UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

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

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

Plaintiffs' Opposition brief confirms that Plaintiffs have failed to state a claim or plead standing. Plaintiffs lack standing because the declaratory judgment they seek would bind only the parties to this case, not the vaccine administrators and manufacturers that they wish to sue. Plaintiffs cannot escape binding Fifth Circuit precedent holding that immunity statutes do not offend due process because a party has no protected interest in the continued application of a rule of tort law. Further, Plaintiffs still have not remedied the fundamental flaw identified by this Court in a status conference, that Plaintiffs present a disorganized list of complaints about the CICP without explaining how they add up to a constitutional violation. Plaintiffs' substantive due process claim fails because no fundamental right is at issue, and Congress had a rational basis to confer immunity to incentivize the development and deployment of medical countermeasures.

ARGUMENT

I. Plaintiffs Fail To Plead A Basis For Standing

Plaintiffs claim to be injured because the PREP Act enables vaccine manufacturers to assert immunity from state tort claims. But Plaintiffs fail to show that a declaratory judgment about the rights and obligations of the parties in *this* case would remedy that injury, given that vaccine manufacturers would remain free to assert immunity in future cases against them. Defs.' Mem. 11-13, ECF No. 53-1 ("Mem." or "Memorandum"). Plaintiffs therefore lack standing.

Plaintiffs argue that a declaratory judgment from this Court would "[i]mplicit[ly] . . . strik[e] down . . . the immunity provisions," meaning that the PREP Act would "be considered unconstitutional when applied to everyone." Pls.' Opp'n 5-6, ECF No. 58 ("Opp'n" or "Opposition"). That fundamentally misunderstands the nature of a declaratory judgment. Article III vests federal courts with limited authority to decide "Cases" and "Controversies" between the parties before them. U.S. Const. art. III, § 2. Consistent with that limitation, the Declaratory Judgment Act authorizes courts to declare the rights of "any interested party," 28 U.S.C. § 2201(a),

thereby limiting the scope of declaratory judgments to the parties. "Even if [the Court] were to issue a decision in the plaintiffs' favor" declaring the PREP Act unconstitutional, the statute "would remain on the books," parties "not before this Court" would not be bound, and Plaintiffs therefore "would remain in the same position they were in when they filed the operative complaint." *See Support Working Animals, Inc. v. Governor of Florida*, 8 F.4th 1198, 1205 (11th Cir. 2021). The fact that a judgment from this Court "could be cited as persuasive authority," Opp'n 6, is insufficient: Redressability requires that relief be provided by the coercive effect of a court's judgment, not the persuasive force of its opinion. *Support Working Animals, Inc.*, 8 F.4th at 1205. Further, a court's judgment generally does not bind nonparties. *Taylor v. Sturgell*, 553 U.S. 880, 893 (2008). The narrow exception to this rule invoked by Plaintiffs, Opp'n 6, applies only when a "special statutory scheme" such as "bankruptcy" or "probate" authorizes a court to foreclose later litigation by nonparties. *Taylor*, 553 U.S. at 895. Nothing of the sort applies here.

None of Plaintiffs' cases hinges on the impact of a declaratory judgment on a nonparty. In *Sanchez v. R.G.L.*, a parent seeking her children's return to Mexico established redressability by suing the director of the child placement agency who had "authority over the [children's] physical custodian" and could therefore "oversee the children's return." 761 F.3d 495, 506 (5th Cir. 2014). In *Consumer Data Industry Ass'n v. Texas through Paxton*, No. 21-51038, 2023 WL 4744918, at *6 (5th Cir. July 25, 2023), the Fifth Circuit noted that relief "directed to the Texas Attorney General would not in itself preclude consumers from seeking relief" under a statute, but would partially redress the plaintiff's injury by precluding enforcement by the Texas Attorney General. In these cases, redressability hinged on the judgment's impact on the parties, not nonparties.

Other cases cited by Plaintiffs confirm that declaratory judgments bind only the parties. In *Kentucky v. Federal Highway Administration*, No. 5:23-CV-162-BJB, 2024 WL 1402443, (W.D.

Ky. Apr. 1, 2024), the court noted that a declaratory judgment could support later injunctive relief "against any adverse party whose rights have been determined by such judgment," but that such a declaratory judgment "binds the parties alone." *Id.* at *18-19 (quoting 28 U.S.C. § 2202). Similarly, in *Christopher Village, Ltd. Partnership v. Retsinas*, 190 F.3d 310, 315 (5th Cir. 1999), the court concluded that a declaratory judgment against the Department of Housing and Urban Development (HUD) could support a later "damages action against HUD," one of the parties. None of these cases would support applying a declaratory judgment against the federal government to nonparty vaccine manufacturers and administrators in future tort litigation.

Even if a declaratory judgment could have the effect that Plaintiffs imagine, they have not shown how their potential future tort claims could be timely. Mem. 13. Plaintiffs respond that it is not their burden to show that their tort claims will be successful, Opp'n 4, but it is hard to see how relief here could possibly redress their injuries if the tort claims they want to bring are facially time-barred, as Plaintiffs do not meaningfully dispute.[1]

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

A. Plaintiffs Fail To State A Procedural Due Process Claim

Plaintiffs' procedural Due Process claim fails at both steps of the analysis: They allege no deprivation of a protected property interest, Mem. 14-18, and, they fail to allege that the CICP's procedures are constitutionally inadequate, *id.* at 19-29. Plaintiffs fail to establish otherwise.

[1] Plaintiff Carolina Bourque invokes the tolling doctrine of "contra non valentum," Mem. 7 n.2, but the case cited states that this tolling doctrine applies "when the plaintiff does not know nor [] reasonably should know of the cause of action," *Firefighters' Ret. Sys. v. Grant Thornton, L.L.P.*, 894 F.3d 665, 673 (5th Cir. 2018), which she does not claim is the case here. Plaintiff Michelle Zimmerman argues that the applicable Washington statute of limitations is three years, Mem. 7 n.3, but she alleges that she received a COVID-19 vaccine on March 14, 2021 (more than three years ago), and suffered injuries almost immediately afterward. 3d Am. Compl. ¶¶ 69-70. The other Plaintiffs say nothing regarding timeliness.

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

Binding Fifth Circuit precedent forecloses Plaintiffs' argument that they have been deprived of a protected property interest in a cause of action, because "[i]t is well settled that a plaintiff has no vested right in any tort claim for damages under state law." *Ducharme v. Merrill-National Labs.*, 574 F.2d 1307, 1309 (5th Cir. 1978) (per curiam); *see also Keller v. Dravo Corp.*, 441 F.2d 1239, 1242 (5th Cir. 1971) ("A person has no property, no vested interest, in any rule of the common law.") (quoting *Mondou v. N.Y., New Haven & Hartford R.R. Co.*, 223 U.S. 1, 50 (1912)); Mem. 14-18 (citing additional cases). Plaintiffs try to distinguish *Ducharme* and *Keller* by positing that in those cases, the remedies that the statutes established to replace abrogated common-law claims were "more equitable" than the CICP. Opp'n 11. But the Due Process claims in *Keller* and *Dravo* failed based on the lack of a protected property interest, not the adequacy of the replacement schemes. Indeed, *Ducharme* recognized that legislation providing immunity "has even been upheld where no remedy was substituted in place of the cause of action that was taken away." 574 F.2d at 1310. As a more recent example, courts upheld the Protection of Lawful Commerce in Arms Act ("PLCAA"), which abrogated tort claims against firearms manufacturers without providing any substitute remedy. *Ileto v. Glock, Inc.*, 565 F.3d 1126, 1141 (9th Cir. 2009); *D.C. v. Beretta U.S.A. Corp.*, 940 A.2d 163, 175-76 (D.C. 2008).

Plaintiffs cite several cases to support their contention that they have been deprived of a protected property interest in a cause of action, Opp'n 8-9, but Defendants already explained why Plaintiffs misread this case law, Mem. 17-18 & n.11. In particular, the principal case relied on by Plaintiffs, *Logan v. Zimmerman Brush Co.*, 455 U.S. 422 (1982), affirms that consistent with the Due Process Clause, legislatures may "create substantive defenses or immunities for use in adjudication" because "the legislative determination provides all the process that is due," *id.* at

432-33.[2] Plaintiffs also cite a string of cases recognizing property or liberty interests that have nothing to do with a prospective cause of action, such as a professional license, a job, or monetary benefits. *See* Opp'n 10 & nn.5-17. These cases are inapposite and cannot justify disregarding binding precedent holding that a potential future cause of action is not a protected interest.

Additionally, Plaintiffs argue that "one has a vested property right in a cause of action once it has somehow accrued," and that a final judgment is not necessary for a property right to vest. Opp'n 23. Even if that were true, it is irrelevant: The PREP Act was enacted in 2005, Pub. L. No. 109-148, 119 Stat. 2680, Div. C (2005), long before Plaintiffs' vaccine injury claims accrued (at the earliest) in 2021, when Plaintiffs allegedly received COVID-19 vaccines and were injured, *see* 3d Am. Compl. ¶¶ 26-28, 38-39, 58, 69-70, 84-86, ECF No. 49.[3]

Plaintiffs also argue that they have been deprived of a protected interest in pursuing CICP remedies, Opp'n 13-14, but that argument fails because Plaintiffs have been allowed to submit CICP claims and have their claims considered in accordance with the PREP Act and governing regulations, Mem. 18. Plaintiffs fail to contend or show otherwise.

2. Plaintiffs Fail To Allege That The CICP's Procedures Are Constitutionally Inadequate

Even if Plaintiffs had alleged the deprivation of a protected property interest, they have not alleged any constitutional deficiency in the CICP's procedures. Mem. 19-29. Their Opposition

[2] Plaintiffs cite *Alliance of Descendants of Texas Land Grants v. United States*, 37 F.3d 1478 (Fed. Cir. 1994), but in that case the court rejected the plaintiff's Takings Clause claim because the causes of action released by a treaty were time-barred, *id.* at 1483. And in that case, unlike here, the claims had arisen long before the treaty released the claims. *Id.* at 1480. The case therefore sheds no light on whether prospective grants of immunity implicate a protected property interest.

[3] The HHS Secretary issued the PREP Act declaration covering COVID-19 vaccines in March 2020 (with an effective date of February 4, 2020), also before Plaintiffs' potential vaccine injury claims accrued. *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 Fed. Reg. 15,198, 15,198 (Mar. 17, 2020). The PREP Act declaration has been amended several times but has been continuously in effect since February 4, 2020.

confirms as much. Plaintiffs again list numerous aspects of the CICP that they dislike. Opp'n 15 (citing 3d Am. Compl. ¶ 152). Yet as the Court explained regarding an earlier iteration of Plaintiffs' Complaint, which contained a similar laundry list of complaints, Plaintiffs have "alleged disorganized causes of action," and even if "the Plaintiffs believe CICP is an ineffective process," they must explain "why such a process is a procedural due process violation." Minutes from Dec. 1, 2023 Status Conference 2-3, ECF No. 33. Plaintiffs have still failed to do so.

Plaintiffs argue that the fact that some CICP claims have been denied establishes a Due Process violation, Opp'n 15-16, but they do not dispute Defendants' showing that such denials were based on failure to meet requirements in the PREP Act and governing regulations, Mem. 20-21. Rather, Plaintiffs argue that "[e]ven if true" that CICP claim decisions "reflect[] the standard set forth in the PREP Act and regulations," the CICP nonetheless "den[ies] due process rights." Opp'n 15-16. Yet Plaintiffs cite no law in support of the mistaken notion that Due Process requires awarding parties relief even when they do not meet the governing legal standards. To the contrary, it is only "the risk of an *erroneous* deprivation" of protected interests that potentially implicates the Due Process Clause, *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976) (emphasis added), not correct application of statutory requirements.[4]

[4] Plaintiffs criticize the CICP for not establishing an injury table for COVID-19 injuries, Opp'n 16, yet the PREP Act states that the agency can establish a table only when it "determines, based on compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury." 42 U.S.C. § 247d-6e(b)(5)(A). Furthermore, the Director of the DICP testified that the CICP is in "the process of establishing an Injury Table for COVID-19 vaccine injuries." Commander George Reed Grimes, Testimony before the United States House of Representatives, Committee on Oversight and Accountability, Select Subcommittee on the Coronavirus Pandemic 7 (Feb. 15, 2024), *available at* https://oversight.house.gov/wp-content/uploads/2024/02/HRSA_SSCP-Testimony-for-02.15.2024-Hearing.pdf. When such a table is established, requesters whose injuries are covered by such a table will have one year from the effective date of the table to submit claims, even if their claims otherwise would have been untimely. *See* 42 C.F.R. § 110.42(f). The PREP Act does not set a deadline for the agency to publish an injury table, and Plaintiffs' dissatisfaction with the

Plaintiffs complain that the CICP does not publish enough information about its processes, Opp'n 17-18, but they cite no case law holding that Due Process requires disclosing any of the information they assert is withheld. Nor do they dispute Defendants' showing that they have disclosed ample information about the CICP both in detailed regulations and on the CICP's website. Mem. 22. Furthermore, Defendants issue a signed letter setting forth the basis of every decision on a CICP claim or reconsideration request. 42 C.F.R. §§ 110.73, 110.74, 110.92.

Plaintiffs acknowledge that Defendants have disclosed the names of the officials with actual decisionmaking authority, who issue signed letters deciding CICP claims and requests for reconsideration, but they criticize Defendants for not disclosing names of lower-level staffers, and redacting names of those staffers in responding to a FOIA request by Plaintiffs' counsel. Opp'n 17-18. Yet Defendants explained that they 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. More important, Plaintiffs cite no law stating that the Due Process Clause requires agencies to name lower-level staffers.

Plaintiffs argue incorrectly that the CICP "plainly" lacks an "impartial decision-maker" because CICP employees are employed by a subcomponent of HHS, and other subcomponents of HHS authorized the COVID-19 vaccines (FDA) and issued guidance regarding administration of the vaccines (CDC). Opp'n 18 & n.26. No such conflict of interest exists. The CICP, FDA, and CDC share the same mission of promoting public health. Contrary to Plaintiffs' assertion, it is not "highly problematic" for FDA and CDC, Opp'n 18 n.26, if the CICP concludes that some requesters have submitted valid claims (as the CICP concluded with respect to Plaintiff Emma

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agency's progress does not raise a Due Process concern; notably, their Third Amended Complaint does not bring an Administrative Procedure Act claim alleging that the agency has "unreasonably delayed" the discharge of any statutory duty. 5 U.S.C. § 706(1).

Burkey, 3d Am. Compl. ¶ 56). Inherent in the PREP Act's design is the recognition that even where a treatment is safe, effective, and necessary to deploy during a public health emergency, it may cause serious injuries to some people, and those people should be able to submit a claim for administrative compensation. Plaintiffs' argument would call into question any administrative adjudication where the adjudicators are employed by the same agency that performs other functions. Yet the Supreme Court has made clear that a Due Process challenge to agency adjudication based on impartiality "must overcome a presumption of honesty and integrity in those serving as adjudicators" and must demonstrate "a risk of actual bias or prejudgment." *Withrow v. Larkin*, 421 U.S. 35, 47 (1975). Plaintiffs have failed to do so.

Plaintiffs argue that the CICP violates due process because claims take too long to resolve. Opp'n 19. Yet they do not dispute that the CICP has significantly increased its pace of resolving claims by bringing on dozens of new staff members in response to a wave of COVID-19 claims and making other process improvements. Mem. 24.[5]

Plaintiffs fail to rebut Defendants' showing that under the third *Mathews* factor, "the Government's interest," 424 U.S. at 335, weighs against their Due Process claim because the federal government has a vital public health interest in maintaining PREP Act immunity to encourage development of and secure the availability of countermeasures to combat public health emergencies. Mem. 27-29. Plaintiffs argue that holding the PREP Act unconstitutional "will impose no additional financial burden on the federal government," Opp'n 21, but as Defendants' explained, the PREP Act is designed to protect public health, not the public fisc. Mem. 28-29.[6]

[5] Plaintiffs also do not dispute that civil litigation often takes as long or longer to resolve than CICP claims, Mem. 25, yet they appear to contend that the CICP has a constitutional obligation to resolve claims *faster* than civil litigation, Opp'n 19 n.27. No case law supports this contention.

[6] Plaintiffs mischaracterize *Mathews* as looking only to "the financial and administrative burden on the government in implementing additional procedural safeguards," Opp'n 21, but *Mathews* is

Plaintiffs also speculate that even if PREP Act immunity were called into question, "pharmaceutical manufacturers . . . should have no difficulty bearing the cost of any harms" from potential tort litigation. Opp'n 22. But Congress made the opposite judgment—namely, that immunity was a necessary incentive so that the threat of litigation would not chill the development or deployment of medical countermeasures to combat public health emergencies. Indeed, COVID-19 vaccine manufacturers insisted on PREP Act immunity as an essential term of procurement contracts with the federal government. *See* Mem. 28 & n.18.

B. Plaintiffs Fail To Plead A Substantive Due Process Claim

Plaintiffs likewise fail to state a substantive Due Process claim because they identify no fundamental right at issue, and the PREP Act satisfies rational basis review. Mem. 29-31. Plaintiffs do not argue that a fundamental right is at stake, but they argue that the PREP Act lacks a "rational basis." Opp'n 24. Yet rational basis review entails "broad deference" to the legislature, and courts uphold a statute "if there is any reasonably conceivable state of facts that could provide a rational basis for the classification." *Harris v. Hahn*, 827 F.3d 359, 365 (5th Cir. 2016) (citation omitted). The government "is under no obligation to prove its reasons; it need only offer them," and "[t]he burden is on the one attacking the legislative arrangement to negative every conceivable basis which might support it." *Id.* (citation omitted).

Plaintiffs fail to meet this burden. It is manifestly rational to grant immunity with respect to medical countermeasures in order to incentivize their development and deployment. Indeed, as Defendants showed and Plaintiffs do not dispute, Congress has done the same thing before in statutes stretching across decades that have either been upheld as constitutional or have not been

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not so limited. It directs courts to examine "the Government's interest, *including* the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail." 424 U.S. at 335 (emphasis added).

challenged. Mem. 30. Plaintiffs seek to distinguish *Ileto*, 565 F.3d 1126, which upheld a statute granting immunity to firearms manufacturers, by arguing that while it was "foreseeable" that those who took COVID-19 vaccines would raise product liability claims, it was "not foreseeable" that plaintiffs would sue firearms manufacturers. Opp'n 24. Plaintiffs are doubly incorrect. First, in *Ileto*, it was not only foreseeable when Congress enacted the PLCAA that plaintiffs would sue firearms manufacturers, but those lawsuits were already pending, and the PLCAA expressly targeted those lawsuits by requiring courts "to 'immediately dismiss[ ]' any pending lawsuits preempted by the PLCAA." *Ileto*, 565 F.3d at 1131 (quoting 15 U.S.C. § 7902(b)). Second, here, it is precisely because lawsuits against manufacturers and administrators of vaccines and other medical countermeasures were foreseeable that Congress deemed it necessary to grant immunity so that the threat of litigation would not chill development and deployment of countermeasures.[7]

C. Plaintiffs Lack A Valid Claim For A Declaratory Judgment

Plaintiffs argue that they are entitled to a declaration that the PREP Act is unconstitutional, Opp'n 24, but they do not dispute Defendants' showing that the Declaratory Judgment Act does not create a freestanding cause of action and only authorizes a remedy for otherwise valid claims, Mem. 31. If the Court dismisses Plaintiffs' substantive claims, as it should, the Court should also dismiss Plaintiffs' declaratory judgment claim.

CONCLUSION

Plaintiffs' Third Amended Complaint should be dismissed.

[7] *See* 42 U.S.C. § 247d-6d(b)(6) (requiring Secretary of HHS to "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" when deciding whether to issue a PREP Act declaration).

Dated: May 20, 2024

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 20, 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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