

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

JEANNE MATERESE,

Plaintiff,

v.

CASE NO: 2:26-cv-212-KCD-DNF

ROBERT F. KENNEDY JR., Secretary
Department of Health and Human Services,

Defendant.

_____ /

PLAINTIFF'S RESPONSE
TO DEFENDANT'S MOTION TO DISMISS

The Secretary has failed to meet his statutory obligation under the Vaccine Act to add the COVID vaccine to the Vaccine Injury Table. Ms. Materese brought this action under the Vaccine Act to compel the Secretary to comply with his mandatory statutory obligation. Contrary to the Secretary's motion to dismiss, the Vaccine Act provides Ms. Materese with standing and this Court with jurisdiction compel the Secretary to comply with the Vaccine Act.

I. The Vaccine Act created a compensation system for adverse vaccine reactions.

In the 1980s, Congress passed the Vaccine Act creating the National Vaccine Injury Compensation Program (VICP), an insurance-like system to provide compensation to people suffering injuries from adverse reactions to

covered vaccines. Pub. L. No. 99-660, § 311,100 Stat. 3743 (1986). Claims are brought in the United States Court of Federal Claims (CFC) in Washington, DC; defended by the Department of Justice; heard by specialized judges; and awards taken from a dedicated excise tax funded trust. 42 U.S.C. §§ 300aa-10–300aa-44. During the past three plus decades, 12,925 vaccine injury claims have been compensated by the VICP with compensation exceeding 5.5 billion dollars. *See* HRSA Data & Statistics, <https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-04-01-26.pdf> (Last visited 4/15/2026). Compensation is paid from the Vaccine Injury Compensation Trust Fund which is funded by an excise tax on each dose of covered vaccine sold. 42 U.S.C. § 300aa-15(i)(2).

II. The Secretary has failed to comply with a mandatory statutory requirement of the Vaccine Act.

Within two years of the recommendation of a vaccine for routine administration to children, the Vaccine Act mandates that the Secretary add the vaccine to the Vaccine Injury Table. 42 U.S.C. § 300aa-14(e)(2). Ms. Materese alleged in her complaint and the Secretary does not dispute in his motion that deadline has long since passed. *See* Complaint para 22-23.

The Secretary contends on page 2 of his motion that “Plaintiff asks the Court to compel the Secretary to bypass the rulemaking process and add COVID-19 vaccines to the Vaccine Injury Table.” Contrary to the Secretary’s

claim, no rule making is required for the Secretary to add a vaccine once recommended for routine administration to children to the Vaccine Injury Table. Instead, the Vaccine Act mandates that “the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table ... to include ... vaccines which were recommended for routine administration to children...” 42 U.S.C. § 300aa-14(e)(2). While the Secretary must go through rulemaking to add the conditions warranting a presumption of causality to the table, 42 U.S.C. § 300aa-14(c)(1), (3), this is not required to add a new vaccine recommended for routine administration to children to the Vaccine Injury Table. *Compare* 42 U.S.C. § 300aa-14(e)(2)(A) *and* § 300aa-14(e)(3). Moreover, adding a new vaccine to the Table is a unique action under the statute that is not an “administrative revision” authorizing the Secretary to change the Vaccine Injury Table through rulemaking. *Id.* § 300aa-14(c)(3) (listing permissible Vaccine Injury Table modifications, which do not include adding vaccines); *contrast* § 300aa-14(e)(2)(A).

III. Addition of a vaccine to the Vaccine Injury Table serves multiple functions, including preventing the expiration of claims.

Adding the new vaccine to the Vaccine Injury Table serves multiple purposes. First, it is a requirement for VICP coverage to commence. 42 U.S.C. § 300aa-14(e)(2). Second, it serves as a recommendation to Congress to fund claims against the vaccine by enacting an excise tax. *Cf.* H.R. Rep. No. 908,

99th Cong., 2d Sess. 1986, 1986 U.S.C.C.A.N. 6344, 6361. Third, it triggers the Vaccine Act’s savings clause, preserving claims like Ms. Materese’s from expiring until Congress acts. 42 U.S.C. § 300aa-16(b).

In regard to the last purpose, the Vaccine Act includes a look-back provision that allows persons injured by a newly covered vaccine to bring claims for two years after the Court of Federal Claims gains jurisdiction over vaccine injuries caused by the vaccine—but only if the injury occurred less than eight years before the vaccine was added to the Vaccine Injury Table. 42 U.S.C. § 300aa-16(b). Thus, the addition of a vaccine to the Vaccine Injury Table importantly preserves the ability to bring a claim when the additional funding requirement is met.

IV. The Vaccine Act explicitly provides for a citizen suit to enforce covered provisions in the event of the Secretary’s failure to comply.

Congress provided a mechanism to enforce the Secretary’s obligations under the Vaccine Act. It empowered “any person” to sue the Secretary for any “failure to perform an act or duty” related to the vaccine injury compensation portion of the Vaccine Act. 42 U.S.C. § 300aa-31(a). The Secretary has failed to comply with the requirements of the Vaccine Act and thus Ms. Materese brought this lawsuit as explicitly authorized by Congress.

The Secretary conflates Ms. Materese’s interest in ensuring the savings clause preserves her vaccine injury claim with her vaccine injury claim

itself. *See* Motion, p. 16 (misstating Ms. Materese’s argument as being a “contention[] that an amendment to the Vaccine Injury Table would...allow her to file her claim immediately, thereby preserving a right to compensation...”). But the harm done to Ms. Materese from the Secretary’s failure to trigger the Act’s savings clause is distinct from the harm of her being unable to file a vaccine claim. The savings provision’s preservation of a vaccine claim until Congress passes an excise tax is a separate and important function of the requirement the Secretary add new vaccines to the Vaccine Injury Table, which should not be folded into other arguments for rhetorical purposes.

In his motion, the Secretary also repeatedly cites to *Brundage v. Kennedy*, Civil Action No. 25-119 (D.D.C. 2025), *appeal pending*, No. 26-5004 (D.C. Cir.). In so doing the Secretary conclusorily avers on page 3 of his motion that “... another district court recently dismissed a similar lawsuit because of the lack of standing.” Yet, Plaintiff in the instant case has pled facts not pled in *Brundage*; added arguments based on last year’s Supreme Court holding in *Diamond Alternative Energy* not considered in *Brundage*; and as the Secretary himself concedes, the *Brundage* case is currently on appeal before the D.C. Circuit.

V. Ms. Materese has standing under the citizen suit provision to bring suit in this Court to compel the Secretary’s compliance with the law.

Rather than fulfill his duty or answer the complaint on its merits, the Secretary argues that Ms. Materese, and thus any other person injured by an adverse reaction to the COVID vaccine, lacks standing. He principally argues that an order of this Court compelling the Secretary to add the COVID vaccine to the Vaccine Injury Table would not redress her injuries.

Ms. Materese has standing in this matter for purposes of Article III. There is nothing speculative about the Secretary's inaction interfering with her right to pursue an opportunity for a benefit; his deprivation of her claim's protection by the savings clause; or the violation of the procedural protection of a Congressionally legislated deadline. As shown below, all are redressable through an order compelling the Secretary to add the COVID vaccine to the Vaccine Injury Table.

VI. Ms. Materese satisfies all elements of standing for each of the three legal injuries caused by the Secretary's failure to comply with the Vaccine Act.

Standing doctrine comprises both constitutional limitations on federal-court jurisdiction and prudential limitations on its exercise. *Bennett v. Spear*, 520 U.S. 154, 162 (1997) (citing *Warth v. Seldin*, 422 U.S. 490, 498 (1975)). Article III standing generally requires a plaintiff to demonstrate "injury in fact," that the injury is "fairly traceable" to the actions of the defendant (conceded by the Secretary on page 12 of the motion), and that the injury will likely be redressed by a favorable decision. *Bennett*, 520 U.S. at 162 (citing

Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–561 (1992) and *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 471–472 (1982)).

A. The Secretary’s interference with three of Ms. Materese’s legal rights, not her vaccine injury, are the injuries-in-fact.

Analysis of Article III standing first requires properly comprehending the injuries alleged. This case concerns only one legal violation—the Secretary’s failure to timely add the COVID vaccine to the Vaccine Injury Table.

“The actual or threatened injury required by Art. III may exist solely by virtue of ‘statutes creating legal rights, the invasion of which creates standing’” *Warth v. Seldin*, 422 U.S. 490, 500 (1975) (quoting *Linda R.S. v. Richard D.*, 410 U.S., 614, 617 n. 3.); *Sierra Club v. Morton*, 405 U.S. 727, 732, (1972).

The injuries-in-fact caused Ms. Materese by the Secretary’s inaction are three: first, it delays her eligibility for compensation through the VICP; second, it denies her the protection of the Vaccine Act’s savings clause; and third, it violates a procedural right to timely action by the Secretary.

1. The Secretary’s delay unlawfully deprives Ms. Materese of an opportunity to pursue a benefit.

A plaintiff suffers a constitutionally cognizable injury by the loss of an *opportunity to pursue a benefit* ... even though the plaintiff may not be able to

show that it was *certain to receive* that benefit had it been accorded the lost opportunity.” *Teton Historic Aviation Found. v. U.S. Dep't of Def.*, 785 F.3d 719, 724 (D.C. Cir. 2015) (quoting *CC Distribs., Inc. v. United States*, 883 F.2d 146, 150 (D.C.Cir.1989) (emphasis in *CC Distribs., Inc*)). As long as the COVID vaccine is not added to the Vaccine Injury Table, Ms. Materese remains ineligible for compensation. Certainty of success on her vaccine injury claim, and certainty that Congress will impose the excise tax, are not required to show an Article III injury.

2. The Secretary’s delay deprives Ms. Materese of protection of the Vaccine Act’s savings clause.

As addressed in greater detail below, the Secretary’s continued inaction also jeopardizes Ms. Materese’s right to ever seek compensation through the Vaccine Injury Compensation Program, even when the excise tax is passed. Section 16(b) of the Act addresses the handling of vaccine-injury claims that predate VICP coverage of the vaccine at issue. It contains a savings clause (also called the “look-back” provision) that preserves claims for injuries arising in the eight years before the Secretary revises the table, and reposes claims arising before that date. 42 U.S.C. § 300aa-16(b)(1)-(2). The savings clause is triggered on “the date of the revision of the table,” *not* its “effective date. *Id.* By withholding the Table addition, the Secretary will cause injured COVID vaccine recipients’ claims to expire. *Id.* The Secretary had a duty to

add the COVID vaccine to the Vaccine Injury Table within two years of it being recommended for routine administration to children, *Id.* § 300aa-14(e)(2), which he is violating. This invades Ms. Materese’s legal rights by depriving her of the benefit of the savings clause. Uncorrected, her concrete injury at present—unlawful delay of benefit eligibility—will become permanent.

3. The Secretary’s inaction deprives Ms. Materese of a procedural right to timely action that protects her interest in expanding the VICP to cover her vaccine injury.

Ms. Materese’s potential vaccine claim states a concrete interest in timely compliance with procedures for the VICP coverage of new vaccines. The Secretary has a nondiscretionary, procedural, and ministerial role in that process: he amends the Table, within two years, to add the vaccine. 42 U.S.C. § 300aa-14(e)(2)(A).

A plaintiff can establish procedural-rights status when 1) an agency’s procedural violation concretely injures an interest of the plaintiff that the statute was designed to protect, and 2) it is substantially probable that the procedural breach will cause the essential injury to the plaintiff’s own interest. *Sierra Club v. Johnson*, 436 F.3d 1269, 1278-79 (11th Cir. 2006) citing *Florida Audubon Soc. v. Bentsen*, 94 F.3d 658 at 665 (D.C. Cir. 1996) (en banc); see also *Pac. Northwest Generating Co-op v. Brown*, 38 F.3d 1058,

1065 (9th Cir. 1994) (noting that by requiring a certain procedure in a statute, Congress has causally linked that procedure with the goal of the statute).

The Secretary’s procedural failure to timely amend the Table harms Ms. Materese’s interests in a timely clarification of her potential benefits under the Vaccine Act. The procedural duty violated is intended to protect the interests she seeks to have vindicated—access to compensation for those injured before a recommended vaccine becomes a “covered vaccine.” Therefore, her claims in this suit for injunctive relief are those of a procedural-rights plaintiff for standing purposes.

B. Traceability: Ms. Materese’s injuries due to the Secretary’s inaction is directly traceable.

Each of the harms alleged above is directly traceable to the Secretary’s unlawful delay and inaction. Furthermore, the Secretary has conceded as much. *See* page 12 of the motion where the Secretary concedes that traceability has been met. For traceability, the relevant inquiry is whether the plaintiffs’ injury can be traced to allegedly unlawful conduct of the defendant. *Collins v. Yellen*, 594 U.S. 220, 243 (2021). “[T]raceability does not equate to proximate cause, noting that “[e]ven a showing that a plaintiff’s injury is indirectly caused by a defendant’s actions satisfies the traceability requirement.” *Garcia-Bengochea v. Carnival Corp.*, 57 F.4th 916, 927 (11th

Cir. 2023) (citing *Resnick v. AvMed, Inc.*, 693 F.3d 1317, 1324 (11th Cir. 2012) at 1324.))

C. Redressability: The injury caused by the Secretary’s inaction can be remedied by this Court.

For each invasion of Ms. Materese’s legal rights, an order directing the Secretary to add the COVID vaccine to the Vaccine Injury Table will provide redress. An injury caused by an unlawful delay is remedied by an order that ends the unlawful delay. The requested order may not immediately allow Ms. Materese to file a VICP claim, but it will end the *unlawful* delay and thus provides sufficient redress for Article III. Moreover, it provides *complete* relief for the harms of depriving Ms. Materese of the protection of the savings clause, and for denying her procedural right to a timely Vaccine Injury Table addition. Indeed, “[a] procedural violation is remedied by process, and so long as that process protects a concrete interest, the plaintiff has shown redressability.” *Center for a Sustainable Coast v. U.S. Army Corps of Engineers*, 100 F.4th 1349 (11th Cir. 2024) at 1359.

1. Ms. Materese’s lost pursuit of benefit claim is redressable because a court order creates a “substantial probability” of ultimate relief.

Redressability requires a plaintiff to show “a ‘substantial likelihood’ that the requested relief will remedy the alleged injury in fact.” *Teton Historic Aviation Found. v. U.S. Dep’t of Def.*, 785 F.3d at 724 (D.C. Cir.

2015). “A party seeking judicial relief need not show to a certainty that a favorable decision will redress [its] injury.” *Teton Historic Aviation Found.*, 785 F.3d at 726. A “significant increase in the likelihood,” or a “substantial probability” of ultimate relief suffices. *Town of Barnstable, Mass v. F.A.A.* 659 F.3d 28 (D.C. Cir. 2011) at 31. To be sure, “...when ‘a litigant is vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant.’... ; if certainty about future administrative outcomes was needed to show standing, citizen-suit provisions ‘would be a dead letter.’” *Center for a Sustainable Coast v. U.S. Army Corps of Engineers*, 100 F.4th at 1357 (quoting *Cahaba Riverkeeper v. EPA*, 938 F.3d 1157, 1162 (11th Cir. 2019) and *Sugar Cane Growers Co-Op of Florida v. Veneman*, 289 F.3d 89, 95 (D.C. Cir. 2002)).

a. Partial relief suffices for standing purposes.

The fact that an order to the Secretary would not immediately give the Court of Federal Claims jurisdiction over Ms. Materese’s injury does not defeat redressability, because the prospect of partial relief is sufficient for standing purposes. *Made in the USA Found. v. United States*, 242 F.3d 1300, 1310 (11th Cir. 2001) (citing *Swan v. Clinton*, 100 F.3d 973, 981 (D.C. Cir. 1996)). “The remedy need not be complete or relieve every injury alleged in order to satisfy Article III standing.” *Reeves v. Comm’r, Alabama Dep’t of*

Corr., 23 F.4th 1308, 1318 (11th Cir. 2022) (citing *Uzuegbunam v. Preczewski*, 592 U.S. 279, 141 S. Ct. 792, 209 L. Ed. 2d 94 (2021)).

Article III does not demand a demonstration that victory in court will without doubt cure the identified injury. *Teton Historic Aviation Found. v. U.S. Dep't of Def.*, 785 F.3d 719, 727 (D.C. Cir. 2015). Redressability is established “when a favorable decision ‘would amount to a significant increase in the likelihood that the plaintiff would obtain relief that directly redresses the injury suffered.’” *S. River Watershed All., Inc. v. Dekalb Cnty., Georgia*, 69 F.4th 809, 820 (11th Cir. 2023) (quoting *Utah v. Evans*, 536 U.S. 452, 464 (2002)). See also, *Maron v. Chief Fin. Officer of Fla.*, 136 F.4th 1322, 1331 (11th Cir. 2025).

Notably, a plaintiff seeking to remove a barrier to the exercise of her rights, as Ms. Materese does, need not show that the removal immediately affords complete relief. *Sierra Club v. U.S. Dep't of the Interior*, 899 F.3d 260, 285 (4th Cir. 2018) (“The removal of even one obstacle to the exercise of one’s rights, even if other barriers remain, is sufficient to show redressability”).

b. Congress’ role does not serve a legal shield for the Secretary’s inaction.

Redressability is not defeated simply because ultimate relief may depend on a third party’s action. In *Diamond Alternative Energy, LLC*, the Supreme Court articulated a clear standard for assessing redressability that

depends on likely third-party behavior: a plaintiff “must simply ‘show a predictable chain of events’ that would likely result from judicial relief and redress the plaintiff’s injury.” *Diamond Alternative Energy, LLC*, 606 U.S. at 121 (quoting *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367, 385 (2024)). The Supreme Court also affirmed that courts may apply commonsense economic principles and draw commonsense inferences to predict third party behavior. *Id.* at 116. *Diamond’s* holding relied on *Department of Commerce v. New York*, 588 U.S. 752, 768 (2019), in which the Court found standing based on a much more attenuated chain of causality and redressability than is the case for Ms. Materese.

2. An order directing the Secretary to add the COVID vaccine to the Vaccine Injury Table redresses Ms. Materese’s injuries.

The Secretary’s denial of the benefit of the savings clause to Ms. Materese, and his procedural obstructionism can be relieved without any action from Congress. When the Secretary adds the COVID vaccine to the Vaccine Injury Table, those harms end. The order Ms. Materese seeks therefore satisfies Article III’s redressability requirement.

a. Ms. Materese’s vaccine injury claim is protected from repose once the COVID vaccine is added to the Vaccine Injury Table, regardless of its “effective date.”

The statutory note’s “effective date” determination has no effect on the savings clause. The savings clause enters into force on “the date of the revision of the table.” § 16(b). The first principle of statutory construction is to start with the text. The relevant text here provides:

If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa-11(b)(2) of this title, file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program ... if--

- (1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or*
- (2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.*

42 U.S.C.A. § 300aa-16 (emphasis added). This subsection shows careful attention to the description of dates for: triggering the savings clause (“if at any time the [Table] is revised [to expand eligibility]”); the expiration of the limitations period (“2 years after the effective date”); and calculation of the savings and repose dates (“8 years before the date of the revision”). Dates are either determined in reference to the date of the revision of the Table or the effective date of the revision. Thus, the savings clause plainly states that the relevant date for calculating its protection is “the date of the revision of the Table.” *Id.* § 16(b)(1), (2). The difference is that counting from the “effective date” can only occur once an excise tax has been passed, whereas “the date of

the revision of the Table” counts from the day the Secretary adds the vaccine to the Vaccine Injury Table.

On the day the Secretary amends the Vaccine Injury Table, claims that assert a vaccine injury occurring eight years or less before the revision of the Table by the Secretary are protected from repose. Once the Secretary adds the COVID vaccine to the Table, Ms. Materese’s right to bring her claim cannot then be lost if Congress delays imposing the excise tax.

b. The violation of Ms. Materese’s procedural right has a lower threshold for redressability, which she has met.

A plaintiff asserting violation of a procedural right need not show that correction of the violation cures her underlying injury. Where a related procedure is implicated that would not be bound the court’s decision, it is enough that she show the correction will provide “a significant increase in the likelihood” of substantive relief. *Utah*, 536 U.S. at 464; *Polelle v. Fla. Sec’y of State*, 131 F.4th 1201, 1224 (11th Cir.), cert. denied, 146 S. Ct. 298 (2025).

In Utah, the Supreme Court reiterated its holding from *Franklin v. Massachusetts*, 505 U.S. 788 (1992), that in an APA challenge to Census Bureau decisions a court can “assume it is substantially likely that the President and other executive and *congressional officials would abide by [a court’s interpretation] even though they would not be directly bound.*” *Utah*, 536 U.S. at 460 (emphasis added). The Court explained this holding further

in *Utah*, at 463, emphasizing the changed legal status that results even from a court declaration. It recognized that a significantly better chance of ultimate relief was the “practical consequence” of such a ruling. *Id.* at 464.

VII. Defendant asks the Court to adopt an impermissible construction of the Vaccine Act.

The Secretary argues throughout his motion that the “effective date” language in the statute’s § 14 Note prevents this Court from ordering effective relief on Ms. Materese’s behalf. *See* motion pages 6, 7, 8, 16, and 17. The Note only says that “[a Table revision adding a new vaccine] shall take effect upon the effective date of a tax enacted to provide funds from compensation paid with respect to the vaccine to be added to the [Table].” 42 U.S.C. § 300aa-14 Note.

The Secretary’s proposed construction of the Note requires this Court to adopt changes to the Act judicially. Such “repeals by implication are not favored.” *TVA v. Hill*, 437 U.S. 153, 189 (1978). “The only permissible justification for a repeal by implication is when the earlier and later statutes are irreconcilable.” *TVA*, at 190 (quoting *Morton v. Mancari*, 417 U.S. 535, 549 (1974)). The doctrine equally applies to amendments by implication. *National Ass’n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 663-64, n.8. The Secretary has not shown that the Note is irreconcilable with the Act’s substantive provisions, so the Court has no basis for doing so.

The Defendant's interpretation of the Secretary's duties under the Vaccine Act likewise changes the word "shall" in that provision to "may." "When the word *shall* can reasonably be read as mandatory, it ought to be so read." Scalia & Garner, *supra*, § 11, p. 114. By providing a right of action against the Secretary's "failure to perform any act or duty" related to the Program, § 31, Congress made clear that *shall*, in the National Childhood Vaccine Injury Act, means "must." See Scalia & Garner, *supra*, § 11, p. 112 ("The...rule is that *shall* is mandatory and *may* is permissive." Courts should not adopt such amendments by implication. See *National Ass'n of Home Builders*. This Court should reject the Defendant's proposal to re-write the Vaccine Act.

VIII. Ms. Materese pled alternative causes and likewise has standing to bring these causes.

Ms. Materese pled alternative causes of action in counts 2 through 5 of her complaint. The Secretary has also challenged her ability to bring these counts. However, these alternative causes of action and relief were pled in anticipation of the Secretary's arguments. For example, should this Court accept the Secretary's construction of the Note, Ms. Materese will no longer have an adequate remedy at law through the Vaccine Act's citizen-suit provision. In that instance, Defendant's argument that her APA claim should be dismissed will have no basis. She therefore states a valid alternative claim

for violation of her procedural rights under the APA. Likewise, the other counts as pled provide alternative mechanism of redressing the failure of the Secretary to comply with the requirements of the Vaccine Act.

The Secretary also claims that the Countermeasures Injury Compensation Program (CICP) serves an adequate remedy barring Ms. Materese from relief from the Mandamus Act or All Writs Act. The CICP is far from an adequate alternative remedy – it provides no due process – and is therefore no remedy at all. CICP claims must be filed within one year (a deadline long since past for Ms. Materese), are decided in secret, the criteria employed is unknown, there is no record, no opportunity to present evidence or witnesses, no ability to dispute evidence or cross-examine witness, and appeal to any court is barred. 42 U.S.C.A. § 247d-6e. The CICP has been called by legal commentators a “black hole” and “the right to file and lose.” *See, Immunizing the Immunizers: How Covid-19 Vaccine Injury Claims and the CICP Will Increase Anti-Vaccine Sentiment in the United States and How HRSA Can Prevent It*, Kimberly K. Henrickson, 77 Food & Drug L.J. 93, 99 (2022) and *Insult to the Injured: The Case for Modernizing Vaccine Injury Compensation*, Health Affairs Forefront, July 19, 2023.

Furthermore, the PREP Act which established the CICP specifically states, “Nothing in this section, or any amendment made by the Public Readiness and Emergency Preparedness Act, shall be construed to affect the

National Vaccine Injury Compensation Program...” 42 U.S.C. § 247d-6d(h).

Therefore, the Secretary’s attempted use of CICIP to bar Ms. Materese’s standing in bringing a Vaccine Act citizen suit flies in the face of the explicit limitation of the PREP Act.

CONCLUSION

Ms. Materese asks this Court to deny the Secretary’s motion and allow this matter to proceed on its merits.

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CERTIFICATE OF SERVICE

I hereby certify that on April 20th, 2026, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system, which will provide electronic notice to all counsel of record.

/s/ Abigail Fleming