UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

ALICIA SMITH, *et al.*, Plaintiffs, v. UNITED STATES HEALTH RESOURCES AND SERVICES ADMINISTRATION, *et al.*, Defendants.	Case No. 3:23-cv-01425 Judge Elizabeth E. Foote Magistrate Judge Kayla D. McClusky

DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS THE THIRD AMENDED COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

INTRODUCTION

In the Public Readiness and Emergency Preparedness (PREP) Act, Congress struck a careful balance to ensure access to vital countermeasures in response to public health emergencies. Concerned that the specter of litigation could impede development of and access to such countermeasures, Congress granted broad immunity in connection with the provision of countermeasures covered by a PREP Act declaration issued by the Secretary of Health and Human Services. At the same time, Congress provided that where administration of a covered countermeasure directly causes serious physical injury or death, the injured person or her survivors can seek compensation in a no-fault administrative claims process — the Countermeasures Injury Compensation Program (CICP). Plaintiffs ask this Court to unravel this statutory scheme by declaring the entirety of the PREP Act unconstitutional — both its liability protections and the operation of the CICP — as an affront to their rights to procedural and substantive due process under the Fifth Amendment. But they fall well short of stating a claim.

Plaintiffs' procedural due process claim fails at the outset because they cannot establish that the PREP Act's immunity provisions deprived them of a protected property interest. It is well established that there is no vested interest in the continued operation of any rule of common law. *See Ducharme v. Merrill-National Labs.*, 574 F.2d 1307, 1309 (5th Cir. 1978) (per curiam); *Leuz v. Sec'y of Health & Hum. Servs.*, 63 Fed. Cl. 602 (2005). Rather, consistent with due process, Congress may enact (and often has enacted) statutes that prospectively abrogate or offer immunity for state law causes of action.

Even if the PREP Act implicated a protected interest, Plaintiffs fail to show any constitutional inadequacy in the CICP's procedures. Instead, they raise a series of criticisms of the CICP, without explaining how any of them violate their constitutional rights. Beyond that fundamental flaw, most of Plaintiffs' criticisms of the CICP are refuted by their own allegations,

the materials cited in their Complaint, and the governing statutes and regulations. Although Plaintiffs describe the CICP as a "star chamber" that "comes to a predetermined conclusion" of wrongfully denying claims, Third Am. Verified Compl. for Inj. Relief ¶ 9, ECF No. 41 ("3d Am. Compl."), their own success rate under the CICP is 50%: one Plaintiff has received a decision that her claim is compensable, another has received a decision denying his claim, and the other three Plaintiffs' claims are pending.

Plaintiffs' substantive due process claim fares no better. Substantive due process is limited to protecting "deeply rooted" "fundamental rights and liberties" that are "implicit in the concept of ordered liberty." *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997). Plaintiffs identify no such rights at stake. Rather, their substantive due process claim is merely a repackaging of their failed procedural due process claim.

As clear as it is that Plaintiffs' claims fail, the Court need not even reach the merits, as their case suffers from a more fundamental problem: lack of standing. Plaintiffs ask the Court to declare the entirety of the PREP Act unconstitutional — both the provisions providing immunity from liability and those creating the compensation fund that the CICP administers. *See* 3d Am. Compl., Prayer for Relief, § 1 (seeking declaration that "the provisions of the PREP Act which create the scheme providing liability protection and a compensation process for COVID-19 vaccines, including but not limited to 42 U.S.C. §§ 247d-6d and 247d-6e, are unconstitutional"). But a declaratory judgment against the federal government defendants in this lawsuit would not bind the vaccine "manufacturers and administrators," 3d Am. Compl. ¶ 2, that Plaintiffs allege they would like to sue. Therefore, the requested declaratory judgment would not preclude those vaccine manufacturers and administrators from asserting PREP Act immunity as a defense to tort claims. At the same time, such a declaratory judgment could, as a practical matter, prevent Plaintiffs from

pursuing their CICP claims (including Plaintiff Emma Burkey, whose CICP claim has already been found compensable, *see id.* ¶ 56). Such relief would not redress Plaintiffs' claimed injuries but would leave them worse off. Furthermore, Plaintiffs fail to allege that they would have viable tort claims even absent PREP Act immunity. Rather, they implicitly concede that such tort claims would likely be untimely and fail to articulate any tolling doctrine that would allow them to bring such claims.

Thus, whether for lack of standing or failure to state a claim, this case should be dismissed.

BACKGROUND

I. The Public Readiness and Emergency Preparedness (PREP) Act

In 2005, Congress enacted the PREP Act, Pub. L. No. 109-148, 119 Stat. 2680, Division C (2005) (codified at 42 U.S.C. §§ 247d-6d, 247d-6e), to encourage the development and deployment of medical countermeasures to combat public health emergencies.[1] Two aspects of the PREP Act operate in tandem to achieve this result: broad immunity from liability for those involved in making covered countermeasures available, and an opportunity for those injured by covered countermeasures to seek compensation from the federal government through a no-fault administrative claims program, the CICP.

The PREP Act's provisions come into effect when the Secretary of Health and Human Services issues a declaration after making the determination that a disease, health condition, or other threat to health constitutes a public health emergency or there is a credible risk that it may in the future constitute such an emergency and that the manufacture, testing, development, distribution, administration, or use of one or more countermeasures is covered. 42 U.S.C. § 247d-6d(b)(1). In deciding whether to issue such a declaration with respect to a countermeasure, "the

[1] *See* Cong. Rsch. Serv., Compensation Programs for Potential COVID-19 Vaccine Injuries 2 (Oct. 20, 2021), https://crsreports.congress.gov/product/pdf/LSB/LSB10584.

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." *Id.* § 247d-6d(b)(6). Such a declaration triggers immunity from liability "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," with the exception of claims for willful misconduct. *Id.* § 247d-6d(a)(1).[2]

II. The Countermeasures Injury Compensation Program (CICP)

A. Applicable Statutes and Regulations

The PREP Act authorized the Secretary to create the CICP. Under the CICP, those who allege they have been seriously injured by, and survivors who allege that a decedent died from, the administration or use of a covered countermeasure can bring a claim for compensation from the federal government in a no-fault administrative claims process. *See generally id.* § 247d-6e. Compensation is available under the statute for serious physical injury or death "directly caused by the administration or use of a covered countermeasure pursuant to such declaration." *Id.* § 247d-6e(a), (b)(1). A determination "as to the direct causation of a covered injury" must be "based on compelling, reliable, valid, medical and scientific evidence." *Id.* § 247d-6e(b)(4). Congress imposed a one-year deadline for filing claims. *Id.* (incorporating procedural provisions from 42 U.S.C. § 239a); *id.* § 239a(d).[3]

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[2] That immunity extends to the United States and those who produce, sell, distribute, plan and execute programs for, prescribe, administer, or dispense those covered countermeasures. *Id.* § 247d-6d(i)(2). As an exception to this immunity, the Act provides "an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct." *Id.* § 247d-6d(d)(1).

[3] Certain requesters also have an additional one year to file a claim from the date of publication of or amendment to a Countermeasures Injury Table if the effect of the publication or amendment is

The Department of Health and Human Services (HHS) and its component, the Health Resources and Services Administration (HRSA), promulgated regulations establishing and governing the CICP. *See* 42 C.F.R. Part 110. The regulations provide that an individual who suffered a serious injury directly caused by a covered countermeasure, or the survivor of a decedent whose death was directly caused by an injury caused by a covered countermeasure, can file a claim for compensation. 42 C.F.R. § 110.10(a). The claim generally must be filed within one year of administration or use of the covered countermeasure. *Id.* § 110.42(a). A requester must submit a request package with the documentation necessary to determine eligibility, such as medical records and (in a claim for death benefits) the death certificate and documentation that the requester is an eligible survivor. *Id.* §§ 110.41, 110.50, 110.51, 110.52.

B. The Process For Reviewing CICP Claims

The CICP's regulations govern many aspects of the determination of CICP claims, *see generally* 42 C.F.R. Part 110, and the process for submission of CICP claims is also outlined on the CICP's website. HRSA, Countermeasures Injury Compensation Program (CICP) Filing Process, https://www.hrsa.gov/cicp/filing-process. If a requester has not submitted sufficient documentation to determine whether the requester is eligible for compensation, the program will inform the requester and give the requester an opportunity to submit the necessary documentation. 42 C.F.R. § 110.71. The CICP's medical staff conduct an initial medical review of request packages. https://www.hrsa.gov/cicp/filing-process. The Director of the Division of Injury Compensation Programs (DICP) (currently Commander George Reed Grimes, M.D., M.P.H.) then makes determinations concerning whether a requester is eligible for compensation. *See* 3d Am. Compl., Ex. 5, ECF No. 49-1 (decision letter signed by Dr. Grimes). If the requester is eligible

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that a requester who previously could not establish a Table injury can now do so. 42 U.S.C. § 247d-6e(b)(5)(B) (incorporating 42 U.S.C. § 239b(a)(2)); 42 C.F.R. § 110.42(f).

for compensation, the program will inform the requester what documentation the requester must submit to establish the amount of compensation. *See* 42 C.F.R. § 110.60; *see also id.* §§ 110.80-110.82 (regulations setting forth how benefits are calculated). The Director then determines the amount of benefits and notifies the requester in a written decision letter. *See id.* § 110.73. If the Director determines that the requester is not eligible for compensation, the Director will issue a written decision letter to the requester, explaining the basis for the disapproval. *See id.* § 110.74; *see*, *e.g.*, 3d Am. Compl., Ex. 5. Therefore, regardless of how the claim is resolved, the requester will receive a written decision letter setting forth the basis of the Director's determination.

A requester may seek reconsideration, of either a determination that the requester is not eligible for benefits or the amount of such benefits, by submitting a letter seeking reconsideration within 60 days of the decision on the requester's claim. 42 C.F.R. § 110.90(a). A qualified panel, independent of the CICP, reviews the reconsideration request (including the documentation previously submitted to the CICP) and makes a recommendation as to the merits of the claim. *Id.* § 110.90(c). The Associate Administrator of the Health Systems Bureau (HSB), a bureau within HRSA, reviews the panel's recommendation and makes a final written determination of eligibility or benefits amount, which is sent to the requester or his or her representative. *Id.* § 110.90(c). The Associate Administrator's determination is not subject to further administrative or judicial review. *See* 42 C.F.R. §§ 110.90(c), 110.92; 42 U.S.C. § 247d-6e(b)(4); 42 U.S.C. § 239a(f)(2).

III. Procedural Background

Plaintiffs filed their original Complaint on October 10, 2023. ECF No. 1. On October 31, 2023, Plaintiffs filed their First Amended Complaint, ECF No. 18 ("1st Am. Compl."), as a matter of course, *see* Fed. R. Civ. P. 15(a)(1), to conform their claims and allegations to a concurrently filed Motion for Preliminary Injunction, ECF No. 20. Plaintiffs raised claims under the Fifth Amendment (procedural and substantive due process) and Seventh Amendment (right to jury trial)

and sought a declaratory judgment and preliminary and permanent injunctive relief. *See* 1st Am. Compl. ¶¶ 168-208. After the Court identified numerous deficiencies in Plaintiffs' claims during a December 1, 2023 status conference, *see* ECF No. 33 (minutes of status conference), Plaintiffs withdrew their Motion for Preliminary Injunction, and Defendants consented to Plaintiffs further amending their complaint, ECF No. 34, ¶¶ 1-2. Plaintiffs then filed the Second Amended Complaint, ECF No. 35 ("2d Am. Compl."). Although Plaintiffs subsequently informed the Court that they did not intend to renew their Motion for Preliminary Injunction, *see* Order, ECF No. 39, the Second Amended Complaint continued to seek permanent injunctive relief enjoining the federal government defendants from enforcing the PREP Act unless the federal government made a series of changes to the CICP, *see* 2d Am. Compl., Prayer for Relief, § 2. Defendants moved to dismiss the Second Amended Complaint, explaining that it failed to cure the deficiencies in the prior pleadings, *see* Mem. in Supp. of Defs.' Mot. to Dismiss 2d Am. Compl., ECF No. 41-1.

Plaintiffs then sought leave to file the currently operative Third Amended Complaint, *see* ECF No. 45, and Defendants responded by providing consent, *see* ECF No. 47. The Third Amended Complaint narrows Plaintiffs' claims, legal theories, and relief sought in several respects — specifically, by removing the Seventh Amendment claim, *see* 2d Am. Compl. ¶¶ 169-89, two of the four liberty or property interests that Plaintiffs claimed were at stake in their procedural due process claim, *see id.* ¶¶ 139-40, the theory that the time limit for filing CICP claims violates substantive due process, *see id.* ¶¶ 163-65, and the request for injunctive relief, *see id.*, Prayer for Relief, § 2; *see generally* ECF No. 45-2 (redline of proposed Third Amended Complaint from Second Amended Complaint).

As alleged in the Third Amended Complaint, Plaintiffs are five individuals who received a COVID-19 vaccine and have suffered injuries that they contend were caused by the vaccine.

Plaintiff Carolina Bourque received COVID-19 vaccine doses on March 17, 2021, and June 17, 2021. 3d Am. Compl. ¶¶ 26, 28. She alleges that she suffered injuries immediately after receiving each shot. *Id.* ¶¶ 26, 28. She filed a CICP claim during March 2022. *Id.* ¶ 34. She was informed by a CICP representative on February 8, 2023, that CICP was lacking her medical records. *Id.* She does not allege what subsequent steps she took, if any, to ensure that the CICP had the medical records necessary to resolve her claim. Her claim remains pending. *Id.* ¶ 36.

Plaintiff Emma Burkey received a COVID-19 vaccine dose on March 20, 2021. *Id.* ¶ 38. She alleges that she began to suffer serious injuries shortly after receiving the vaccine. *Id.* ¶¶ 39-46. She submitted a CICP claim in November 2021. *Id.* ¶ 55. On December 20, 2023, the Director of the DICP issued a decision letter to Ms. Burkey's mother (who submitted the claim on Ms. Burkey's behalf), which Ms. Burkey received on January 5, 2024, determining that Ms. Burkey had suffered an injury that was eligible for compensation and requesting additional documentation to determine the amount of benefits. *Id.* ¶ 56.[4]

Plaintiff Christopher Cody Flint received a COVID-19 vaccine dose on February 1, 2021. *Id.* ¶ 58. He alleges that he suffered injuries shortly after receiving the vaccine. *Id.* ¶¶ 58-60. He filed a CICP claim on April 25, 2021. *Id.* ¶ 63. His claim was denied on May 25, 2022, in a letter signed by Dr. Grimes, the Director of the DICP. *Id.*; *see also id.* Ex. 5. The letter concluded that "[t]he compelling, reliable and valid medical and scientific evidence does not support a causal association between the Pfizer COVID-19 vaccine and" Mr. Flint's injuries. *Id.* Ex. 5. On June

[4] Defendants have not attached to this filing the decision letter, which contains medical information about Ms. Burkey, but would be willing to file it under seal if requested by the Court.

15, 2022, Mr. Flint requested reconsideration. *Id.* ¶ 65. His request for reconsideration was denied in a signed letter dated January 18, 2023. *Id.*[5]

Plaintiff Michelle Zimmerman received a COVID-19 vaccine dose on March 14, 2021. *Id.* ¶ 69. She alleges that she immediately began suffering serious injuries. *Id.* She filed a CICP claim on October 1, 2021. *Id.* ¶ 76. Her claim remains pending. *Id.* ¶ 81.

Plaintiff Jessica Krogmeier received a COVID-19 vaccine dose on September 3, 2021. *Id.* ¶ 84. She alleges that she began suffering injuries immediately after receiving the vaccine. *Id.* ¶ 86. Ms. Krogmeier submitted a CICP claim in September 2021. *Id.* ¶ 93. Although she alleges that her physicians submitted medical records, she was informed by a CICP representative on February 9, 2023, that the CICP was lacking her medical records, and that the CICP could not progress with processing her claim without the medical records. *Id.* ¶ 94. She does not allege what steps she subsequently took, if any, to ensure that the CICP had her medical records.

To summarize, one Plaintiff (Ms. Burkey) received a decision letter indicating that her claim was compensable approximately two years after submitting her claim. One Plaintiff (Mr. Flint) had a claim denied 13 months after submission and a reconsideration request denied seven months after submission. Two Plaintiffs (Ms. Bourque, Ms. Krogmeier) were informed by CICP representatives that the CICP did not have medical records needed to process their claims but do not allege what subsequent steps, if any, they took to ensure that CICP had or received those records. And the remaining Plaintiff (Ms. Zimmerman) had a claim pending for approximately two years when Plaintiffs initiated this case.

[5] Defendants have not attached to this filing the decision letter, which contains medical information about Mr. Flint, but would be willing to file it under seal if requested by the Court.

The Third Amended Complaint names HHS and HRSA as Defendants. *See id.* ¶¶ 22-23.[6] Plaintiffs no longer seek injunctive relief, but they seek a declaratory judgment that the PREP Act in its entirety, including its "liability protection and . . . compensation process for COVID-19 vaccines," is unconstitutional in violation of the Fifth Amendment. *Id.*, Prayer for Relief, § 1.[7] Plaintiffs allege that they "desire to bring common law and state law claims for, *inter alia*, negligence, intentional infliction of emotional distress ('**IIED**'), and products liability against the manufacturers and administrators of the products that injured them," *id.* ¶ 2, but they neither identify the manufacturers and administrators that they would like to sue nor name them as defendants to this lawsuit.

LEGAL STANDARD

"Federal Rule of Civil Procedure 12(b)(1) allows a defendant to move for the dismissal of a plaintiff's claims for lack of subject matter jurisdiction." *Strange v. Wal-Mart Inc.*, No. CV 18-0325, 2018 WL 2269919, at *1 (W.D. La. May 16, 2018). "The plaintiff bears the burden of establishing subject matter jurisdiction." *Id.* When a defendant raises a "facial attack" on the court's subject matter jurisdiction based on the pleadings, a court "look[s] to the sufficiency of the allegations in the complaint" to "determine whether [the] complaint sufficiently alleges the necessary jurisdictional facts." *Id.* at *2 (quoting *Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir. 1981)).

[6] Plaintiffs also name three fictional John Doe defendants allegedly involved in operating the CICP. *Id.* ¶ 24.

[7] The Third Amended Complaint contains certain references to injunctive relief that were carried over from the Second Amended Complaint. *See* 3d Am. Compl. ¶¶ 14, 163, 171. However, Plaintiffs' counsel confirmed to Defendants' counsel via email that Plaintiffs intended to remove the request for injunctive relief and no longer continue to request that the Court enter permanent injunctive relief.

"In order to survive a motion to dismiss brought under Rule 12(b)(6), a plaintiff must 'state a claim to relief that is plausible on its face.'" *Joyner v. Kansas City S. R.R. Co.*, No. CV 22-180, 2022 WL 1548097, at *1 (W.D. La. May 16, 2022) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Although "[t]he Court must accept as true all of the factual allegations in the complaint," it "is 'not bound to accept as true a legal conclusion couched as a factual allegation.'" *Id.* (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). "A court may dismiss an otherwise well-pleaded claim if it is premised upon an invalid legal theory." *Id.* In resolving a Rule 12(b)(6) motion to dismiss, a court "may consider the complaint, its proper attachments, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Doe v. United States*, 853 F.3d 792, 800 (5th Cir. 2017) (citations and quotations omitted).

ARGUMENT

I. Plaintiffs Fail To Plead A Basis For Standing

"[T]o establish standing, a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021). "The plaintiff must clearly allege facts at the pleading stage establishing all three criteria." *Satanic Temple Inc. v. Young*, No. 4:21-CV-00387, 2023 WL 4317185, at *2 (S.D. Tex. July 3, 2023). "[S]tanding is not dispensed in gross. To the contrary, a plaintiff must demonstrate standing for each claim he seeks to press and for each form of relief that is sought." *Town of Chester, N.Y. v. Laroe Ests., Inc.*, 581 U.S. 433, 439 (2017) (citations and quotations omitted).

Plaintiffs fail to show that the relief sought would redress their injuries. Plaintiffs seek a declaratory judgment that the entirety of the PREP Act — "the provisions of the PREP Act which create the scheme providing liability protection and a compensation process for COVID-19

vaccines, including but not limited to 42 U.S.C. §§ 247d-6d and 247d-6e," 3d Am. Compl., Prayer for Relief, § 1 — is unconstitutional. Plaintiffs assert that they "desire to bring common law and state law claims . . . against the manufacturers and administrators of" COVID-19 vaccines, who benefit from PREP Act immunity. *Id.* ¶ 2. However, the declaratory judgment Plaintiffs seek would not redress their claimed injuries because it would not be binding on those manufacturers and administrators of COVID-19 vaccines, who would continue to be able to assert PREP Act immunity as a defense to litigation.

In litigation covered by PREP Act immunity, defendants assert the PREP Act as a defense, and if immunity applies, the court dismisses the lawsuit. *See*, *e.g.*, *Bird v. State*, 537 P.3d 332, 336-37 (Wyo. 2023) (affirming decision granting summary judgment to defendant on the basis of PREP Act immunity); *M.T. as next friend of M.K. v. Walmart Stores, Inc.*, 528 P.3d 1067, 1070-71 (Kan. App. 2023) (directing dismissal of all claims pursuant to PREP Act immunity). Potential defendants to such tort claims are not parties here and would not be bound by a judgment entered by this Court. *See Taylor v. Sturgell*, 553 U.S. 880, 893 (2008) (recognizing the general rule that nonparties to litigation are not bound by judgments). In particular, "a declaratory judgment binds the parties, but only the parties, wherever they may be. This result tracks the language of the Declaratory Judgment Act, which empowers courts to declare the rights 'of any interested *party*.' 28 U.S.C. § 2201 (emphasis added). On its face, this statutory language limits the scope of a declaratory judgment to a party." *Skyworks, Ltd. v. Centers for Disease Control & Prevention*, 542 F. Supp. 3d 719, 728 (N.D. Ohio 2021); *see also Lujan v. Defs. of Wildlife*, 504 U.S. 555, 569 (1992) (nonparties are not "obliged to honor an incidental legal determination the suit produced"); *Bituminous Cas. Corp. v. J & L Lumber Co.*, 373 F.3d 807, 814 (6th Cir. 2004) (a declaratory judgment "would not be binding as to" someone who "was not made a party to the declaratory

judgment action" and "could not be *res judicata*" against that party in a separate tort action). Here, the declaratory judgment Plaintiffs seek would not be binding on the private parties they wish to sue in subsequent tort lawsuits and would not redress their claimed injury from the immunity that those parties enjoy under the PREP Act.[8]

Furthermore, even if Plaintiffs' requested relief were sufficient to overcome PREP Act immunity with respect to future lawsuits against private parties (which it is not), they have not shown that such claims would be timely. For example, Ms. Bourque is a Louisiana resident who alleges that she received COVID-19 vaccine doses in 2021. *See* 3d Am. Compl. ¶¶ 17, 26, 28. Louisiana applies a one-year prescriptive period for most tort claims. La. Civ. Code Ann. art. 3492. Plaintiffs assert that "[i]t is Plaintiffs [sic] expectation that, pursuant to the instant litigation, the statutes of limitation on these claims will be tolled." 3d Am. Compl. ¶ 2 n.1. But they do not articulate any tolling doctrine that would apply to their hypothetical future tort claims. It is therefore entirely speculative that, even absent PREP Act immunity, any of their tort claims would remain viable.

II. Plaintiffs Fail To State A Claim Upon Which Relief May Be Granted

A. Plaintiffs Fail To State A Procedural Due Process Claim

The PREP Act's grant of liability immunity in the context of countermeasures to combat a public health emergency (or credible risk of future public health emergency), and the CICP's provision of an administrative path to compensation for injuries caused by such countermeasures,

[8] While a decision from this Court could perhaps be cited as persuasive authority in future cases, it would not be binding precedent on other courts, or even this court, in cases against other defendants. *See Camreta v. Greene*, 563 U.S. 692, 709 n.7 (2011). Thus, whatever force a declaratory judgment has as persuasive authority, that is insufficient to meet the redressability requirement. *See Franklin v. Massachusetts*, 505 U.S. 788, 825 (1992) (Scalia, J., concurring in part and concurring in the judgment) ("Redressability requires that the court be able to afford relief *through the exercise of its power*, not through the persuasive or even awe-inspiring effect of the opinion *explaining* the exercise of its power.").

do not violate Plaintiffs' right to procedural due process. Plaintiffs' contrary arguments fail as a matter of law.

The Due Process Clause of the Fifth Amendment provides, "nor shall any person . . . be deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V.[9] Courts "examine procedural due process questions in two steps: the first asks whether there exists a liberty or property interest which has been interfered with by the [government]; the second examines whether the procedures attendant upon that deprivation were constitutionally sufficient." *Ky. Dep't of Corr. v. Thompson*, 490 U.S. 454, 460 (1989) (citation omitted). At the first step, a court "must look to see if the interest is within the [Due Process Clause]'s protection of liberty and property" in order "to determine whether due process requirements apply in the first place." *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 570-71 (1972). Plaintiffs' claim fails at both steps. They fail to allege that they have been deprived of a protected property interest, and even if they had, they fail to allege that the CICP's procedures are constitutionally insufficient.

1. Plaintiffs Have Not Been Deprived Of A Protected Property Interest

Plaintiffs' procedural due process claim fails at the threshold because they have not shown a deprivation of a protected property interest. Plaintiffs claim that two property interests are at stake, but in each case, their claim fails as a matter of law.

First, Plaintiffs claim that the PREP Act deprives them of a protected property interest because it "extinguished Plaintiffs' common law . . . tort claims" and replaced them with an

[9] The Fourteenth Amendment similarly provides: "nor shall any State deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV. Some of the cases discussed in this section involve analysis of the Fourteenth Amendment's Due Process Clause as applied to state action. "Because the Due Process Clauses use the same language and guarantee individual liberty in the same way, . . . the standards developed in the Fourteenth Amendment context must govern under the Fifth Amendment." *Douglass v. Nippon Yusen Kabushiki Kaisha*, 46 F.4th 226, 238 (5th Cir. 2022).

administrative compensation program. 3d Am. Compl. ¶ 142. But the PREP Act granted immunity for claims relating to covered countermeasures long before Plaintiffs were injured. As the Fifth Circuit has repeatedly held, litigants have no vested right in the continuation of a long-ago abrogated rule of common law, and so Plaintiffs were not deprived of any property interest protected by the Due Process Clause.

In *Keller v. Dravo Corp.*, 441 F.2d 1239 (5th Cir. 1971), the Fifth Circuit upheld against a due process challenge the Longshoremen's and Harbor Workers' Compensation Act, which "makes management immune from damage suits for its maritime torts against repair yard workers," and substitutes an administrative workers' compensation claim. *Id.* at 1241. The court rejected the argument that the workers had a protected property interest in tort claims, explaining that the Supreme Court has held that "[a] person has no property, no vested interest, in any rule of the common law. . . . Rights of property which have been created by the common law cannot be taken away without due process; but the law itself, as a rule of conduct, may be changed at the will . . . of the legislature, unless prevented by constitutional limitations." *Id.* at 1242 (quoting *Mondou v. New York, New Haven & Hartford R.R. Co.*, 223 U.S. 1, 50 (1912)). As the Fifth Circuit explained, "one cannot be heard to question the sufficiency of due process if the rule of law, which merely held the potential to create a property right, was changed before any right vested." *Id.*

The Fifth Circuit later reaffirmed the principle that a statute that prospectively provides immunity from tort claims does not deprive litigants of a protected property interest in *Ducharme v. Merrill-National Laboratories*, 574 F.2d 1307 (5th Cir. 1978) (per curiam), a case that, like this one, involved a statute that provided immunity from tort claims for vaccine injuries. *Ducharme* involved the Swine Flu Act, a statute enacted in 1976 that abrogated tort claims arising out of swine flu vaccinations and replaced them with an exclusive cause of action against the federal

government, with no right to a jury trial. *Id.* at 1309. Rejecting plaintiffs' claim that the act violated the Due Process Clause because it "abrogated plaintiffs' cause of action" against the manufacturer under Louisiana law, the Fifth Circuit held that "[i]t is well settled that a plaintiff has no vested right in any tort claim for damages under state law." *Id.* Because "[p]laintiffs' cause of action against the manufacturer did not arise until after passage of the Swine Flu Act," they "had no prior vested right in a cause of action." *Id.* at 1310. The same is true here of Plaintiffs' tort claims and the PREP Act. These Fifth Circuit decisions are binding and compel rejection of Plaintiffs' due process claim.

Other courts are in accord. Like *Ducharme*, several courts (including the Eighth Circuit) rejected due process challenges to the Swine Flu Act.[10] More recently, the Court of Federal Claims upheld against a due process challenge the National Childhood Vaccine Injury Act ("Vaccine Act"), holding that the Vaccine Act did not deprive litigants of a property interest when it prospectively abrogated tort claims arising out of administration of certain vaccines and replaced them with an exclusive remedy against the United States. *See Leuz v. Sec'y of Health & Hum. Servs.*, 63 Fed. Cl. 602 (2005). Relying on Fifth Circuit case law, the court held that "a plaintiff has no vested right in any tort claim for damages." *Id.* at 610 (quoting *Ducharme*, 574 F.2d at 1309). As the court explained: "The Vaccine Act was the law of the land when petitioners' cause

[10] *See Jones v. Wyeth Labs., Inc.*, 457 F. Supp. 35, 37 (W.D. Ark. 1978) ("No individual has a vested right in any common law cause of action. Any prospective cause of action Plaintiff may have had against a vaccine manufacturer had not vested at the time the Swine Flu Act was passed on August 13, 1976. Therefore, consistent with due process, the prospective cause of action could be abolished and the statutory remedy envisioned by the Swine Flu Act substituted."), *aff'd*, 583 F.2d 1070, 1070-71 (8th Cir. 1978) ("We, thus, affirm on the basis of the District Court's opinion."); *Sparks v. Wyeth Labs., Inc.*, 431 F. Supp. 411, 416 (W.D. Okla. 1977) ("There is no question but that the Swine Flu Act comports with the due process clause of the Fifth Amendment. It is manifest that the statute, insofar as it abolishes a cause of action against a program participant, does so only prospectively."); *Wolfe v. Merrill Nat. Labs., Inc.*, 433 F. Supp. 231, 236 (M.D. Tenn. 1977).

of action arose. As such, the only property rights petitioners had to sue a manufacturer for alleged vaccine-related injuries necessarily flowed through the Vaccine Act. Because petitioners have not been deprived of any property right, they suffered no procedural due process violation." *Id.* at 611. Likewise, the PREP Act was the law of the land when Plaintiffs' claims arose, so the PREP Act's prospective grant of immunity for tort claims did not deprive them of any property right.

Indeed, courts have recognized that even when Congress passes a law abrogating then-pending causes of action and provides no substitute remedy, there has been no deprivation of a protected property interest. In 2005, Congress enacted the Protection of Lawful Commerce in Arms Act ("PLCAA"), which immunized federally licensed firearms manufacturers and sellers from most tort claims resulting from the criminal use of firearms, and applied even to pending claims, requiring courts to "immediately dismiss" such claims. *Ileto v. Glock, Inc.*, 565 F.3d 1126, 1131 (9th Cir. 2009) (quoting 15 U.S.C. § 7902(b)). Yet the Ninth Circuit held that plaintiffs suing firearms manufacturers had no "vested property right" in even a pending state-law cause of action, because "although a cause of action is a species of property, a party's property right in any cause of action does not vest until a final unreviewable judgment is obtained." *Id.* at 1141; *see also D.C. v. Beretta U.S.A. Corp.*, 940 A.2d 163, 175-76 (D.C. 2008) (similarly rejecting Due Process Clause challenge to PLCAA).

The case law cited by Plaintiffs is not to the contrary. Plaintiffs cite *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982), for the proposition that a cause of action is a type of property protected under the Due Process Clause. *Logan* held that a state violated the Fourteenth Amendment's Due Process Clause when it deprived a plaintiff of a valid cause of action under state law because a state commission failed to convene a fact-finding conference during the time period required by the state statute. *Id.* at 427-31. But *Logan* explained that no due process

violation occurs when the legislature changes or eliminates the rule of law that gave rise to the cause of action, explaining: "the State remains free to create substantive defenses or immunities for use in adjudication—or to eliminate its statutorily created causes of action altogether—just as it can amend or terminate its welfare or employment programs. . . . In each case, the legislative determination provides all the process that is due." *Id.* at 432-33.[11]

Second, Plaintiffs allege that "to the extent the PREP Act provides a right to relief for Plaintiffs and others injured by COVID-19 vaccines, Plaintiffs have a liberty or property interest in seeking proper relief for their injuries." 3d Am. Compl. ¶ 144. But Plaintiffs do not allege that they have been deprived of the right to pursue CICP claims in accordance with the PREP Act. To the contrary, all five Plaintiffs have filed CICP claims and have had or are having those claims resolved in accordance with the PREP Act and applicable regulations. Ms. Burkey's claim was found to be compensable, the claims of Ms. Bourque, Ms. Zimmerman, and Ms. Krogmeier are pending, *id.* ¶¶ 36, 81, 95, and Mr. Flint's claim was denied (on initial decision and reconsideration, with both decisions occurring within two years of his claim submission) in accordance with the PREP Act and the governing regulations, *id.* ¶¶ 63, 65; Ex. 5.[12]

[11] None of the other cases cited by Plaintiffs upheld a challenge to a provision granting immunity for common-law claims. *See Tulsa Prof'l Collection Serv. v. Pope*, 485 U.S. 478, 485 (1988) (upholding challenge to state statute providing that probate claims could be extinguished if not presented to the executor within two months of publication of a notice of commencement of proceedings); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 806-12 (1985) (rejecting due process challenge to opt-out class actions); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 647, 656 (S.D. Tex. 2004) (holding that a statute of limitations was reasonable and consistent with due process).

[12] Mr. Flint criticizes some of the reasoning in the decision denying his claim, *id.* ¶ 64, but he does not allege facts showing that there is "compelling, reliable, valid, medical and scientific evidence" that his injuries directly resulted from the vaccine, as would be necessary to establish a valid CICP claim. 42 U.S.C. § 247d-6e(b)(4).

2. Plaintiffs Fail To Identify Any Constitutional Infirmity In The CICP's Procedures

Plaintiffs' due process claim fails at the first step, so the Court need not and should not advance to the second step of assessing the adequacy of the CICP's procedures. But if the Court reaches that step, Plaintiffs fail to plead the existence of any constitutional inadequacy in the CICP procedures.

In an earlier status conference in this case, the Court noted that in the First Amended Complaint and the since-withdrawn Motion for Preliminary Injunction, Plaintiffs stated that they "believe CICP is an ineffective process," but had not "enumerate[d] why such a process is a procedural due process violation." *See* Minutes from Dec. 1, 2023 Status Conference 2-3, ECF No. 33. Plaintiffs have not cured this deficiency. The Third Amended Complaint raises criticisms of the CICP and asserts that "taken together," these criticisms "demonstrate the government's disregard of basic due process protections." 3d Am. Compl. ¶ 155. Yet Plaintiffs cannot show that any alleged feature of the CICP is unconstitutional, and they fail to explain how various constitutional features of the CICP somehow morph into a constitutional violation when "taken together."

When assessing whether administrative procedures are constitutionally adequate, courts generally consider

> three distinct factors: First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

Mathews v. Eldridge, 424 U.S. 319, 335 (1976).

On the first factor, as explained above, Plaintiffs have not shown that any protected property interest is at stake, *see supra*, Part II.A.1. The crux of Plaintiffs' argument is their

contention that, at the second factor, the CICP employs unfair procedures that create a significant risk of erroneous denial of claims. But their allegations fail to show that such a significant risk exists.

Plaintiffs' criticisms of the CICP are misguided and are either unsupported or are contradicted by their factual allegations and the statutes and regulations governing the CICP. Plaintiffs allege that only a small number of CICP claims based on COVID-19 countermeasures have been compensated, 3d Am. Compl. ¶ 101, but they plead no facts to support the inference of an "established record of erroneous" denials of CICP claims. *Id.*, heading before ¶ 150 (emphasis and capitalization omitted). As Plaintiffs acknowledge, the CICP has explained the reasons why claims have been denied. Those reasons are all grounded directly in the PREP Act and governing regulations. According to data on the CICP's website cited in the Third Amended Complaint, as of January 1, 2024, 2,174 COVID-19 claims have been denied, for the following reasons:

- 1,320 (60.7%) claims were denied because requesters did not file within the one-year filing deadline required by the PREP Act and governing regulations. *See id.* ¶ 102; 42 U.S.C. § 247d-6e(b)(4) (incorporating procedural provisions from 42 U.S.C. § 239a); *id.* § 239a(d) ("[t]he Secretary shall not consider any" claim "unless" it is filed "not later than one year after the date of administration of the vaccine"); 42 C.F.R. § 110.42(a) ("All Request Forms . . . must be filed within one year of the date of the administration or use of a covered countermeasure that is alleged to have caused the injury.").

- 251 (11.5%) claims were denied because the requester did not identify any covered countermeasure that had been administered, 3d Am. Compl. ¶ 102, reflecting that under the PREP Act, compensation is only available for "a covered injury directly caused *by the administration or use of a covered countermeasure* pursuant to [a PREP Act] declaration," 42 U.S.C. § 247d-6e(b)(1) (emphasis added); *see also* 42 C.F.R. § 110.20(a) (requiring requester to show that a covered injury was caused by "the administration or use of a covered countermeasure").

- 263 (12.1%) claims were denied based on failure to show that the covered countermeasure directly caused a covered injury, 3d Am. Compl. ¶ 102, which again reflects the standard set forth in the PREP Act and regulations, *see* 42 U.S.C. § 247d-6e(b)(1); 42 C.F.R. § 110.20(a).

- 340 (15.6%) claims were denied because the requester failed to submit requested medical records, 3d Am. Compl. ¶ 102, as required by the governing regulations, 42 C.F.R. § 110.50.

Plaintiffs allege no facts to call into question the accuracy of these determinations.[13] Although Plaintiffs suggest that the CICP "look[s] for every possible technicality to throw out otherwise legitimate claims," 3d Am. Compl. ¶ 102, their factual allegations regarding CICP's reasons for denying claims refute that conclusory assertion. Three of the reasons provided for denying claims — failure to file a timely claim, failure to show administration of a covered countermeasure, and failure to show that the covered countermeasure caused a covered injury — reflect direct requirements of the PREP Act and governing regulations. The fourth — failure to submit medical records — reflects a requirement of the governing regulations that is necessary to ensure that the CICP has adequate information to evaluate eligibility for compensation. Furthermore, 40 COVID-19 claims have been found eligible for compensation, including Ms. Burkey's claim (many of those eligible claims, including Ms. Burkey's, are currently awaiting determinations of the amount of benefits). *See* HRSA, Countermeasures Injury Compensation Program (CICP) Data, Aggregate Data as of January 1, 2024, https://perma.cc/883K-PYFJ.[14]

[13] Plaintiffs criticize the denial of Mr. Flint's claim because a doctor told him "*I think* that shot made you one sick son of a bitch," and he allegedly suffered a "rapid onset of symptoms post-vaccination." 3d Am. Compl. ¶ 60 (emphasis added). But he does not allege facts showing that there is "compelling, reliable, valid, medical and scientific evidence" that his injuries directly resulted from the vaccine, as would be necessary to establish a valid CICP claim. 42 U.S.C. § 247d-6e(b)(4). Allegations that the onset of injury occurred close in time to countermeasure administration are insufficient because the governing regulations provide that "[t]emporal association between receipt of the countermeasure and onset of the injury is not sufficient by itself to prove that the countermeasure caused the injury." 42 C.F.R. § 110.20(c). Yet even if the Court believed that Plaintiffs had reasonably called into question the accuracy of a single claim determination, that would hardly establish that the program as a whole violates due process.

[14] Plaintiffs affirmatively rely on the CICP data and do not question its accuracy. *See* 3d Am. Compl. ¶¶ 101-02. Therefore, this data is fairly encompassed in the Third Amended Complaint and is subject to judicial notice. *See Doe*, 853 F.3d at 800 (court may consider "documents incorporated into the complaint by reference"); Fed. R. Evid. 201(b)(2) (court can take judicial notice of facts that "can be accurately and readily determined from sources whose accuracy cannot

These favorable compensation determinations disprove Plaintiffs' assertion that the CICP "comes to a predetermined conclusion" of wrongfully denying claims. 3d Am. Compl. ¶ 9.

Plaintiffs complain that the "CICP's process is shrouded in secrecy." *Id.* ¶ 104. Yet they themselves cite four separate pages on CICP's website, *see* www.hrsa.gov/cicp, which describe the CICP's process. 3d Am. Compl. ¶¶ 105-06.[15] In addition to the information on the CICP's website, HHS has issued regulations published in the Code of Federal Regulations that govern the CICP's operations. *See* 42 C.F.R. Part 110. When HHS promulgated these regulations, HHS published notices that together comprised 37 pages in the Federal Register. *See Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Interim Final Rule*, 75 Fed. Reg. 63,656 (Oct. 15, 2010); *Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Final Rule*, 76 Fed. Reg. 62,306 (Oct. 7, 2011). The publication of such extensive information about the CICP's operations hardly indicates a program shrouded in secrecy.

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reasonably be questioned"). This data is available on the CICP's website at https://www.hrsa.gov/cicp/cicp-data. Because the data is updated monthly, Defendants have provided a permanent link to the version of the data current as of the time of this filing.

[15] The CICP's website contains pages generally describing the CICP, https://www.hrsa.gov/cicp; describing the meaning of "covered countermeasures," https://www.hrsa.gov/cicp/covered-countermeasures; describing who can file for benefits, https://www.hrsa.gov/cicp/who-can-file-benefits; describing the CICP's process, https://www.hrsa.gov/cicp/filing-process; describing the types of available CICP benefits, https://www.hrsa.gov/cicp/types-cicp-benefits; describing the criteria used to determine whether a covered injury occurred, https://www.hrsa.gov/cicp/criteria-demonstrate-covered-injury-occurred; summarizing claims processing data, with ten monthly-updated Excel spreadsheets available for download, https://www.hrsa.gov/cicp/cicp-data; a frequently asked questions page with 40 questions and answers categorized by subject matter, https://www.hrsa.gov/cicp/faq; a chart comparing the CICP to another compensation program, the Vaccine Injury Compensation Program, https://www.hrsa.gov/cicp/cicp-vicp; and a page collecting links to further resources, including the governing statute and regulations. https://www.hrsa.gov/cicp/resources. The website also lists a street address, email address, and toll-free telephone number for the CICP.

Plaintiffs assert that they do not know who decides CICP claims, 3d Am. Compl. ¶ 109, but eligibility determinations are made by the Director of the DICP (currently Dr. Grimes), and the Director issues signed letters explaining the basis of eligibility determinations. *See* 3d Am. Compl., Ex. 5 (decision letter signed by Dr. Grimes); 42 C.F.R. §§ 110.3(y), 110.73-110.74. In response to a FOIA request submitted by Plaintiffs' counsel asking for the identity of CICP personnel, HRSA disclosed the identities of DICP's Director and Deputy Director but did not disclose the identities of lower-level staff "[d]ue to credible threats and harassment against the DICP staff and to protect the safety and wellbeing of the DICP staff." 3d Am. Compl. ¶ 109; *id.* Ex. 14, ECF No. 49-1. Plaintiffs do not question that DICP has faced credible threats and harassment against its staff, nor do they articulate why the Fifth Amendment provides them a right to learn the names of lower-level agency staff members.

Plaintiffs similarly assert they do not know who decides requests for reconsideration, 3d Am. Compl. ¶ 116, but the regulations provide that reconsideration determinations are made by the Associate Administrator of the Health Systems Bureau (currently Suma Nair, Ph.D., M.S.), after receiving a recommendation from a panel of qualified reviewers independent from the CICP. 42 C.F.R. § 110.90(c). The Associate Administrator explains her decisions in written letters that are "sent to the requester (or his or her representative)," such as the letter denying Mr. Flint's request for reconsideration. *Id.*; *see also* 3d Am. Compl. ¶ 65 (indicating that Mr. Flint was notified of the denial of his request for reconsideration).

Plaintiffs assert that they "have no way to confirm whether any individuals deciding claims have any conflicts of interests." 3d Am. Compl. ¶ 110. But as noted, the decisionmakers are the Director of the DICP (who makes initial determinations) and the Associate Administrator of the Health Systems Bureau (who makes reconsideration determinations), each of whom issued a

signed decision letter to Mr. Flint. Plaintiffs allege no facts suggesting that these officials have a conflict of interest.

Plaintiffs complain that the government provides no definitive timeline for resolving claims, *id.* ¶ 111, but Mr. Flint received an eligibility decision in just over a year and Ms. Burkey received an eligibility decision in just over two years. That it would take some time for the CICP to progress through COVID-19 claims is understandable, given that the program went from receiving only about 500 non-COVID-19 claims in its entire history to receiving a wave of around 13,000 COVID-19 claims over the last few years. *See* HRSA, Countermeasures Injury Compensation Program (CICP) Data, Aggregate Data as of January 1, 2024, https://perma.cc/883K-PYFJ (13,406 claims filed in CICP's history, of which 12,854 are COVID-19 claims). As Plaintiffs' own pleadings in this case reveal, the CICP has been increasing its pace of resolving COVID-19 claims. *Compare* Compl. ¶ 153 (1,161 COVID-19 claims decided as of Sep. 1, 2023), *with* 3d Am. Compl. ¶ 102 (2,214 COVID-19 claims resolved as of January 1, 2024). Plaintiffs acknowledge that the CICP's rate of deciding claims increased to 90 claims per month in 2023. 3d Am. Compl. ¶ 103. They speculate that the pace "will, as [CICP] runs out of technical reasons, likely slow down greatly as CICP will need to find other reasons to continue denying claims or giving near-nothing compensation," *id.*, but they offer no basis for this guess.[16]

[16] Dr. Grimes recently testified to Congress that in response to the wave of COVID-19 claims, the CICP increased its staffing from four to more than thirty-five full-time staff members and made other process improvements to increase the pace of processing claims and enhance transparency, such as allowing requesters to check the status of claims online and introducing a chat function on its website. *See* Commander George Reed Grimes, Testimony before the United States House of Representatives, Committee on Oversight and Accountability, Select Subcommittee on the Coronavirus Pandemic (Feb. 15, 2024), *available at* https://oversight.house.gov/wp-content/uploads/2024/02/HRSA_SSCP-Testimony-for-02.15.2024-Hearing.pdf; 3d Am. Compl. Ex. 13, ECF No. 49-1 (transcript of February 15, 2024 hearing). Congressional testimony is subject to judicial notice. *See*, *e.g.*, *D.A.M. v. Barr*, 474 F. Supp. 3d 45, 55 (D.D.C. 2020) (taking

Indeed, pharmaceutical civil litigation, which Plaintiffs portray as the gold standard of due process, often takes far more than two years to resolve claims, particularly where (as here) hundreds or thousands of parties claim injury from the same products. As an example, a multidistrict litigation involving claims of more than 500 plaintiffs who claim to have suffered atypical femoral fractures caused by the drug Fosamax in the year 2010 or earlier has been pending for well over a decade, and is still involved in litigation over the preliminary question of whether plaintiffs' claims are preempted by federal law. *See In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 593 F. Supp. 3d 96, 103-04 (D.N.J. 2022), *appeal pending*, No. 22-3412 (3d Cir.). As another example from this state, after six years, a multidistrict litigation involving the drug Taxotere only "beg[a]n the orderly process of remanding cases to their appropriate trial courts." Case Management Order No. 33, *In re: Taxotere (Docetaxel) Prods. Liab. Litig.*, MDL No. 2740 (E.D. La. Mar. 18, 2022). Plaintiffs cannot show that the length of time to resolve claims renders this administrative process constitutionally inadequate when the federal courts routinely take far longer to resolve similar claims.

Plaintiffs acknowledge that the CICP has disclosed that to be covered, an injury must "direct[ly] result" from "the administration or use of a covered countermeasure," and that "the CICP may only make such determinations based on compelling, reliable, valid, medical, and scientific evidence," 3d Am. Compl. ¶ 113 (quoting https://www.hrsa.gov/cicp/criteria-demonstrate-covered-injury-occurred), but they argue that "[t]his standard appears to be determined by unidentified individuals," *id.* Yet that standard comes directly from the governing statute. *See* 42 U.S.C. § 247d-6e(b)(1) (compensation available for "a covered injury directly

judicial notice of congressional testimony); *Johnson & Johnson v. Am. Nat. Red Cross*, 528 F. Supp. 2d 462, 464 n.1 (S.D.N.Y. 2008) (same).

caused by the administration or use of a covered countermeasure"); *id.* § 247d-6e(b)(4) (in absence of a covered countermeasure injury table, determinations of causation can be made "only . . . based on compelling, reliable, valid, medical and scientific evidence"). This standard is more favorable in key respects than the standard that would apply in tort litigation, where (depending on the exact cause of action) a plaintiff would need to prove additional elements, such as that a defendant was negligent or that the product was defective.

Plaintiffs complain that requesters cannot present fact or expert witnesses, 3d Am. Compl. ¶ 115, but the CICP regulations allow requesters to submit whatever written evidence they would like, including expert analysis. *See* 42 C.F.R. § 110.50. Requesters can also submit additional evidence at any time before an eligibility determination is made. *Id.* § 110.46(a). If the CICP needs additional information to resolve a claim, the program will inform the requester and give them a chance to submit the necessary documentation. *Id.* § 110.71.

Plaintiffs suggest that the CICP will lack funding to pay claims, 3d Am. Compl. ¶ 120, but the CICP has never failed to pay a compensable claim due to lack of funding, and Plaintiffs do not allege otherwise. Any notion that the CICP will run out of funding in the future and that Congress will not provide funding necessary to pay claims is pure speculation and cannot support a present constitutional claim.

In sum, Plaintiffs fail to allege facts that would show that the CICP's procedures give rise to any meaningful risk of erroneous denials of claims, let alone a risk that is so significant as to be constitutionally unacceptable under the *Mathews* test. Plaintiffs instead argue that because the CICP was created through a statute that provided immunity for tort claims, the adequacy of the CICP must be measured against "the starting point" of the "procedures" present in traditional civil litigation. 3d Am. Compl. ¶¶ 153-54. Essentially, Plaintiffs argue that due process requires that

when a legislature abrogates tort claims, the legislature must provide a substitute remedy that approximates civil litigation. This argument cannot be squared with controlling precedent. As the Fifth Circuit has explained, because "[i]t is well settled that a plaintiff has no vested right in any tort claim for damages under state law," *Ducharme*, 574 F.2d at 1309, Congress need not provide *any* substitute remedy when abrogating tort claims, *see id.* at 1310 ("Legislation has even been upheld where no remedy was substituted in place of the cause of action that was taken away."); *see also Logan*, 455 U.S. at 432, 433 (when legislature "create[s] substantive defenses or immunities for use in adjudication" or "eliminate[s] . . . causes of action altogether," such "legislative determination provides all the process that is due"). Indeed, Congress provided no substitute remedy when abrogating certain tort claims against firearms businesses in the PLCAA, which was upheld as consistent with due process. *See Ileto*, 565 F.3d at 1141-42; *Beretta*, 940 A.2d at 175-76. Plaintiffs therefore are incorrect to contend that the inclusion of immunity protections in the PREP Act gives rise to "heighten[ed]" scrutiny of the CICP under the Due Process Clause. 3d Am. Compl. ¶ 153.

The third *Mathews* factor directs courts to consider "the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail." *Mathews*, 424 U.S. at 335. This factor weighs against Plaintiffs given the federal government's vital public health interest in maintaining PREP Act immunity. Congress enacted the PREP Act "[t]o encourage expeditious development and deployment of medical countermeasures during a public health emergency."[17] That is why when deciding whether to issue a PREP Act declaration, "the Secretary shall consider the desirability of

[17] Cong. Rsch. Serv., Compensation Programs for Potential COVID-19 Vaccine Injuries 2 (Oct. 20, 2021), https://crsreports.congress.gov/product/pdf/LSB/LSB10584.

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." 42 U.S.C. § 247d-6d(b)(6). PREP Act immunity has become a vital inducement for private companies to invent, manufacture, and distribute life-saving countermeasures. For example, during the COVID-19 pandemic, the availability of PREP Act immunity was made an essential term of the procurement contracts through which the federal government initially acquired doses of COVID-19 vaccines.[18] If PREP Act immunity were invalidated, that would imperil the federal government's ability to secure the availability of countermeasures to respond to COVID-19 and other public health emergencies.

Plaintiffs argue that because they now seek only a declaratory judgment holding the PREP Act unconstitutional and no longer ask this Court to enter injunctive relief requiring Defendants to change the operations of the CICP,[19] their remedy would "impose no additional financial burden

[18] *See* Statement of Work for COVID-19 Pandemic—Large Scale Vaccine Manufacturing Demonstration, § 11.1, *available at* https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf ("The Government may not use, or authorize the use of, any products or materials provided under this Agreement, unless such use occurs in the United States and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act declaration of equal or greater scope."); Statement of Work Large Scale Production of SARS-CoV-2 Vaccine, § H.8, *available at* https://www.hhs.gov/sites/default/files/vaccine-contract-with-moderna-modifications-p00001-p00002-p00003.pdf ("The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope.").

[19] Plaintiffs previously sought an injunction preventing Defendants from enforcing the PREP Act "unless the federal government reforms CICP" by making fifteen enumerated changes. *See* 2d Am. Compl., Prayer for Relief, § 2; *id.* ¶ 13. In moving to dismiss the Second Amended Complaint, Defendants explained that the changes sought by Plaintiffs would be incredibly burdensome, and many would be beyond HHS's statutory authority. *See* ECF No. 41-1, at 24. Plaintiffs responded by removing the request for injunctive relief and seeking only declaratory relief. *See* 3d Am. Compl., Prayer for Relief, § 1.

on the federal government" and would "have the opposite effect because the government will no longer need to administer CICP or pay out any benefits to claimants therein." 3d Am. Compl. ¶ 157. This argument blithely ignores that the federal government's interest in maintaining PREP Act immunity is not to avoid the expenditure of funds but to protect the public health by encouraging the availability of countermeasures to combat public health emergencies. The importance of PREP Act immunity to public health weighs heavily against Plaintiffs' due process claim.

B. Plaintiffs Fail To Plead A Substantive Due Process Claim

Plaintiffs' substantive due process claim is largely a repackaging of their procedural due process claim and fails for the same reasons. Substantive due process "protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition, and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed. *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997) (quotations and citations omitted). Plaintiffs do not and cannot show that there exists such a fundamental right to any particular procedure to obtain compensation for injuries, or a fundamental right that a common-law cause of action, once recognized, will never be altered by the legislature. Any such fundamental right would run counter to longstanding precedent holding that "[a] person has no property, no vested interest, in any rule of the common law. . . . Rights of property which have been created by the common law cannot be taken away without due process; but the law itself, as a rule of conduct, may be changed at the will . . . of the legislature, unless prevented by constitutional limitations." *Keller*, 441 F.2d at 1242 (quoting *Mondou*, 223 U.S. at 50).

As the Ninth Circuit has held, because a law granting immunity does not infringe fundamental rights, to satisfy substantive due process, it need only "withstand rational basis review," which it does "as long as the legislature was pursuing a rational policy." *Ileto*, 565 F.3d

at 1140. Here, it was rational for Congress to provide liability immunity concerning countermeasures to incentivize development and deployment of countermeasures to combat public health emergencies, and provide those injured by countermeasures with an alternative remedy against the federal government, as Congress has done several times before. *See*, *e.g.*, *Leuz*, 63 Fed. Cl. 602 (upholding act establishing Vaccine Injury Compensation Program against constitutional challenges, including substantive due process); *Ducharme*, 574 F.2d 1307 (upholding constitutionality of Swine Flu Act); Smallpox Emergency Personal Protection Act, Pub. L. No. 108-20, 117 Stat. 638 (2003) (codified at 42 U.S.C. §§ 239-239h) (establishing liability immunity and administrative compensation scheme for smallpox vaccines).

Plaintiffs cite two Supreme Court cases that they argue suggest that substantive due process requires that when legislation abrogates a common law tort claim, the legislature must offer a "just and reasonable substitute." 3d Am. Compl. ¶ 165. But neither case held as such. In *Duke Power Co. v. Carolina Environmental Study Group*, 438 U.S. 59 (1978), the Supreme Court strongly suggested that a statute abrogating tort claims presents no issue under the Due Process Clause. Although the Supreme Court noted that it had not definitively resolved the question, it stated that it was "not at all clear that the Due Process Clause in fact requires that a legislatively enacted compensation scheme either duplicate the recovery at common law or provide a reasonable substitute remedy," because the Supreme Court's "cases have clearly established that '[a] person has no property, no vested interest, in any rule of the common law,'" and "statutes limiting liability are relatively commonplace and have consistently been enforced by the courts." *Id.* at 88 & n.32 (quoting *Mondou*, 221 U.S. at 50). In *New York Central Railroad Co. v. White*, 243 U.S. 188 (1917), the Supreme Court upheld a state statute that abrogated tort claims for workplace injuries, holding: "No person has a vested interest in any rule of law, entitling him to insist that it shall

remain unchanged for his benefit." *Id.* at 198. Although the Court noted that the statute replaced the abrogated tort claims with a workers' compensation scheme that was "just," *id.* at 202, it never held that a substitute remedy was constitutionally required. As noted, courts have upheld the PLCAA against due process challenges even though that statute abrogated tort claims without providing any substitute remedy. Further, Congress provided a substitute remedy through the CICP, so Plaintiffs' argument boils down to their erroneous procedural due process argument that the CICP employs constitutionally inadequate procedures. *See supra*, Part II.A.2.[20]

C. Plaintiffs Lack A Valid Claim For A Declaratory Judgment

Finally, Plaintiffs purport to bring a separate claim titled "Declaratory Judgment," in which they argue that they "are entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201." 3d Am. Compl. ¶ 135. However, "the Declaratory Judgment Act alone does not create a federal cause of action." *Harris Cnty. Texas v. MERSCORP Inc.*, 791 F.3d 545, 552 (5th Cir. 2015). "[T]he [Declaratory Judgment Act] 'enlarged the range of remedies available in the federal courts,' but it did not create a new right to seek those remedies." *Id.* (quoting *Skelly Oil Co. v. Phillips Petrol. Co.*, 339 U.S. 667, 671 (1950)). Plaintiffs claim entitlement to a declaratory judgment because the PREP Act purportedly "violate[s] the Fifth Amendment," 3d Am. Compl. ¶ 135, the same arguments pursued in the Third Amended Complaint's substantive counts. Because those substantive counts fail to plead a valid claim, *see supra*, Parts II.A-B, Plaintiffs have failed to plead entitlement to a declaratory judgment.

[20] Plaintiffs argue in a footnote that "CICP also extinguishes state constitutional rights to a just alternative remedy." 3d Am. Compl. ¶ 168 n.36. But the Third Amended Complaint asserts no claim for violation of state constitutional rights. And as explained above, the CICP provides reasonable access to a remedy.

CONCLUSION

For the foregoing reasons, the Court should dismiss Plaintiffs' Third Amended Complaint for lack of subject-matter jurisdiction and failure to state a claim.

Dated: April 8, 2024

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 8, 2024, a copy of the foregoing was filed electronically with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to all counsel of record by operation of the Court's electronic filing system.

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