4] Moreover, to the extent that the Notice of Claim alleges that some or all of the Respondents "planned" the November 12, 2021, vaccine clinic (Notice of Claim, ¶ 16). Respondents also are "program planners" for purposes of the PREP Act. *See* 42 U.S.C. § § 247d-6d(i)(2), (6) (stating that a program planner is a "covered person" and defining a "program planner" as a "person who supervised or administered a program

§ 247d-6d(i)(2), (5), (8); *see* March 2020 Declaration, §§ IV-VI; *Gerber*, 2022 WL 3586477, at *3 (E.D.N.Y. Aug. 22, 2022) (recognizing that a "qualified person" includes "hospitals, nursing homes and other entities."). In short, Respondents' alleged administration of the COVID-19 vaccine to Claimant , and the alleged harm to Claimants resulting therefrom, fall squarely within the PREP Act's immunity.

Other cases are illustrative in applying the PREP Act to Claimants' Notice of Claim. In New York, for example, a county public health department held a vaccination clinic at a local school for administration of the 2009 H1N1 influenza vaccine during a public health emergency. *Parker v. St. Lawrence Cnty. Pub. Health Dep't*, 954 N.Y.S.2d 259, 261 (N.Y. App. Div. 2012). At the vaccine clinic, a nurse administered the influenza vaccine to a kindergartner without the parent's consent. *Id.* However, based on the protections provided by the PREP Act, the court concluded that the plaintiff's "state law claims for negligence and battery are preempted by the PREP Act and, inasmuch as the exclusive remedy under the statute is a federal cause of action to be brought in federal court, the complaint must be dismissed." *Id.* at 263. Similarly, in Kansas, a mother brought suit against Walmart and one its pharmacists for administering the COVID-19 vaccine to her minor child without the mother's consent, asserting claims for, among other things, negligence, battery, and interference with parental rights. *M.T. as next friend of M.K. v. Walmart Stores, Inc.*, 528 P.3d 1067, 1071 (Kan. Ct. App. 2023). In that case, the appellate court concluded that "any claim causally related to the administration by a covered person of a covered countermeasure is covered by the [PREP] Act, even claims based on the failure to obtain consent." *Id.* at 1084. As a result, the court remanded the matter with instructions to dismiss all claims asserted by the mother. *Id.* In applying the PREP Act to similar claims arising out of the

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with respect to the administration, dispensing, distribution, provision, or use of . . . a qualified pandemic or epidemic product").

administration of the COVID-19 vaccine, other courts have reached analogous conclusions regarding the PREP Act's broad reach. *See, e.g., Politella v. Windham Southeast School Dist.*, No. 22-CV-01707, 2022 WL 18143866, at *6 (Vt. Super. Ct. Dec. 28, 2022) (relying on PREP ACT and granting motion to dismiss parents' claims for loss arising out of vaccination of minor at school without parental consent); *Cowen v. Walgreen Co.*, No. 22-CV-157-TCK-JFJ, 2022 WL 17640208, at *3 (N.D. Okla. Dec. 13, 2022) (dismissing plaintiff's claims for negligence based on administration of COVID-19 vaccine without consent); *Storment v. Walgreen, Co.*, No. 1:21-CV-00898 MIS/CG, 2022 WL 2966607, at *3 (D.N.M. July 27, 2022) (dismissing plaintiff's claim for injuries suffered in fall in pharmacy parking lot following administration of COVID-19 vaccine).

Accordingly, like the cases cited above, all claims asserted in Claimants' Notice of Claim are alleged to be "caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure"—that is, the claims arise out of the Pfizer-BioNTech mRNA COVID-19 vaccine allegedly administered to Claimant on November , 2021. 42 U.S.C. § 247d-6d(a)(1). (Notice of Claim, ¶ 2.) Thus, the claims arise out of the "physical provision of" the Pfizer-BioNTech mRNA COVID-19 vaccine to Claimant. March 2020 Declaration, § IX. Therefore, Respondents are "immune from suit and liability under Federal and State law" with respect to such claims. 42 U.S.C. § 247d-6d(a)(1); *see M.T. as next friend of M.K.*, 528 P.3d 1067 at 1084; *Politella*, 2022 WL 18143866, at *6; *Cowen*, 2022 WL 17640208, at *3; *Parker*, 954 N.Y.S.2d at 263.

Therefore, given that Respondents are immune under the PREP Act for the claims asserted against them in Claimants' Notice of Claim, the Notice of Claim must be dismissed. In this case, Claimants are not entitled to "relief under any set of facts that [they] might prove in support of [their] claim." *Argereow*, 2018 ME 140. ¶12, 195 A.3d 1210 (quotation marks omitted).

C. Claimants' claims of loss are preempted by the PREP Act.

Claimants' Notice of Claim should also be dismissed because the allegations are governed by the PREP Act, which preempts the claims asserted here by Claimants.

Under the PREP Act, a State may not "establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that "is different from, or is in conflict with, any requirement applicable under [42 U.S.C. § 247d-6d]," or that "relates to the . . . prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under [42 U.S.C. § 247d-6d]." 42 U.S.C. § 247d-6d(b)(8). Notably, as the Supreme Court has "repeatedly recognized" in regards to other similar statutory language, "the phrase 'relate to' in a preemption clause expresses a broad pre-emptive purpose" and is a term "notably expansive in sweep." *Coventry Health Care of Missouri, Inc. v. Nevils*, 581 U.S. 87, 95–96 (2017) (quotation marks and alterations omitted). Here, Claimants' claims are inherently "different from" and "in conflict with" the PREP Act's immunity and exclusive remedy provisions, 42 U.S.C. § 247d-6d(b)(8), and therefore are completely preempted by the Act. *See, e.g., Parker*, 954 N.Y.S.2d at 263.

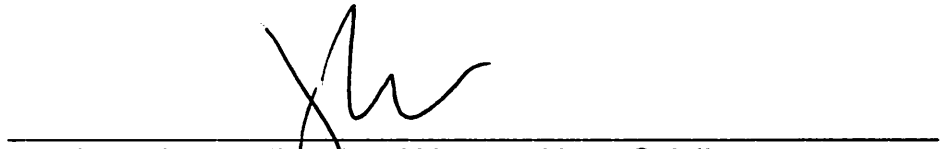
As noted above, the PREP Act "provides two avenues of recourse: the Covered Countermeasure Process Fund, and for cases of willful misconduct, a federal suit in the District of Columbia. Otherwise, a 'covered person' under the Act is completely immune from suit for conduct relating to covered countermeasures." *Goins*, No. 2022 WL 17413570, at *4. Thus, Claimants may seek relief through the Covered Countermeasure Process Fund or, alternatively, through a civil action for "willful misconduct" filed in the US District Court for the District of Columbia. 42 U.S.C. §§ 247d-6d(c)-(e), 247d-6e.

Therefore, to the extent that Respondents are not otherwise immune from liability for the claims asserted against them, the Claimants' claims are preempted by federal law.

CONCLUSION

For all of the foregoing reasons, Respondents respectfully request that that the Court dismiss Claimants' Notice of Claim with prejudice because the federal PREP Act provides immunity to Respondents and preempts the claims asserted in this forum.

Dated at Portland, Maine, this 31st day of August, 2023.



Attorneys for Respondents

Portland, ME 04112-4600

Pursuant to M.R.Civ.P. 5(b)(2):

IMPORTANT NOTICE

Opposition to this motion must be filed not later than twenty-one (21) days after the filing of this motion. FAILURE TO FILE TIMELY OPPOSITION WILL BE DEEMED A WAIVER OF ALL OBJECTIONS TO THE MOTION, WHICH MAY BE GRANTED WITHOUT FURTHER NOTICE OR HEARING.

Ohio, Court of Federal Claims No: 20–0225V
71. Shannon Pyers, Dresher, Pennsylvania, Court of Federal Claims No: 20–0231V
72. Lisa Macon, Englewood, New Jersey, Court of Federal Claims No: 20–0232V

[FR Doc. 2020–05525 Filed 3–16–20; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of declaration.

SUMMARY: The Secretary is issuing this Declaration pursuant to section 319F–3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID–19.

DATES: The Declaration was effective as of February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving "willful misconduct" as defined in the PREP Act. This Declaration is subject to amendment as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F–3, which addresses liability immunity, and Section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d-6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of "Covered Countermeasures" and "qualified pandemic and epidemic products" in Section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

COVID–19 is an acute respiratory disease caused by the SARS-CoV-2 betacoronavirus or a virus mutating therefrom. This virus is similar to other betacoronaviruses, such as Middle Eastern Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). Although the complete clinical picture regarding SARS-CoV-2 or a virus mutating therefrom is not fully understood, the virus has been known to cause severe respiratory illness and death in a subset of those people infected with such virus(es).

In December 2019, the novel coronavirus was detected in Wuhan City, Hubei Province, China. Today, over 101 countries, including the United States have reported multiple cases. Acknowledging that cases had been reported in five WHO regions in one month, on January 30, 2020, WHO declared the COVID–19 outbreak to be a Public Health Emergency of International Concern (PHEIC) following a second meeting of the Emergency Committee convened under the International Health Regulations (IHR).

To date, United States traveler-associated cases have been identified in a number of States and community-based transmission is suspected. On January 31, 2020, Secretary Azar declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, for the entire United States to aid in the nation's health care community response to the COVID–19 outbreak.[1] The outbreak remains a significant public health challenge that requires a sustained, coordinated proactive response by the Government in order to contain and mitigate the spread of COVID–19.[2]

Description of This Declaration by Section

Section I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a Declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may constitute such an emergency. This determination is separate and apart from the Declaration issued by the Secretary on January 31, 2020 under Section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other Declarations or determinations made under other authorities of the Secretary. Accordingly in Section I of the Declaration, the Secretary determines that the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease, COVID–19, constitutes a public health emergency for purposes of this Declaration under the PREP Act.

Section II. Factors Considered by the Secretary

In deciding whether and under what circumstances to issue a Declaration with respect to a Covered Countermeasure, the Secretary must 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 the countermeasure. In Section II of the Declaration, the Secretary states that he has considered these factors.

Section III. Activities Covered by This Declaration Under the PREP Act's Liability Immunity

The Secretary must delineate the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures

[1] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[2] CDC COVID–19 Summary; *https://www.cdc.gov/coronavirus/2019-ncov/summary.html*, accessed 27Feb2020.