IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PAUL BRUNDAGE,

Plaintiff,

v. Civil Action No. 1:25-CV-00119-SLS

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

Defendant.
_____/

RESPONSE OF PAUL BRUNDAGE

TO DEFENDANT'S MOTION TO DISMISS

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INTRODUCTION

The Secretary of Health & Human Services (Secretary) has failed to live up to his statutory obligation under the Vaccine Act to timely add the COVID vaccine to the Vaccine Injury Table. The Secretary's addition of the COVID vaccine to the Vaccine Injury Table is required for Plaintiff Paul Brundage to be able to bring a claim under the Vaccine Act in the Vaccine Injury Compensation Program (VICP). Mr. Brundage's claim under the VICP would be for his injuries from a severe blood clotting disorder as the result of an adverse reaction to a COVID vaccination. The Vaccine Act provides a specific mechanism, a citizen suit provision, to compel the Secretary's compliance with the Act. That is the very provision that Mr. Brundage has employed to compel the Secretary to comply with his mandatory statutory obligation.

Rather than accede that he has failed meet his mandatory statutory obligation under the Vaccine Act, the Secretary raises various procedural defenses. In effect, the Secretary attempts to argue that he is not subject to the citizen suit provision of the Vaccine Act or the oversight of this Court. The Secretary claims that Mr. Brundage, and if not Mr. Brundage indeed no one, has standing to compel his compliance with the Vaccine Act via the very provision included in the Act to do so.

The Secretary hides behind the remaining requirement that Congress impose a 75-cent payment on future COVID vaccine sales to finalize Mr. Brundage's ability to seek compensation in the VICP. Indeed, both must occur before Mr. Brundage

and others can seek compensation for serious injuries from COVID vaccine adverse reactions in the VICP. However, the Secretary's obligation to timely add the COVID vaccine to the Vaccine Injury Table under the Vaccine Act is not dependent upon, nor his failure excused by, the status of the authorization of the 75-cent excise tax.

The failure of the Secretary to timely add the COVID vaccine to the Vaccine Injury Table imposes a continuing harm to Mr. Brundage. Unfortunately, the failure of the Secretary to meet his mandatory statutory obligation under the Vaccine Act does not harm Mr. Brundage alone. As one would expect for a novel vaccine administered to a significant percentage of the population, Mr. Brundage is but one of many that have suffered adverse severe injuries from COVID vaccine adverse reactions. Sadly, the Secretary disingenuously argues that Mr. Brundage and those like him can seek redress in the Countermeasures Injury Compensation Program (CICP). Lacking any semblance of due process, the CICP has been insult added to injury for those suffering serious injuries from COVID vaccine adverse reactions. It is hard to fathom how the Secretary is unaware that the CICP provides Mr. Brundage and those in his position no real remedy.

In sum, the Secretary offers a series of unfounded procedural defenses but does not meaningfully challenge Mr. Brundage's core assertion: the Secretary has failed to fulfil his non-discretionary statutory requirement to include the COVID vaccine on the Vaccine Injury Table, harming the legal interests of Mr. Brundage. When members of the Executive Branch fail to properly execute federal law, those

who suffer harm as a result turn to a court for a relief. That is precisely what Mr. Brundage is doing here.

1. **The Secretary has a mandatory duty to add the COVID vaccine to the Vaccine Injury Table within 2 years of the CDC's recommendation for routine administration to children.**

The plain language of the Vaccine Act mandates that the Secretary has 2 years to amend the Vaccine Injury Table to include vaccines which, like the COVID vaccine, have been recommended for routine administration to children. The Act expressly provides:

> When after August 1, 1993, the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, *the Secretary shall*, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include—
>
> (A) vaccines which were recommended for routine administration to children,

42 U.S.C. § 300aa-14(e)(2) (emphasis supplied).

In its argument in favor of dismissing Plaintiff's citizen suit to enforce this statutory obligation, the Secretary cites to a decision in the Gardasil Multi-District Litigation reviewing the constitutionality of the Vaccine Act. Doc. 9, Page 20, citing *In re Gardasil Prods. Liab. Litig.*, No. CV 3:22-MD-03036-KDB, 2024 WL 3240677, at *3 (W.D.N.C. June 27, 2024). However, the Secretary omits the very relevant analysis of the MDL court found later in that same decision, which held that the Secretary's duty to timely add a vaccine to the Vaccine Injury Table is *mandatory*. *Id.* at *4. The MDL court there affirmed that "[T]he addition of new vaccines to the

Table is not discretionary. The Act requires the Secretary to add all vaccines recommended by the CDC for routine administration to children 'within 2 years of such recommendation.' See § 300aa–14(e)(2)." *Id.*

2. Mr. Brundage has standing: he continues to suffer injury in fact caused by the Secretary's failure to comply with the Vaccine Act and the relief sought will help address Mr. Brundage's legal injury.

In his motion to dismiss, the Secretary cites to *Coal. for Mercury-Free Drugs v. Sebelius*, 725 F. Supp. 2d 1, 8 (D.D.C. 2010) for the proposition that the citizen suit provision of the Vaccine Act does not confer standing in the absence of satisfying the traditional standing requirements. While the decision of the trial court in *Coal. for Mercury-Free Drugs* was upheld on appeal, the Circuit Court opinion, authored by now Justice Kavanaugh, detailed in its review the basis for determining standing under the citizen act provision in that case:

> The "irreducible constitutional minimum of standing contains three elements": (1) the plaintiff must have suffered an "injury in fact – an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent," not abstract, generalized, remote, or speculative; (2) there must be a "causal connection" between the injury and the challenged action of the defendant; and (3) it must be "likely," not merely "speculative," that the relief sought will redress the injury. *Lujan*, 504 U.S. at 560-61 (internal quotation marks and citations omitted).

Coal. for Mercury-Free Drugs v. Sebelius, 671 F.3d 1275, 1279 (D.C. Cir. 2012). In *Coal. for Mercury-Free Drugs*, the Circuit Court held against the plaintiffs in the Vaccine Act citizen suit, finding: "To establish standing, plaintiffs must allege likely future injury to Coalition members, not to other members of the public. Plaintiffs have not done so." *Id.*

In stark contrast, Mr. Brundage personally suffers an ongoing injury in fact from the failure of the Secretary to timely add the COVID vaccine to the Vaccine Injury Table. Compelling the Secretary to comply with the Vaccine Act would provide a necessary element to remedy that legal injury.

The Secretary's claim that the Vaccine Act does not help Mr. Brundage establish standing is not accurate. The Vaccine Act creates a legal interest for those who suffer an injury as a result of a vaccination. 42 U.S.C.A. § 300aa-1 through 300aa-34. That legal interest gives rise to standing. "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, 95 S. Ct. 2197, 2206, (1975). The citizen suit provision of the Vaccine Act (42 U.S.C.A. § 300aa-31(a)) is properly invoked in establishing standing when that legally protected interest is harmed by the illegal in(action) of the Secretary.

Mr. Brundage's harm is concrete and particularized. Mr. Brundage personally suffered serious ongoing injury due to an adverse reaction to a COVID vaccine—a vaccine that the CDC over two years prior to the filing of Mr. Brundage's complaint recommended for routine administration to children—but cannot seek compensation under the Vaccine Act because the Secretary has failed to fulfill his non-discretionary statutory duty to add the COVID vaccine to the Vaccine Injury Table.

3. The Secretary's argument that Congress must authorize the 75-cent excise tax before a vaccine can be added to the Vaccine Injury Table is incorrect.

The Vaccine Act imposes the duty on the Secretary to timely add the COVID vaccine to the Vaccine Injury Table. 42 U.S.C. 300aa 11-14(e)(2). The Vaccine Act imposes no such timing obligation on Congress. *See* 26 U.S.C. § 9510 (Vaccine Injury Compensation Trust Fund); 26 U.S.C. § 4131 (imposition of 75-cent tax on taxable vaccines); 26 U.S.C. § 4132(a) (definition of taxable vaccines); Omnibus Budget Reconciliation Act of 1993, PL 103–66, August 10, 1993, 107 Stat 312, at 42 U.S.C.A. § 300aa–14 NOTE (referencing taxes enacted to provide funds for vaccine compensation); 42 CFR 100.3(e)(8) (referencing taxes enacted to provide funds for vaccine compensation).

Until the COVID vaccine is added by the Secretary to the Vaccine Injury Table, Congress has no eligible vaccine on which to impose the 75-cent excise tax on future COVID vaccine sales. It is the Secretary's act of identifying the vaccine to be added to the Vaccine Injury Table that paves the way for Congress to provide the funding for compensation. Omnibus Budget Reconciliation Act of 1993, PL 103–66, August 10, 1993, 107 Stat 312 at 42 U.S.C.A. § 300aa–14 NOTE. Under the statutory scheme, the Secretary fulfilling his obligation will allow Congress to authorize the excise tax.

In his motion to dismiss, the Secretary argues the contrary position, writing that "one of the prerequisites for adding a vaccine to the VICP as a covered vaccine and to the Vaccine Injury Table is the enactment of an excise tax to provide the funds that will be used for compensation with respect to the vaccine to be added to

the Table." Doc. 9, Pages 11, 17. The Secretary's argument that the enactment of the excise tax by Congress is a *prerequisite* for adding the COVID vaccine to the Vaccine Injury Table is incorrect.

In addressing the interplay of the excise tax and the Secretary's amendment of the Vaccine Injury Table, Congress noted, "*A revision by the Secretary* under section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) (as amended by paragraph (2)) *shall take effect upon the effective date of a tax* enacted to provide funds for compensation paid…" Omnibus Budget Reconciliation Act of 1993, PL 103–66, August 10, 1993, 107 Stat 312 at 42 U.S.C.A. § 300aa–14 NOTE (emphasis supplied). Thus, the Secretary acts first in revising the Vaccine Injury Table, which revision later becomes effective when Congress passes the excise tax. *Id*.

Indeed, the plain language of the statute includes no such prerequisite. The Vaccine Act provides:

> …the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include—
>
> (B) vaccines which were recommended for routine administration to children,

42 U.S.C. § 300aa-14(e)(2). The Act does not mandate, or in any way discuss, the Secretary being required to wait for an excise tax before complying with this statutory obligation. The Secretary's interpretation of the Act to the contrary is a construct unfounded in the language of the Act. The argument that the excise tax is

a prerequisite to the Secretary's statutory obligation under 42 U.S.C. § 300aa-14(e)(2) contradicts the plain language of the statute which mandates action within 2 years of the recommendation of the vaccine for routine administration and which contains no other qualifiers or requirements.

Despite the lack of statutory basis, in further support of this argument, the Secretary goes on to heavily rely on the notice of inclusion of Trivalent Influenza Vaccines to the VICP. Doc. 9, Page 17-18. The Secretary's argument in this respect fails for two reasons.

First, the Secretary's claim that he cannot add the COVID vaccine to the Injury Table before the enactment of the excise tax is contradicted by the example of the addition of the hepatitis B, Hib and varicella vaccines which the Secretary also cites. A prior Secretary added those vaccines to the Vaccine Injury Table before the excise tax was enacted. "The tax for the hepatitis B, the Hib and the varicella vaccines has not been enacted yet . . . As soon as the tax becomes effective, a petitioner may file a claim for an injury or death allegedly caused by these vaccines." *National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table—II*, 62 FR 7685-01 (Feb. 20, 1997).

The Secretary modified the Vaccine Injury Table to include those vaccines for the same reason that the COVID vaccine should be added. Contrary to what the Secretary is now arguing, the Secretary in 1997 explained in the notice of inclusion of those vaccines into the Vaccine Injury Table that even though the Congress had not yet levied the excise tax: "section 2114(e)… *directed the Secretary to add to the*

Table, by rulemaking, coverage of additional vaccines which are recommended by the Centers for Disease Control and Prevention for routine administration to children." *Id.* (emphasis added). Thus, the Secretary in 1997 expressly acknowledged that his statutory obligation was independent of the excise tax. Following the inclusion of the hepatitis B, Hib and varicella vaccines in the Vaccine Injury Table, Congress then authorized the excise tax. Taxpayer Relief Act of 1997, PL 105–34, August 5, 1997, 111 Stat 788 (amending 26 U.S.C. § 4132(a)(1)).

Second, the example of influenza vaccine cited by the Secretary does not support his arguments in this case because the enactment of excise tax and inclusion of the influenza vaccine onto the Vaccine Injury Table all occurred within the two-year statutory prescribed timeframe. The influenza vaccine was recommended for routine administration to children on May 28, 2004, the excise tax was enacted the same year, and the notice of inclusion into the program became effective on April 12, 2005. *See National Vaccine Injury Compensation Program: Addition of Trivalent Influenza Vaccines to the Vaccine Injury Table*, 70 FR 19092 (Apr. 12, 2005).

Because neither the Vaccine Act nor the history of the VICP support the Secretary's argument that Congress' passage of an excise tax is a prerequisite to the Secretary's statutory obligation to add the COVID vaccine to the Vaccine Injury Table, this argument for dismissal cannot succeed.

4. The Secretary's failure to comply with the requirements of the Vaccine Act cannot be blamed on a third-party, in this case Congress, in order to avoid the jurisdiction of this Court.

The Secretary contends this Court lacks subject matter jurisdiction because even if the Secretary fulfilled his statutory obligation to add the COVID vaccine to the Vaccine Injury Table, Mr. Brundage would still be unable to file his claim in the VICP until Congress authorizes the 75-cent payment by manufacturers for future COVID vaccine sales. The Secretary makes this argument under the headings of both standing and ripeness. As shown above, this argument that the Secretary's statutory obligation is dependent on Congress first enacting an excise tax is not accurate.

To satisfy the requirements of standing, Mr. Brundage must show that his injury "'fairly can be traced to the challenged action' of the Secretary, and 'not … some third party not before the court.'" *Massachusetts Coal. for Immigr. Reform v. U.S. Dep't of Homeland Sec.*, 698 F. Supp. 3d 10, 23 (D.D.C. 2023) (quoting *Simon v. E. Kentucky Welfare Rts. Org.*, 426 U.S. 26, 41–42, 96 S. Ct. 1917, 48 L. Ed. 2d 450 (1976)). That is not the case here. The Secretary has failed to perform his statutory duty as mandated by the Vaccine Act, not some third party.

The Supreme Court has held that for the purpose of standing, the challenged action, or inaction in the instant case, need not to be "the very last step in the chain of causation." *Bennett v. Spear*, 520 U.S. 154, 168, 117 S. Ct. 1154, 137 L. Ed. 2d 281 (1997) at 168-169. In this case, the Vaccine Act required the Secretary to add the COVID vaccine to the Vaccine Injury Table within two years of the CDC recommendation of the vaccine for routine administration to children. The Omnibus

Budget Reconciliation Act of 1993, PL 103–66, August 10, 1993, 107 Stat 312 did not abrogate this statutory requirement. The Act only sets the effective date for a claim to be eligible under the VICP. The Omnibus Budget Reconciliation Act does not change the obligation of the Secretary to timely add a vaccine such as the COVID vaccine to the Vaccine Injury Table.

Even though Mr. Brundage cannot file a petition in the VICP until the 75-cent excise tax takes effect, for the purpose of standing, Mr. Brundage's harm is "fairly traceable" to the Secretary's failure to meet his statutory requirements. Moreover, Mr. Brundage's injury can be remedied if this Court orders the Secretary to fulfill his statutory duty because once the Secretary does so the sole step that will remain is for Congress to levy the requisite excise tax on future COVID vaccine sales pursuant to the provisions of the Vaccine Act. As shown above, this is exactly what Congress did in the instance of the addition of the hepatitis B, Hib, and varicella vaccines where the Secretary at that time modified the Vaccine Injury Table prior to the enactment of excise tax on those vaccines. *See Attias v. Carefirst, Inc.*, 865 F.3d 620, 625 (D.C. Cir. 2017) (Analyzing the elements of standing under the light burden plaintiffs bear at the pleading stage.).

In fact, there do not appear to be any instances where a Secretary has added a vaccine to the Vaccine Injury Table following the recommendation of the CDC for routine administration to children and Congress has not subsequently authorized the excise tax on the future sale of that vaccine necessary to provide coverage under the VICP. The Secretary has offered no explanation as to why the inclusion of the

COVID vaccine should be treated differently by Congress here. Thus, Mr. Brundage's injury is "likely to be redressed" by a favorable decision. *Attias v. Carefirst, Inc.*, 865 F.3d at 629 (finding potential to be made whole satisfied the requirement that a plaintiff's injury be "likely to be redressed by a favorable judicial decision.").

Under the heading of ripeness, the Secretary asserts that Mr. Brundage's claim is not yet ripe due to the need for Congress to pass an excise tax even if this Court orders the Secretary to comply with its statutory duty. Doc. 9, Pages 20-21. This argument conflates Mr. Brundage's claim in this citizen suit, which seeks to compel the Secretary to comply with the Vaccine Act, and Mr. Brundage's claim for compensation in the VICP. The Secretary argues that Mr. Brundage's vaccine compensation claim rests on contingent future events, such as the passage of an excise tax (which the Secretary again incorrectly characterizes as a prerequisite to the Secretary's statutory duty). The Secretary submits that as the excise tax has not passed, Mr. Brundage's claim for vaccine compensation is not ripe. Doc. 9, Pages 20-21.

This argument would be well and good if this Court were the Court of Federal Claims and the ripeness of Mr. Brundage's vaccine compensation claim at the VICP were at issue. However, the argument fails in light of the fact that the claim under consideration by this Court is Mr. Brundage's citizen suit to enforce the Secretary's statutory duties under the Vaccine Act. The doctrine of ripeness considers the sufficiency of the "fitness for review of the legal issue presented" to the court so that

courts may avoid "entangling themselves in abstract disagreements." *Cohen v. United States*, 650 F.3d 717, 734 (D.C. Cir. 2011). Notably, ripeness concerns the issue presented to the court and not issues pending in other courts.

Here, the legal issue presented is whether the Secretary has complied with the duties assigned him by the Vaccine Act. That issue is not contingent on future events, as the Secretary argues. Rather, it is a straightforward question of what actions the Secretary has taken with respect to the COVID vaccine and the VICP. Accordingly, Mr. Brundage has submitted a justiciable issue before this Court and his citizen suit claim is ripe for adjudication. Despite the Secretary's protests to the contrary, Congress' separate obligation to pass an excise tax cannot dispel the Secretary's statutory duty to comply with the Vaccine Act. Nor can such argument negate subject matter jurisdiction here.

5. The Secretary's interpretation of the Vaccine Act is contrary to basic rules of statutory construction.

If this Court were to adopt the Secretary's interpretation of the citizen's suit provision of the Vaccine Act, it would render the requirement that the Secretary add a vaccine to the Vaccine Injury Table within two years of the CDC's recommendation of routine administration to children toothless in the absence of prior authorization by Congress of an excise tax. This would effectively render the requirement in the Vaccine Act surplusage. The canon of statutory construction against surplusage holds:

> For one thing, the surplusage canon is primarily a tool of linguistic interpretation, reflecting an assumption applicable to "all sensible writing: Whenever a reading arbitrarily ignores linguistic components or inadequately accounts for them, the

> reading may be presumed improbable." Scalia & Garner 174 (internal quotation marks omitted).

Feliciano v. Dep't of Transportation, 145 S. Ct. 1284, 1294 (2025). Courts should avoid interpretations that "treat statutory terms as surplusage," *Babbitt v. Sweet Home Chapter of Cmtys. for a Great Or.*, 515 U.S. 687, 698, 115 S.Ct. 2407, 132 L.Ed.2d 597 (1995). "It is 'a cardinal principle of statutory construction' that 'a statute ought, upon the whole, to be construed'" in a manner that ensures that "'no clause, sentence, or word shall be superfluous, void, or insignificant.'" *Amarin Pharms. Ireland Ltd. v. Food & Drug Admin.*, 106 F. Supp. 3d 196, 209 (D.D.C. 2015), dismissed, No. 15-5214, 2015 WL 9997417 (D.C. Cir. Dec. 9, 2015) quoting *TRW Inc. v. Andrews*, 534 U.S. 19, 31, 122 S.Ct. 441, 151 L.Ed.2d 339 (2001) (citation omitted). "It is a familiar canon of statutory construction that, if possible, we are to construe a statute so as to give effect to every clause and word." *Ascendium Educ. Sols., Inc. v. Cardona*, 78 F.4th 470, 480 (D.C. Cir. 2023) quoting *Air Transp. Ass'n of Am., Inc. v. Dep't of Agric.*, 37 F.4th 667, 672 (D.C. Cir. 2022) (cleaned up); accord *Williams v. Taylor*, 529 U.S. 362, 404, 120 S.Ct. 1495, 146 L.Ed.2d 389 (2000); *see also Antonin Scalia & Bryan Garner, Reading Law: The Interpretation of Legal Texts*, 174 (2012).

The Secretary's argument that it has no statutory obligation to add a vaccine to the Vaccine Injury Table until Congress enacts an excise tax reads the timing requirements of section 14(e)(2) out of the Vaccine Act. Under the surplusage canon of statutory construction, such interpretation of the Secretary's duty under the Vaccine Act is improbable. The surplusage canon instead requires that the Act's

provision that the Secretary amend the Vaccine Injury Table within 2 years of recommending a vaccine for routine administration be given full effect.

6. Mr. Brundage's claim is ripe for adjudication and Mr. Brundage has pled adequate facts that are not in dispute.

The Secretary argues that Mr. Brundage's claim is not ripe for adjudication because Mr. Brundage did not specifically plead when the CDC recommended COVID for routine administration to children. However, on a motion to dismiss for lack of subject matter jurisdiction, the well-pled factual allegations are accepted as true and all reasonable inferences are drawn in the plaintiff's favor. *In re U.S. Off. of Pers. Mgmt. Data Sec. Breach Litig.*, 928 F.3d 42, 54 (D.C. Cir. 2019). The question before the Court at this stage in the proceedings is whether jurisdiction is plausibly alleged. *Id.*

The Secretary does not provide contrary evidence to dispute Mr. Brundage's allegation that over two years elapsed between the CDC's recommendation for routine administration of the COVID vaccine to children and the filing by Mr. Brundage of his suit. The Secretary does not do so because he cannot – as alleged in the complaint, the COVID vaccine was recommended for routine administration to children by the CDC well over two years before Mr. Brundage sent his pre-suit notice and well over two years before he brought suit. Doc. 1 ¶¶ 14-16.

Moreover, such specificity of allegation is not required at this juncture. *In re U.S. Off. of Pers. Mgmt. Data Sec. Breach Litig.*, 928 F.3d 42, 60–61 (D.C. Cir. 2019) ("Nor are we troubled, as OPM suggests we should be, by certain Arnold Plaintiffs' failure to specify exactly when, in relation to the data breaches, fraudsters first

misused their data. The Supreme Court has explained that '[a]t the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we presume that general allegations embrace those specific facts that are necessary to support the claim.'" citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992)).

As the Secretary has failed to provide any contrary evidence, Mr. Brundage's well-pled, plausible allegations stand, and his claim is ripe for adjudication.

7. There is no requirement that Mr. Brundage plead the "basic thresholds to obtain compensation in the VICP" in this action, however, Mr. Brundage could certainly do so.

The Secretary appears to suggest that Mr. Brundage needs to plead his VICP claim in the instant matter. Doc. 9, Page 18. Mr. Brundage disagrees that there is any such requirement to survive a motion to dismiss here. Mr. Brundage can certainly plead the necessary requirements of a VICP claim: that he received the vaccine within 8 years of inclusion of coverage of the vaccine by the VICP, that he received the vaccine in the United States, that his vaccine receipt was the cause in fact of his injury, and that his injuries have lasted more than 6 months. 42 U.S.C. § 300aa–11. However, there is no requirement that he do so.

8. The Secretary's argument that the Mandamus Act count must be dismissed as the CICP provides an adequate alternative remedy is sadly misguided.

In the second count of his complaint, Mr. Brundage moved in the alternative for this Court to grant relief under the Mandamus Act if it found that it could not so under the Vaccine Act. The Secretary in his motion claimed that the count must be

dismissed as the Countermeasures Injury Compensation Program (CICP) provides Mr. Brundage an adequate alternative remedy. Doc. 9, Pages 22-23.

The CICP is far from an adequate alternative remedy – it provides no due process – and is therefore no remedy at all. Who of the Secretary's employees decides CICP claims is secret, the criteria they employee is unknown, there is no record, no opportunity to present evidence or witnesses, no ability to dispute evidence or cross-examine witness, and no appeal of an adverse decision to any court. 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.

The outcome for COVID vaccine injury claims filed in the CICP is telling. According to data from the CICP itself, as of May 1, 2025, 13,794 COVID adverse reaction claims have been filed with the CICP. *See*, https://www.hrsa.gov/cicp/cicp-data (Last visited 5/19/2025). Of those claims, 34 have been compensated. *Id*. With the exception of two significantly higher awards, the average amount awarded by the Secretary's employees is approximately four thousand dollars. *Id*. This is despite the fact that compensable claims under the CICP are limited by statute to serious physical injury or death. 42 U.S.C.A. § 247d-6e ("The term 'covered injury' means serious physical injury or death.")

Furthermore, the PREP Act which establishes 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 under title XXI of this Act." 42 U.S.C. § 247d-6d(h). Therefore, the Secretary's attempted use of CICP to bar access to the VICP flies in the face of the explicit limitation of the PREP Act.

9. If the Court were to conclude that it could not otherwise grant the requested relief, Mr. Brundage would be entitled to relief under the Mandamus Act.

To show entitlement to mandamus, a petitioner "must demonstrate (1) a clear and indisputable right to relief, (2) that the government agency or official is violating a clear duty to act, and (3) that no adequate alternative remedy exists." *Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 189 (D.C. Cir. 2016) (citation omitted).

Assuming the Court is unable to grant the relief sought by Mr. Brundage in Count 1, he meets all three requirements. As a person who has suffered a serious injury to his health caused by an adverse reaction to a COVID vaccine, Mr. Brundage has a legal interest, established by the Vaccine Act, to be able to file a claim under the VICP to recover for his injury. The Secretary has violated the Secretary's non-discretionary statutory duty to timely add the COVID vaccine to the Vaccine Injury Table as required by the Vaccine Act. There is no adequate alternative for Mr. Brundage to be able to remedy the harm that he has suffered.

The Secretary in his motion claims that Mr. Brundage was required to plead exactly when and how the CDC recommended the COVID vaccine for routine administration to children to be eligible for mandamus. Doc 9, Page 22. As

discussed above, Mr. Brundage has adequately pled that the Secretary failed to timely add the COVID vaccine to the Vaccine Injury Table and his failure is ongoing. The Secretary has provided no contravening evidence or even denied the accuracy of the allegation. As a result, the Secretary's argument fails and the Mandamus Act count should remain available to the Court as an alternative means of relief.

10. Plaintiff has established that this Court has jurisdiction over this matter, so Defendant's motion to dismiss Count III on the basis of lack of subject matter jurisdiction fails.

The Secretary claims that "the Court lacks subject matter jurisdiction to grant Plaintiff relief under the All Writs Act." Doc 9, Page 24. As discussed above, the Secretary's challenges under 12(b)(1) and 12(b)(6) lack merit. This Court has jurisdiction over this action pursuant to 42 U.S.C.A. § 300aa-31(a), 28 U.S.C.A. § 1331, and 28 U.S.C.A. §2201. In the event the Court concludes that it cannot grant relief under the first or second counts, because there is jurisdiction over Mr. Brundage's claim, this Court is empowered by the All Writs Act to provide the requested remedy once it concludes Mr. Brundage is entitled to his requested relief.

CONCLUSION

This Court should deny the Secretary's motion to dismiss. Mr. Brundage meets the requirements of standing because he has suffered a concrete and particularized injury to his legally protected interest under the Vaccine Act, his injury is "fairly traceable" to the failure of the Secretary to timely include the COVID vaccine on the Vaccine Injury Table. Mr. Brundage's claim is ripe for adjudication because the enactment of the 75-cent excise tax is NOT a prerequisite

for inclusion of the COVID vaccine in the Vaccine Injury Table. Under the Vaccine Act's citizen suit provision, this Court can and should compel the Secretary to comply with the plain language of the Act, which requires the Secretary to include the COVID vaccine in the Vaccine Injury Table. In the alternative, this Court can grant relief under the Mandamus Act or All Writs Act because the Secretary has violated his non-discretionary duty to include the COVID vaccine in the Vaccine Injury Table.

If this Court finds any pleading requirements of the initial complaint deficient, Mr. Brundage seeks leave to amend to address any such deficiency through amendment of his complaint.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this 19th day of May, 2025, 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/ Grace Keenan
Grace Keenan, Paralegal
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