UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

JESSICA SMITH, *et al.*,	)	
Plaintiffs,	)	
v.	)	Case No. 4:24-cv-0334-P
UNITED STATES OF AMERICA, *et al.*,	)	
Defendants.	)	

BRIEF IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT

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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 and their right to a jury trial under the Seventh Amendment. But they lack standing and fall well short of stating a valid claim.

Plaintiffs lack standing because the relief they seek would not redress their injuries. Plaintiffs claim to be harmed because they cannot bring tort claims related to their alleged vaccine injuries against nonparties to this case, such as vaccine administrators and manufacturers. They ask this Court to declare the CICP unconstitutional, enjoin its operation, and issue an order purporting to allow them to bring tort claims against third parties. But those third parties are not parties here and would not be bound by any judgment from this Court. "'It is a principle of general application in Anglo-American jurisprudence that one is not bound by a judgment *in personam* in a litigation in which he is not designated as a party or to which he has not been made a party by service of process.'" *Taylor v. Sturgell*, 553 U.S. 880, 884 (2008) (quoting *Hansberry v. Lee*, 311 U.S. 32, 40 (1940)). Thus, as a district court in Louisiana held in dismissing a substantially similar

lawsuit for lack of standing, regardless of any judgment issued by this Court, "vaccine manufacturers would remain free to assert immunity in future cases against them." Mem. Ruling & Order at 14, *Smith v. U.S. Health Res. and Servs. Admin.* (*Smith I*), No. 3:23-cv-1425, ECF No. 70 (W.D. La. Sep. 30, 2025) ("*Smith I* Order").

Even if the Court reached the merits, Plaintiffs' claims would fail. 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-Nat'l Lab'ys*, 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.

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) (citation omitted). Plaintiffs identify no such rights at stake. Accordingly, the PREP Act is subject to deferential rational basis review, which it easily satisfies.

Plaintiffs' claim to a jury trial right in pursuing compensation from the federal government also fails. "When the sovereign waives immunity it may attach any conditions (including no right

to trial by jury) to its consent." *Ducharme*, 574 F.2d at 1311. Therefore, "if Congress waives the Government's immunity from suit, . . . the plaintiff has a right to a trial by jury only where that right is one of the terms of the Government's consent to be sued. Like a waiver of immunity itself, [it] must be unequivocally expressed." *Lehman v. Nakshian*, 453 U.S. 156, 160 (1981) (citations omitted). Plaintiffs identify no such waiver here, much less an unequivocal one.

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* Kevin J. Hickey & Erin H. Ward, Cong. Rsch. Serv., LSB10584, *Compensation Programs for Potential COVID-19 Vaccine Injuries* 2 (updated 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). Determinations 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. 42 U.S.C. § 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 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).

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 (last reviewed June 2025). 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* 1st Am. Compl., Ex. 6, ECF No. 36-6 (decision letter signed by Dr. Grimes). If the requester is eligible 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.*, 1st Am. Compl., Ex. 6. 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.* 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 in this case on April 18, 2024. *See* Compl., ECF No. 1. Plaintiffs sued the United States, HHS, and certain HHS components or officials; Plaintiffs alleged that they were four individuals who suffered injuries caused by COVID-19 vaccines, and that they wished to pursue tort claims against vaccine manufacturers and administrators, but were precluded from doing so by the PREP Act. *See id.* ¶¶ 1-3. They sought a declaratory judgment that the PREP Act was unconstitutional, bringing claims under the Declaratory Judgment Act, Due

Process Clause, Takings Clause, and Seventh Amendment. *See id.* ¶¶ 136-202. On May 28, 2024, before Defendants had been properly served with the Complaint, Plaintiffs filed a Motion for Summary Judgment. *See* Pls.' Mot. for Summ. J., ECF No. 13. On May 30, 2024, this Court *sua sponte* issued an order denying Plaintiffs' Motion for Summary Judgment without prejudice as premature. *See* Order, ECF No. 17.

On June 21, 2024, Defendants filed a motion to stay this case. *See* Defs.' Mot. to Stay Proceedings and to Extend Answer Deadline While this Mot. Is Resolved, ECF No. 18 ("Stay Mot."). Defendants pointed out that Plaintiffs' Complaint was very similar to, with large portions taken verbatim from, the operative complaint in a case brought by the same counsel on behalf of different plaintiffs in the Western District of Louisiana, *Smith I*, No. 3:23-cv-1425 (W.D. La.). *See* Stay Mot. 1-2, 6-10. *Smith I* was similarly brought by individuals (and an organization representing such individuals) wishing to bring tort claims against vaccine manufacturers and administrators against the federal government, claiming that the PREP Act violated the Due Process Clause, and seeking a declaratory judgment. *See generally* 3d Am. Compl., *Smith I*, ECF No. 49. Defendants argued that this case should be stayed pending the *Smith I* court's resolution of the government's motion to dismiss the operative complaint in *Smith I*. *See* Stay Mot. 10-14. Plaintiffs opposed the motion to stay. *See* Pls' Mem. of Law in Opp'n to Defs.' Mot. to Stay Proceedings and to Extend Answer Deadline While this Mot. Is Resolved, ECF No. 20.

The Court granted the stay motion. *See* Order, ECF No. 22. The Court noted that "the relevant legal inquiries overlap significantly between *Smith I* and *Smith II*," and that "there's no denying the sibling-cases bear striking resemblances." *Id.* at 3. Explaining that "[t]he Rule 12 arguments in *Smith I* have case-dispositive implications here," the Court concluded that "[a]rmed with a determination in [*Smith I*], the Court would be able to adjudicate Plaintiffs' claims here far

more efficiently." *Id.* at 4. In particular, "the ripe dismissal motions in *Smith I* necessarily implicate issues here—including threshold jurisdictional issues." *Id.* at 5-6. The Court accordingly stayed this case pending the resolution of the motion to dismiss in *Smith I*. *Id.* at 6.

On September 30, 2025, the *Smith I* court granted the government's motion to dismiss. *See Smith I* Order (submitted in this case as ECF No. 25-1). The court held that the plaintiffs failed to plead a basis for standing, specifically the redressability element. *Id.* at 10-11. As the court explained, the plaintiffs wished to sue vaccine manufacturers or administrators, who benefit from PREP Act immunity; although the plaintiffs sought a declaratory judgment against the government defendants that the PREP Act was unconstitutional, "a declaratory judgment binds the parties, but only the parties." *Id.* at 12 (quoting *Skyworks, Ltd. v. Ctrs. for Disease Control & Prevention*, 542 F. Supp. 3d 719, 728 (N.D. Ohio 2021)). "[T]he intended defendants of Plaintiffs' tort claims are nonparties who would not be bound by this Court's judgment." *Id.* at 13. Even if the plaintiffs obtained a favorable judgment, "vaccine manufacturers would remain free to assert immunity in future cases against them." *Id.* at 14. Thus, the plaintiffs "fail[ed] to show that a declaratory judgment about the rights and obligations of the parties in [*Smith I*] would remedy their injury." *Id.* at 13-14. Because the court dismissed the case for lack of standing, it did not need to consider the government's arguments that the plaintiffs failed to state a claim. Plaintiffs in *Smith I* did not appeal. *See* Joint Status Report ¶ 9, ECF No. 29.

The day after the *Smith I* court issued its ruling, much of the federal government, including the Department of Justice and HHS, entered a lengthy lapse in appropriations. *See* Defs.' Unopposed Mot. to Extend Stay in Light of Lapse of Appropriations, ECF No. 25. Defendants accordingly notified this Court of the *Smith I* ruling and moved to extend the stay in this case, *see id.*, a motion this Court granted, *see* Order Granting Defs.' Unopposed Mot. to Extend Stay in

Light of Lapse of Appropriations, ECF No. 26. On March 24, 2026, Plaintiffs filed a consent motion to lift the stay, explaining that they intended to file an amended complaint. Pls.' Consent Mot. to Lift Stay, ECF No. 32. On March 25, 2026, the Court granted that motion and lifted the stay. *See* Order, ECF No. 35. Plaintiffs filed the operative First Amended Complaint later that same day. *See generally* 1st Am. Compl., ECF No. 36.

IV. The First Amended Complaint

As alleged in the First Amended Complaint, Plaintiffs are four individuals who allege injuries caused by a COVID-19 vaccine. *Id.* ¶ 1. Plaintiffs wish to "fil[e] common law and state law claims for COVID-19 vaccine-related injuries against the manufacturers," but have been "precluded from" doing so by the PREP Act. *Id.* ¶ 4.

Plaintiff Jessica Smith received a dose of the Pfizer COVID-19 vaccine on September 3, 2021. *Id.* ¶ 28. She began to experience severe symptoms approximately one week later, *id.* ¶ 29, and was diagnosed with dysautomania in October 2021, *id.* ¶ 32. She submitted a CICP claim less than a year after receiving the COVID-19 vaccine. *Id.* ¶ 46. Smith alleges that she submitted some unspecified documents in 2022, but in January 2026, a CICP employee informed her that the CICP needed additional medical records to process her claim. *Id.* ¶¶ 47, 50. She is in the process of collecting those records. *Id.* ¶ 51. Her CICP claim remains pending. *Id.* ¶ 52.

Plaintiff Joel Wallskog received a dose of the Moderna COVID-19 vaccine on December 30, 2020. *Id.* ¶ 55. A week later, Wallskog began to experience symptoms, *id.* ¶ 57, and "[d]ays later, . . . Dr. Wallskog knew he was seriously injured," *id.* He submitted a CICP claim around May 2021. *Id.* ¶ 69. On November 29, 2022, his CICP claim was denied in a two-page single-spaced letter signed by Dr. Grimes, the Director of DICP. *Id.* ¶ 70; *id.* Ex. 6. Dr. Grimes explained that "[t]he current medical and scientific evidence does not show a causal link between the Moderna COVID-19 vaccine" and the ailments suffered by Wallskog. *Id.* Ex. 6, at 3. Dr. Grimes

concluded: "As there is not compelling, reliable, valid, medical, and scientific evidence that the COVID-19 vaccine directly caused your injury, the CICP has determined that you are not eligible for programs benefits." *Id.* Dr. Grimes informed Wallskog that he had a right to request reconsideration, which request would be reviewed by "a qualified panel, independent of the [CICP]," and the Associate Administrator of the HSB would make a "final determination" on his reconsideration request. *Id.* Wallskog submitted a timely request for reconsideration. 1st Am. Compl. ¶ 71. The Associate Administrator denied his request for reconsideration in a written letter. *Id.* ¶ 72.

Plaintiff Theodore Cabaniss's minor child, T.C., received a dose of the Pfizer vaccine on June 7, 2021. *Id.* ¶ 75. Eleven days after receiving the vaccine, T.C. was rushed to the emergency room with red spots caused by burst blood vessels. *Id.* ¶ 76. He was later diagnosed with Immune Thrombocytopenic Purpura. *Id.* On April 13, 2022, T.C.'s family submitted a timely CICP claim in T.C.'s behalf. *Id.* ¶ 85. That claim remains pending. *Id.* Cabaniss filed a lawsuit against Pfizer in federal district court based on T.C.'s injury, but the district court dismissed it based on PREP Act immunity, and the court of appeals affirmed. *Id.* ¶ 86.

Plaintiff Elizabeth Thiele received a dose of a COVID-19 vaccine on August 29, 2021. *Id.* ¶ 88. She began to experience shoulder pain "[s]oon thereafter." *Id.* ¶ 89. Her symptoms "significantly worsened" in November 2021. *Id.* ¶ 94. In February 2022, Thiele was diagnosed with multiple shoulder ailments. *Id.* ¶¶ 98-100. After performing exercises recommended by a physical therapist, "Dr. Thiele's symptoms largely (though not completely) resolved by mid-2022." *Id.* ¶ 102. Thiele did not file a CICP claim because "she was unaware of the program until after the one-year deadline to submit a claim passed." *Id.* ¶ 104.

The First Amended Complaint names as Defendants HHS, the Secretary of HHS (in his official capacity), the United States, the President (in his official capacity), HRSA, the Administrator of HRSA (in his official capacity), and three John Doe Defendants allegedly involved (as federal employees) in operating the CICP. *Id.* ¶¶ 19-25. It does not name as a Defendant any person or entity that manufacturers a vaccine taken by Plaintiffs or that administered a vaccine to Plaintiffs. The First Amended Complaint contains four causes of action. Count II claims that the CICP is a procedural due process violation. *Id.* ¶¶ 151-83. Count III claims that the CICP violates the substantive due process doctrine. *Id.* ¶¶ 184-95. Count IV claims that the CICP violates Plaintiffs' Seventh Amendment right to a jury trial. *Id.* ¶¶ 196-208. Count I seeks a declaratory judgment that the CICP violates Plaintiffs' constitutional rights, citing to the substantive claims raised in Counts II-IV. *Id.* ¶¶ 142-50.

In addition to costs and attorneys' fees, Plaintiffs seek three forms of relief: (1) a declaration "that CICP is unconstitutional and unlawful under the Fifth and Seventh Amendments"; (2) "a permanent injunction prohibiting Defendants and all persons acting in concert or participation with Defendants from implementing, enforcing, or administrating CICP"; (3) a declaration "that the applicable statutes of limitations for Plaintiffs' state and common law claims equitably tolled from the date of onset of their injuries and an order permitting Plaintiffs to pursue their state and common law claims in a court of competent jurisdiction." *Id.*, Prayer for Relief.

LEGAL STANDARD

"Federal Rule of Civil Procedure 12(b)(1) requires dismissal when a federal district court does not have the right to exercise its limited jurisdiction over the subject matter presented in the complaint." *Leal v. Tex. Dep't of Crim. Just.*, No. 4:23-CV-999-P, 2024 WL 899398, at *1 (N.D. Tex. Mar. 1, 2024). "It is incumbent on all federal courts to dismiss an action whenever it appears

that subject matter jurisdiction is lacking. This is the first principle of federal jurisdiction." *Id.* (quoting *Stockman v. FEC*, 138 F.3d 144, 151 (5th Cir. 1998)). "The burden of proof for a Rule 12(b)(1) motion to dismiss is on the party asserting jurisdiction. Accordingly, the plaintiff constantly bears the burden of proof that jurisdiction does in fact exist." *Id.* (quoting *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001)). "Article III of the United States Constitution limits the jurisdiction of federal courts to actual 'Cases' and 'Controversies.'" *Crane v. Johnson*, 783 F.3d 244, 251 (5th Cir. 2015) (quoting U.S. Const. art. III, § 2). "The doctrine of standing provides definition to these constitutional limits by 'identify[ing] those disputes which are appropriately resolved through the judicial process.'" *Id.* (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)).

"To defeat a motion to dismiss pursuant to Rule 12(b)(6), a plaintiff must plead 'enough facts to state a claim to relief that is plausible on its face.'" *Snider v. Cain*, No. 4:20-CV-00670-P, 2020 WL 6262192, at *1 (N.D. Tex. Oct. 23, 2020) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009)). Although "the Court must accept all well-pleaded facts in the complaint as true" in ruling on a Rule 12(b)(6) motion, "[t]he Court is not bound to accept legal conclusions as true." *Id.* at *2.

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 omitted).

Plaintiffs fail to show that the relief sought would redress their injuries. Plaintiffs claim to be injured by the inability to bring state law and common law claims against vaccine manufacturers and administrators. *See* 1st Am. Compl. ¶ 2 ("[t]he PREP Act stripped vaccine injured individuals of the ability to bring common law and state law claims" because "the PREP Act shields vaccine manufacturers, administrators, distributors, and others"); *id.* ¶ 176 ("the core rights at stake are Plaintiffs' liberty interests in redressing grievances through common-law claims against the manufacturers of the products that severely harmed them."). Plaintiffs seek a declaration that the CICP is unconstitutional, a permanent injunction prohibiting Defendants and those acting concert with Defendants from administering the CICP, and an order purporting to "equitably toll[]" "Plaintiffs' state and common law claims" and "permit[] Plaintiffs to pursue their state and common law claims in a court of competent jurisdiction." *Id.*, Prayer for Relief. However, the relief Plaintiffs seek would not redress their claimed injuries because it would not be binding on the manufacturers and administrators of COVID-19 vaccines that Plaintiffs wish to sue, who would continue to be able to assert PREP Act immunity as a defense to litigation. Indeed, in litigation covered by PREP Act immunity, defendants typically 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. Ct. App. 2023) (directing dismissal of all claims pursuant to PREP Act immunity).

Even if this Court granted all the relief Plaintiffs request, the vaccine manufacturers and administrators that Plaintiffs wish to sue would still be able to assert PREP Act immunity as a defense in any litigation filed against them. That is because those potential defendants to such tort claims are not parties here and would not be bound by a judgment entered by this Court. "'It is a principle of general application in Anglo-American jurisprudence that one is not bound by a judgment *in personam* in a litigation in which he is not designated as a party or to which he has not been made a party by service of process.'" *Taylor*, 553 U.S. at 884 (quoting *Hansberry*, 311 U.S. at 40); *accord Students for Fair Admissions, Inc. v. Univ. of Tex. at Austin*, 142 F.4th 819, 825 (5th Cir. 2025).

The principle that nonparties are not bound by judgments derives from age-old principles of due process. A "judicial action enforcing [a judgment] against the person or property of the absent party is not that due process which the Fifth and Fourteenth Amendments requires." *Hansberry*, 311 U.S. at 41. In *Taylor*, the Supreme Court recognized six narrow historically-based exceptions to the general rule that a judgment has no preclusive effect on a nonparty, 553 U.S. at 893-95. However, none of those exceptions applies here. In *Smith I*, plaintiffs invoked just one exception, where "a special statutory scheme may expressly foreclose successive litigation by nonlitigants if the scheme is otherwise consistent with due process." *Id.* at 895 (citation modified). But as the *Smith I* court explained, this "narrow exception" does not apply here, because it "applies only when a 'special statutory scheme' such as 'bankruptcy' or 'probate' authorizes a court to foreclose later litigation by nonparties." *Smith I* Order 12 (quoting *Taylor*, 553 U.S. at 895).

Because a judgment issued by this Court would not be binding on the nonparties Plaintiffs wish to sue, it would not empower Plaintiffs to sue those nonparties or prevent those nonparties from invoking PREP Act immunity. The *Smith I* court explained that a declaratory judgment that the PREP Act was unconstitutional would not redress plaintiffs' injuries. Such a declaratory judgment was "unlikely to redress Plaintiffs' injuries because '[t]his form of relief conclusively resolves the legal rights of *the parties*.'" *Smith I* Order 12 (quoting *Haaland v. Brackeen*, 599 U.S. 255, 293 (2023)). "Importantly, 'a declaratory judgment binds the parties, but only the parties.'" *Id.* (quoting *Skyworks*, 542 F. Supp. 3d at 728); *see also id.* 12 n.79 ("nonparties are not 'obliged to honor an incidental legal determination the suit produced'") (quoting *Lujan*, 504 U.S. at 569). Even with such a declaratory judgment, "the constitutionality issues would not be settled between Plaintiffs and the vaccine manufacturers and/or administrators, which would leave the declaratory judgment powerless to remedy the alleged harm." *Id.* at 12. To put it another way, even if Plaintiffs obtained such a declaratory judgment, "vaccine manufacturers would remain free to assert immunity in future cases against them." *Id.* at 14.

To be sure, the *Smith I* court's opinion is not binding here. Yet given what this Court deemed "striking resemblances" between the "sibling-cases," Order, ECF No. 22 at 3, this Court should give careful consideration and due respect to the *Smith I* court's cogent analysis. Indeed, this Court explained that the government's motion to dismiss in *Smith I* "necessarily implicate[s] issues here—including threshold jurisdictional issues." *Id.* at 5-6. This Court kept this case stayed for more than a year so that it could benefit from the *Smith I* court's analysis, and because the *Smith I* plaintiffs (represented by Plaintiffs' counsel here) elected not to appeal the *Smith I* ruling, that ruling is final. Although this Court is not bound by *Smith I*, the Court should follow its persuasive reasoning.

Perhaps seeking to avoid the force of *Smith I*, Plaintiffs added to their First Amended Complaint two additional forms of requested relief beyond a declaratory judgment: an injunction prohibiting Defendants from administering the CICP, and an order purporting to "equitably toll[]" the statutes of limitations for Plaintiffs' potential tort claims against nonparties and "permitting Plaintiffs to pursue" those claims "in a court of competent jurisdiction." 1st Am. Compl., Prayer for Relief, ¶¶ B-C. Even putting aside the question of whether this Court would have the authority to order tolling of a statute of limitations in another case, in another (possibly state) court, neither of these requested remedies can fix the fundamental problem dooming Plaintiffs' standing: that a judgment issued by this Court would not be binding on the nonparties Plaintiffs wish to sue. With exceptions inapplicable here, the principle that judgments do not bind nonparties extends to injunctions, just as it does to declaratory judgments. *See Scott v. Donald*, 165 U.S. 107, 117 (1897) ("[t]he decree is also objectionable because it enjoins persons not parties to the suit," without alleging "any conspiracy between" the defendants and nonparties purportedly bound by the injunction).[4] Thus, this Court could not enjoin those nonparties from asserting PREP Act immunity in a subsequent lawsuit.

Nor would an order by this Court purporting to equitably toll statutes of limitations for claims against nonparties or permitting Plaintiffs to sue nonparties be binding on those nonparties in any subsequent lawsuit. Because this Court lacks authority to issue a judgment binding those nonparties, nothing in a judgment of this Court could preclude them from asserting PREP Act

[4] Furthermore, to the extent Plaintiffs contend that they are harmed by claimed unfairness in the administration of the CICP, an injunction completely halting administration of the CICP would not redress any perceived unfairness. In fact, such an injunction could leave Plaintiffs worse off. It would prevent them from pursuing CICP claims, but (for the reasons explained elsewhere in this section) would not enable them to pursue tort claims against the manufacturers and administrators of COVID-19 vaccines.

immunity, the statute of limitations, or any other defense. And under "the rule against nonparty preclusion," *Taylor*, 553 U.S. at 895, a court adjudicating such a subsequent lawsuit would not grant preclusive effect to a judgment from this Court. To purport to apply a judgment from this Court against nonparties in a subsequent lawsuit to prejudice their rights would not comply with the "due process which the Fifth and Fourteenth Amendments requires." *Hansberry*, 311 U.S. at 41.

Because none of the relief sought by Plaintiffs would redress their claimed injuries, the Court should dismiss this lawsuit for lack of standing.

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, 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.[5] 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

[5] 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).

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 protected 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 and state tort law claims" and replaced them with an administrative compensation program. 1st Am. Compl. ¶ 153. 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 (second omission in original) (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 "abrogate[d] 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.[6] 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*, 63 Fed. Cl. 602. 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 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

[6] *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." (citation omitted)), *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'l Labs., Inc.*, 433 F. Supp. 231, 236 (M.D. Tenn. 1977).

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 (citation omitted); *see also District of Columbia 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.[7]

[7] None of the other cases cited by Plaintiffs upheld a challenge to a provision granting immunity for common-law claims. *See Tulsa Pro. Collection Servs. Inc. 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

Second, Plaintiffs allege that "to the extent CICP 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." 1st Am. Compl. ¶ 155. 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, three of the four Plaintiffs have filed CICP claims and have had or are having those claims resolved in accordance with the PREP Act and applicable regulations. One Plaintiff had his claim and motion for reconsideration denied in letters from the Director of the DICP and the Associate Administrator of the HSB, respectively. *See id.* ¶¶ 70, 72; *id.* Ex. 6. Two Plaintiffs have pending CICP claims. *See id.* ¶¶ 52, 85. And one Plaintiff suffered injuries within months of receiving a COVID-19 vaccine and could have filed a timely CICP claim, but did not do so because she allegedly was unaware of the CICP. *See id.* ¶¶ 88, 94-98, 104.

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.

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

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).

> 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, 1st Am. Compl. ¶ 105, but they plead no facts to support the inference of an "established record of erroneous" denials of CICP claims. *Id.*, heading before ¶ 161 (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 First Amended Complaint, *see id.* ¶ 113 n.23, currently up to date as of May 1, 2026[8], 7,066 COVID-19 claims have been denied, for the following reasons:

- 2,619 (37.1%) claims were denied because requesters did not file within the one-year filing deadline required by the PREP Act and governing regulations. *See* 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

[8] *See* HRSA, *Countermeasures Injury Compensation Program (CICP) Data*, https://perma.cc/9FYG-DTUK (aggregate data as of May 1, 2026). The CICP updates this data on its website every month. At the time of the filing of the First Amended Complaint, the data was up to date as of March 1, 2026. *See* 1st Am. Compl. ¶ 113 n.23. Therefore, the updated data cited in this brief differs slightly from the data cited in the First Amended Complaint.

within one year of the date of the administration or use of a covered countermeasure that is alleged to have caused the injury.").

- 264 (3.7%) claims were denied because the requester did not identify any covered countermeasure that had been administered, 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").

- 1,415 (20.0%) claims were denied based on failure to show that the covered countermeasure directly caused a covered injury, 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).

- 2,768 (39.2%) claims were denied because the requester failed to submit requested medical records, 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.[9] 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, 102 COVID-19 claims have been found eligible for compensation. *See* HRSA, *Countermeasures Injury Compensation Program (CICP) Data*,

[9] Plaintiffs criticize the CICP's denial of Wallskog's claim, 1st Am. Compl. ¶ 70, but the denial letter explained that "[t]he current medical and scientific evidence does not show a causal link between the Moderna COVID-19 vaccine" and Wallskog's ailments. 1st Am. Compl., Ex. 6, at 3. Thus, there was "not compelling, reliable, valid, medical, and scientific evidence that the COVID-19 vaccine directly caused [his] injury," *id.*, as required by the PREP Act, *see* 42 U.S.C. § 247d-6e(b)(4). Plaintiffs do not allege the existence of any evidence that meets that statutory standard. 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.

https://perma.cc/9FYG-DTUK (aggregate data as of May 1, 2026).[10] These favorable compensation determinations disprove Plaintiffs' assertion that the CICP merely provides a "right to file and lose." 1st Am. Compl. ¶ 4.

Plaintiffs assert that they do not know who decides CICP claims, 1st Am. Compl. ¶ 118, 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* 1st Am. Compl., Ex. 6 (decision letter signed by Dr. Grimes); 42 C.F.R. §§ 110.3(y), 110.73-110.74.

Plaintiffs similarly assert they do not know who decides requests for reconsideration, 1st Am. Compl. ¶ 131, 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 Wallskog's request for reconsideration. *Id.*; *see also* 1st Am. Compl. ¶ 72 (indicating that Wallskog was notified by letter of the denial of his request for reconsideration).

Plaintiffs assert that they have no way to confirm whether individuals deciding claims have conflicts of interests because "unspecified HHS personnel serve as judge, jury, and executioner." 1st Am. Compl. ¶ 117. But as noted, the decisionmakers are the Director of the DICP (who makes

[10] Plaintiffs affirmatively rely on the CICP data and do not question its accuracy. *See* 1st Am. Compl. ¶ 105 & nn.13-16. Therefore, this data is fairly encompassed in the First Amended Complaint and is subject to judicial notice. *See Doe v. United States*, 853 F.3d 792, 800 (5th Cir. 2017) (court may consider "documents incorporated into the complaint by reference" (citation omitted)); 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 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.

initial determinations) and the Associate Administrator of the Health Systems Bureau (who makes reconsideration determinations), each of whom issued a signed decision letter to Wallskog. 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.* ¶ 133. Defendants acknowledge that it has taken some time for the CICP to progress through COVID-19 claims, but that is understandable, given that the program went from receiving only several hundred non-COVID-19 claims in its entire history to receiving a wave of around 14,147 COVID-19 claims over the last few years. *See* HRSA, *Countermeasures Injury Compensation Program (CICP) Data*, https://perma.cc/9FYG-DTUK (aggregate data as of May 1, 2026) (14,744 claims filed in CICP's history, of which 14,135 are COVID-19 claims).[11]

Indeed, pharmaceutical civil litigation, which Plaintiffs portray as the gold standard of due process, often takes far longer 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 the preliminary question of whether plaintiffs' claims are preempted by federal law was not resolved

[11] In 2024, Dr. Grimes 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 Assessing America's Vaccine Safety Systems, Part 1, Hearing before the Select Subcomm. on the Coronavirus Pandemic of the H. Comm. on Oversight & Accountability*, 118th Cong. (2024) (statement of Commander George Reed Crimes, Director, Div. of Injury Comp. Programs, HHS), *available at* https://oversight.house.gov/wp-content/uploads/2024/02/HRSA_SSCP-Testimony-for-02.15.2024-Hearing.pdf. Congressional testimony is subject to judicial notice. *See*, *e.g.*, *D.A.M. v. Barr*, 474 F. Supp. 3d 45, 55 n.12 (D.D.C. 2020) (taking 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).

until 2025. *See In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 118 F.4th 322 (3d Cir. 2024), *cert denied sub nom. Merck Sharp & Dohme Corp. v. Albrecht*, 145 S. Ct. 2792 (2025). As another example, 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 at 1, *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, MDL No. 2740 (E.D. La. Mar. 18, 2022), ECF No. 13946. 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 complain that requesters cannot present fact or expert witnesses, 1st Am. Compl. ¶ 122, 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, 1st Am. Compl. ¶¶ 179-82, 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. 1st Am. Compl. ¶ 165. 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.

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."[12] That is why when deciding whether to issue a PREP Act declaration, "the Secretary shall consider the desirability of

[12] Kevin J. Hickey & Erin H. Ward, Cong. Rsch. Serv., LSB10584, *Compensation Programs for Potential COVID-19 Vaccine Injuries* 2 (updated 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.[13] 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 seek a declaratory judgment holding the PREP Act unconstitutional and injunction halting its operation, their remedy "would not impose undue financial or administrative burden on the federal government" and would "actually benefit[] the government" because the government would no longer need to pay out CICP claims. 1st Am. Compl. ¶¶ 167-68. This argument blithely ignores that the federal government's interest in

[13] *See* U.S. Dep't of Army, Statement of Work for COVID-19 Pandemic—Large Scale Vaccine Manufacturing Demonstration, § 11.1 (July 1, 2020), *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."); Def. Contract Mgmt. Agency, Statement of Work Large Scale Production of SARS-CoV-2 Vaccine, § H.8 (Dec. 11, 2020), *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.").

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." *Glucksberg*, 521 U.S. at 720-21 (quotation marks 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 (last omission in original) (quoting *Mondou*, 223 U.S. at 50). Plaintiffs' view that they have a "fundamental right to redress their claims," 1st Am. Compl. ¶ 136, contradicts this binding precedent, would constitutionalize ordinary tort law, and would go against the Supreme Court's recent caution about expanding the substantive due process doctrine. *See Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 239-40 (2022).

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 (citation omitted). 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." 1st Am. Compl. ¶ 135. But neither case so held. 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 (alteration in original) (quoting *Mondou*, 223 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.

Plaintiffs also argue that the CICP's one-year filing deadline violates the substantive due process doctrine. *See* 1st Am. Compl. ¶ 188. Although this argument sounds in procedural due process rather than substantive due process, it fails in any event. The length of a limitations period "must be settled by the judgment of the legislature, and the courts will not inquire into the wisdom of its decision in establishing the period of legal bar, unless the time allowed is manifestly so insufficient that the statute becomes a denial of justice." *Wilson v. Iseminger*, 185 U.S. 55, 63 (1902). Here, Congress chose to impose a one-year deadline, *see* 42 U.S.C. § 247d-6e(b)(4) (incorporating procedural provisions from 42 U.S.C. § 239a); *id.* § 239a(d) (one-year filing deadline); *see also* 42 C.F.R. § 110.42(a), and Plaintiffs cannot show that this deadline is manifestly so insufficient as to constitute a violation of due process. Plaintiffs advance no reason why it is unreasonable for claimants to submit claims within a year of administration or use of a covered countermeasure. Here, three of four Plaintiffs allege that they filed claims within this deadline, *see* 1st Am. Compl. ¶¶ 46, 69, 85, so nothing in their experience supports the contention that the filing deadline is so far beyond the pale of reason that it violates the constitution. One Plaintiff did not file a timely claim because she was unaware of the program's existence, *id.* ¶ 104,

but Plaintiffs cite no case law to support the notion that a single person's failure to meet a statute of limitations based on ignorance of the law renders that limitations period a constitutional violation.

Furthermore, one-year limitations periods are common, which further undermines Plaintiffs' argument that this period is constitutionally insufficient. Several states have enacted one-year statutes of limitations that either apply generally to most tort claims or to particular tort causes of action. *See*, *e.g.*, Ky. Rev. Stat. Ann. § 413.140 (West 2025) (one-year statute of limitations for personal injury claims and most tort claims), amended by 2026 Ky. Acts ch. 172; Tenn. Code Ann. § 28-3-104(a)(1) (West 2026) (one-year statute of limitations for personal injury and several other types of tort claim); Mich. Comp. Laws Ann. § 500.3145 (West 2026) (one-year statute of limitations for an action for personal protection insurance benefits for injuries from an automotive accident); Ohio Rev. Code Ann. § 2305.113 (West 2025) (one-year statute of limitations for medical malpractice claims); *Compton v. Terrell*, No. CV 25-1050, 2026 WL 508720, at *3 & n.34 (W.D. La. Jan. 9, 2026) (Louisiana had general one-year limitations period for tort claims until 2024, when state legislature prospectively extended the limitations period to two years), *appeal filed*, No. 26-30097 (5th Cir. Feb. 25, 2026). Defendants are not aware of any cases holding that any of these statutes of limitations violated plaintiffs' due process rights. Likewise, the Antiterrorism and Effective Death Penalty Act imposes a one-year deadline on federal habeas corpus petitions, which the Fifth Circuit and other courts have upheld against constitutional attack. *See Molo v. Johnson*, 207 F.3d 773, 775 (5th Cir. 2000); *Miller v. Marr*, 141 F.3d 976, 977-78 (10th Cir. 1998).

C. Plaintiffs Fail To Plead A Violation Of The Seventh Amendment

Plaintiffs also claim that the PREP Act violates their right to a jury trial under the Seventh Amendment. 1st Am. Compl. ¶¶ 196-208. It is not clear whether Plaintiffs are arguing that they

have a right to a jury trial when pursuing monetary claims against the federal government under the CICP, or that they have a right to a jury trial in bringing tort claims against potential defendants who allegedly caused their injuries but enjoy immunity under the PREP Act. Either way, their claim fails as a matter of law.

Plaintiffs lack a Seventh Amendment right to a jury trial in their compensation claims against the United States because "[i]t has long been settled that the Seventh Amendment right to trial by jury does not apply in actions against the Federal Government." *Lehman*, 453 U.S. at 160. Indeed, "[i]t hardly can be maintained that under the common law in 1791 jury trial was a matter of right for persons asserting claims against the sovereign." *Id.* (quoting *Galloway v. United States*, 319 U.S. 372, 388-89 (1943)); *see also* U.S. Const. amend. VII (amendment applies "[i]n suits at common law"). The inapplicability of the Seventh Amendment to claims against the federal government flows not just from constitutional text and history but also from "the general principle that the United States, as sovereign, is immune from suit save as it consents to be sued and the terms of its consent to be sued in any court define that court's jurisdiction to entertain the suit." *Lehman*, 453 U.S. at 160 (cleaned up). Therefore, "if Congress waives the Government's immunity from suit, . . . the plaintiff has a right to a trial by jury only where that right is one of the terms of the Government's consent to be sued. Like a waiver of immunity itself, [it] must be unequivocally expressed." *Id.* (cleaned up); *see also Lynch v. United States*, 292 U.S. 571, 582 (1934) ("When the United States creates rights in individuals against itself, it is under no obligation to provide a remedy through the courts. It may limit the Individual to administrative remedies." (citations omitted)). As the Fifth Circuit has flatly declared, "[w]hen the sovereign waives immunity it may attach any conditions (including no right to trial by jury) to its consent." *Ducharme*, 574 F.2d at 1311; *see also Info. Res., Inc. v. United States*, 996 F.2d 780, 783 (5th Cir.

1993) ("the Seventh Amendment is inapplicable in actions against the United States"); *Mayo v. United States*, No. CIV. A. 98-0052, 1998 WL 877668, at *4 (W.D. La. Nov. 25, 1998) ("The Seventh Amendment right to a jury trial does not apply in actions against the federal government.").[14]

Although the PREP Act provides a limited waiver of the federal government's sovereign immunity—allowing those who have suffered injuries to file administrative compensation claims against the federal government, *see* 42 U.S.C. § 247d-6e(b)(1)—it did not make trial by jury an "unequivocally expressed" term of that waiver, *Lehman*, 453 U.S. at 160 (citation omitted). Therefore, Plaintiffs have no right to a jury trial when pursuing compensation under the CICP.

Plaintiffs provide no basis to disregard this clear precedent. Plaintiffs cite *Curtis v. Loether*, 415 U.S. 189 (1974), which holds that the Seventh Amendment entitles parties "to demand a jury trial in an action for damages in the federal courts," though generally not "in administrative proceedings," *id.* at 192, 194. But because *Curtis* was a suit between private parties, there was no need for it to consider the precedent holding that the Seventh Amendment does not apply to claims for compensation from the federal government. *See id.* at 190. The other cases cited by Plaintiffs similarly do not involve claims for compensation from the federal government.[15]

[14] *Jarkesy v. SEC*, 603 U.S. 109 (2024), is not to the contrary. In *Jarkesy*, the Supreme Court held that a securities professional had the right to a jury trial when the Securities and Exchange Commission brought a proceeding against him for civil penalties based on violations of federal securities laws. *Id.* at 119-20. It did not involve a claim *by* an individual *against* the government. *Jarkesy* thus did not address sovereign immunity or question the longstanding precedent holding that a waiver of the federal government's sovereign immunity need not include the right to a jury trial.

[15] Plaintiffs cite a passage from *Parsons v. Bedford*, 28 U.S. 433, 447 (1830), that is part of the argument of counsel, not the Court's opinion. The opinion of the Court, which held that the Seventh Amendment extends to actions in federal court under Louisiana law involving private parties even though Louisiana has a civil law system, is not relevant here. *See id.* at 448-49.

Furthermore, accepting Plaintiffs' arguments would have wide-ranging and troubling consequences. When Congress waives sovereign immunity to allow parties to pursue monetary compensation against the federal government, it generally *does not* include the right to a jury trial in such waiver, instead leaving such claims to be adjudicated in administrative tribunals, specialized federal courts such as the Court of Federal Claims without a jury, or in federal district court without a jury.[16] Even if Plaintiffs' arguments were not squarely foreclosed by binding precedent, the Court should be wary of upending historical practice by holding that Congress cannot waive sovereign immunity for arguably tort-like claims without triggering a right to a jury trial—a decision that could have profound implications for Congress's willingness to create compensation funds like the CICP in response to future crises.

To the extent Plaintiffs claim that they have been deprived of a jury trial for tort claims against the unspecified individuals or entities who allegedly caused their injuries, that argument fails as well because the PREP Act validly granted immunity from claims. "The 'Constitution does not forbid the creation of new rights, or the abolition of old ones recognized by the common law, to attain a permissible legislative object,'" and "statutes limiting liability are relatively commonplace and have consistently been enforced by the courts." *Duke Power*, 438 U.S. at 88 n.32 (quoting *Silver v. Silver*, 280 U.S. 117, 122 (1929)). "[A]s a matter of logic, it is axiomatic

[16] *See*, *e.g.*, Air Transportation Safety and System Stabilization Act, Pub. L. No. 107-42, §§ 401-409, 115 Stat. 230, 237-41 (2001) (establishing the September 11 Victim Compensation Fund to allow victims of the September 11, 2001, terrorist attacks to bring compensation claims before a special master); Tucker Act, 28 U.S.C. § 1491 (waiving sovereign immunity and providing jurisdiction in the Court of Federal Claims for certain tort claims against the federal government); *Gonzalez-McCaulley Inv. Grp., Inc. v. United States*, 93 Fed. Cl. 710, 713 n.1 (2010) (explaining that "[t]here are . . . no jury trials in the Court of Federal Claims"); Little Tucker Act, 28 U.S.C. § 1346(a)(2) (providing for concurrent jurisdiction in the Court of Federal Claims and federal district courts for certain civil claims against the United States not exceeding $10,000); *id.* § 2402 ("any action against the United States under section 1346 shall be tried by the court without a jury").

that if a cause of action can be abolished, the jury trial of that action is also abolished." *Sparks*, 431 F. Supp. at 418. "[T]he Government can legislate the rights of action out of existence and substitute an exclusive remedy against" the federal government, "notwithstanding that it precludes a jury trial." *Adams v. Jackel*, 220 F. Supp. 764, 766 (E.D.N.Y. 1963). Indeed, the Fifth Circuit has specifically rejected a Seventh Amendment claim where Congress eliminated tort claims and replaced them with a remedy against the United States with no jury trial. *See Ducharme*, 574 F.2d at 1311.

D. Plaintiffs Lack A Valid Claim For A Declaratory Judgment

Finally, Plaintiffs purport to bring a separate claim titled "Declaratory Judgment – Violation of [the] Fifth Amendment Right to Due Process," invoking the Declaratory Judgment Act, 28 U.S.C. § 2201. *See* 1st Am. Compl., Heading for Count I; *id.* ¶ 143. However, "the Declaratory Judgment Act alone does not create a federal cause of action." *Harris County 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 Petroleum Co.*, 339 U.S. 667, 671 (1950)). Plaintiffs claim entitlement to a declaratory judgment because the CICP is being operated "in violation of their Fifth and Seventh Amendment rights," 1st Am. Compl. ¶ 146, the same arguments pursued in the First Amended Complaint's substantive counts. Because those substantive counts fail to plead a valid claim, *see supra*, Parts II.A-C, Plaintiffs have failed to plead entitlement to a declaratory judgment.

CONCLUSION

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

Dated: May 19, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 19, 2026, 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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