IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PAUL BRUNDAGE, Plaintiff, v. ROBERT F. KENNEDY, JR., Secretary, United States Department of Health and Human Services, Defendant.	)	Case No. 1:25-cv-00119-SLS

DEFENDANT'S MOTION TO DISMISS

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), Defendant Robert F. Kennedy, Jr., Secretary, United States Department of Health and Human Services, respectfully requests that the Court dismiss the Complaint filed in this matter. As shown in the accompanying memorandum of law, the relief requested in each of the three counts of the Complaint should be denied. The Court lacks the subject matter jurisdiction necessary to grant the relief Plaintiff requests in Count I under the Vaccine Act or Count III under the All Writs Act. Plaintiff does not have standing to assert his claim for an order directed against the Secretary, nor is that claim ripe for adjudication. Plaintiff's request in Count II should be denied because Plaintiff fails to meet the extraordinary standard for relief under the Mandamus Act.

A proposed order is attached.

Respectfully submitted,

May 5, 2025

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CERTIFICATE OF SERVICE

I hereby certify that I have this May 5, 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/ Glenn S. Greene /s/
Senior Trial Attorney

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DEFENDANT'S MEMORANDUM OF LAW
IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

The National Childhood Vaccine Injury Act of 1986 (the "Vaccine Act"), Pub. L. No. 99–660, 100 Stat. 3755, 1986 U.S.C.C.A.N. (codified as amended at 42 U.S.C. §§ 300aa–1 to –34 (1994)), established the National Vaccine Injury Compensation Program to ensure an adequate supply of vaccines and stabilize vaccine costs. To accomplish these goals, the Vaccine Act created an accessible and efficient forum for individuals found to be injured by covered vaccines to be compensated and provided liability protections for manufacturers and administrators of those vaccines.

In his Complaint, Plaintiff Paul Brundage alleges that he is unable to pursue compensation for an injury he incurred after receiving a COVID-19 vaccine. As a remedy, Plaintiff asks the Court to compel the Secretary of the Department of Health and Human Services to ignore a statutory requirement, bypass a process that has been in place for decades, and ignore the Secretary's role in setting agency policy. Furthermore, Plaintiff overlooks the fact that an alternative forum exists for those who claim to be injured by COVID-19 vaccines.

Plaintiff alleges that he is unable to pursue compensation for his injury because the Secretary has failed to timely comply with a statutorily imposed duty to add the COVID-19 vaccine to the list of vaccines for which injuries are compensable under the Vaccine Act. Complaint ("Compl.") ¶¶ 1-3. He alleges that this step is necessary before Congress can impose an excise tax on COVID-19 vaccines, a requirement for eligibility to pursue a claim under the Vaccine Act. Compl. ¶ 6. In Count I of the Complaint, Plaintiff seeks an order under the Vaccine Act compelling the Secretary to add the COVID-19 vaccine to the list of vaccines covered by the Act. *Id.* ¶¶ 21-24. In Count II, Plaintiff pleads in the alternative that to the extent the Vaccine Act does not fully allow the remedy he requests, the Mandamus

Act, *see* 28 U.S.C. § 1361, provides the Court with jurisdiction to order the Secretary to fulfill his obligations. Compl. ¶¶ 25-29. In Count III, Plaintiff pleads in the alternative that to the extent Counts I and II do not fully allow the remedy he requests, Plaintiff is entitled to an order under the All Writs Act, *see* 28 U.S.C. § 1651, requiring the Secretary to comply with the Vaccine Act. Compl. ¶¶ 30-33.

As shown below, the relief requested in each of the three counts should be denied. The Court lacks the subject matter jurisdiction necessary to grant the relief Plaintiff requests in Count I under the Vaccine Act or Count III under the All Writs Act. Plaintiff does not have standing to assert his claim for an order directed against the Secretary, nor is that claim ripe for adjudication. Plaintiff's request in Count II should be denied because Plaintiff fails to meet the extraordinary standard for relief under the Mandamus Act.

BACKGROUND

The Vaccine Act

The National Childhood Vaccine Injury Act of 1986 established a program administered by the Secretary of the Department of Health and Human Services ("HHS") to increase the safety and availability of vaccines. *See* 42 U.S.C. § 300aa–1. As part of this program, Congress established a Vaccine Injury Compensation Program (the "VICP") through which petitioners could petition the Court of Federal Claims to receive compensation for vaccine-related injuries or death for certain vaccines covered under the VICP. *See id.* §§ 300aa–10(a) and 300aa-11(a), (c)(1)(A). Covered vaccines are subject to an excise tax that provides funds to compensate successful petitioners. *See id.* § 300aa-15(i)(2); 42 C.F.R. § 100.3(e)(8). The Vaccine Act sets forth the initial Vaccine Injury Table, *see id.* 42 U.S.C. § 300aa-14(a), which lists the vaccines and vaccine-related injuries for which compensation was available at the inception of the VICP. For each vaccine, the Table

identifies the parameters of coverage – the "[i]llness, disability, injury, or condition covered," and the "[t]ime period for first symptom or manifestation of onset or of significant aggravation after vaccine administration." *Id.* The Vaccine Act also provides the process for the Secretary to amend the Vaccine Injury Table to add vaccines and vaccine-related injuries for which compensation is available. *Id.* § 300aa-14(e). Coverage under the VICP also affords vaccine manufacturers and administrators liability protections. *See, e.g.*, 42 U.S.C. §§ 300aa–11(a), 300aa-21, and 300aa-22.

The initial Vaccine Injury Table was provided by Congress. *See* 42 U.S.C. § 300aa-14(a). The Vaccine Act provides that after August 1, 1993, whenever the Centers for Disease Control and Prevention (the "CDC") 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 to include—

> (A) vaccines which were recommended for routine administration to children,
>
> (B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and
>
> (C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

Id. § 300aa-14(e)(2). The Vaccine Act includes a similar process for amending the Vaccine Injury Table whenever the CDC recommends a vaccine to the Secretary for routine administration to pregnant women. *Id.* § 300aa-14(e)(3).

Over the years, new categories of vaccines have been added to the Vaccine Injury Table, which can be found at 42 C.F.R. § 100.3(a). Even before the Secretary conducts rulemaking to create a new category of vaccines on the Table, vaccines that meet the requirements discussed above are covered under Item XVII once the Secretary publishes a

notice of coverage. This notice informs the public of the date of coverage for the specified category of vaccines and "the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines." 42 C.F.R. § 100.3(e)(8); *see Baptiste v. Sec'y of Health & Hum. Servs.*, No. 22-1065V, 2022 WL 6988542, at *1 (Fed. Cl. Sept. 7, 2022). The effective date of the tax is the date a vaccine becomes the basis for a claim in the VICP. 42 C.F.R. § 100.3(e)(8); *see* Omnibus Budget Reconciliation Act of 1993, Pub. L. 103–66, § 13632(a)(3), 107 Stat 312, 646 (1993) (codified as amended at 42 U.S.C. § 300aa–14 note (Revisions of Vaccine Injury Table)) (stating that a revision to the Vaccine Injury Table under § 300aa-14(e) "shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table . . ."). Thus, the two prerequisites for a decision by the Secretary of HHS to add a vaccine to the VICP as a covered vaccine and to the Vaccine Injury Table are the CDC recommendation for routine administration to children and/or to pregnant women and the enactment of an excise tax to provide funds for compensation.

Pursuant to regulation, "[a]n amendment to [42 U.S.C. § 100.3] will be published in the Federal Register to announce the effective date of [the excise] tax." 42 C.F.R. § 100.3(e)(8). Categories VII through XVI of the Vaccine Injury Table contain vaccines that have been added to the initial Table, and section (e) specifies the effective dates of their inclusion. *See* 42 C.F.R. § 100.3(a) and (e)(2)-(7). Category XVII covers "Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children and/or pregnant women, after publication by the Secretary of a notice of coverage." *Id.* § 100.3(a).

After a notice is published that a vaccine is covered under Category XVII, the Secretary generally engages in rulemaking to add the new category of vaccines as a separate

category on the Table. For example, on April 12, 2005, the Health Resources and Services Administration published a notice in the Federal Register announcing that trivalent influenza vaccines were covered under the category for new vaccines on the Table. *See* National Vaccine Injury Compensation Program: Addition of Trivalent Influenza Vaccines to the Vaccine Injury Table, 70 Fed. Reg. 19092 (Apr. 12, 2005). The notice specifically states that both prerequisites for adding the trivalent influenza vaccine to the Table were satisfied: the CDC set forth its recommendation, and an excise tax was enacted. *Id.* The notice enabled petitioners to file petitions relating to trivalent influenza vaccines with the VICP even before such vaccines were added as a separate and distinct category to the Table through rulemaking. *Id.* Subsequently, the Secretary engaged in rulemaking to add trivalent influenza vaccines as a separate category on the Table. *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 75 Fed. Reg. 55503 (Sept. 13, 2010) (notice of proposed rule to change Vaccine Injury Table to create separate category for trivalent influenza and other vaccinations); National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 76 Fed. Reg. 36367 (June 22, 2011) (final rule listing trivalent influenza and other vaccinations on Vaccine Injury Table).

The Countermeasures Injury Compensation Program (CICP)

In 2005, Congress enacted the Public Readiness and Emergency Preparedness ("PREP") Act, Pub. L. No. 109-148, 119 Stat. 2680, 2818 (2005) (codified at 42 U.S.C. §§ 247d-6d, 247d-6e), to encourage the development and deployment of medical countermeasures in response to or in anticipation of public health emergencies. 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 HHS issues a PREP Act 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).

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); *see also* 42 C.F.R. §110.10(a). HHS promulgated regulations establishing and governing the CICP. *See* 42 C.F.R. Part 110. Claims generally must be filed within one year of administration or use of the covered countermeasure. 42 U.S.C. § 247d-6e(b)(4) (incorporating procedural provisions from 42 U.S.C. § 239a); id. § 239a(d); *see also* 42 C.F.R. § 110.42(a). 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 enables a requester who previously could not establish a Table injury to 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)).

On March 17, 2020, the Secretary issued a PREP Act declaration, effective on February 4, 2020, relating to COVID-19. *See* Department of Health and Human Services, Declaration Under the Public Readiness and Emergency Preparedness Act for Medical

Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (Mar. 17, 2020). COVID-19 vaccines are covered under the declaration and, as a result, individuals alleging injury from a COVID-19 vaccine may submit a claim for compensation to the CICP. *Id.* at 15,202, 15, 203.

Plaintiff's Complaint

Plaintiff alleges that he suffered an adverse reaction to a COVID-19 vaccination that left him with a severe blood clotting disorder. Compl. ¶ 1. Plaintiff alleges that he should now be eligible to bring a claim under the VICP for compensation for his vaccine-related injury but is unable to do so because the Secretary has yet to add the COVID-19 vaccine to the Vaccine Injury Table. *Id.* ¶ 3. According to Plaintiff, "significantly more" than two years has passed since the CDC recommended the COVID-19 vaccine for routine administration to children. *Id.* ¶ 14. Plaintiff sues to compel the Secretary to add the COVID-19 vaccine to the Vaccine Injury Table, which Plaintiff contends will allow Congress to impose the statutory tax on COVID-19 vaccines that will allow him to seek compensation through the VICP. Plaintiff alleges that he has given the Secretary the sixty (60) days' notice of his intention to bring this action that is required by the Vaccine Act. *Id.* ¶¶ 17-18; 42 U.S.C. § 300aa-31(b).

LEGAL STANDARDS

A motion under Rule 12(b)(1) "'presents a threshold challenge to a court's jurisdiction.'" *Ctr. for Biological Diversity v. Jackson*, 815 F. Supp. 2d 85, 89 (D.D.C. 2011) (quoting *Haase v. Sessions*, 835 F.2d 902, 906 (D.C. Cir. 1987)). The plaintiff "bears the burden of proving by a preponderance of the evidence that the Court has subject-matter jurisdiction over her claims." *Schmidt v. U.S. Capitol Police Bd.*, 826 F. Supp. 2d 59, 69 (D.D.C. 2011) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992)). When reviewing a challenge

under Rule 12(b)(1), "the court may consider documents outside the pleadings to assure itself that it has jurisdiction." *Sandoval v. U.S. Dep't of Just.*, 322 F. Supp. 3d 101, 104 (D.D.C. 2018) (Cooper, J.).

A complaint survives a motion under Rule 12(b)(6) only if it contains "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A complaint is plausible on its face "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). A complaint alleging facts which are "merely consistent with" a defendant's liability "stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (citing *Twombly,* 550 U.S. at 557 (internal quotation marks omitted).

ARGUMENT

I. Count I Asserted Under The Vaccine Act Fails For Lack Of Subject Matter Jurisdiction

A. Plaintiff lacks standing to bring his claim

Article III of the Constitution limits the "'judicial power' of the United States to the resolution of 'cases' and 'controversies.'" *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982). As part of this requirement, the party invoking the court's jurisdiction must have "standing" to challenge the action sought to be adjudicated in the lawsuit. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992); *Grocery Mfrs. Ass'n v. E.P.A.*, 693 F.3d 169, 174 (D.C. Cir. 2012) ("Standing under Article III is jurisdictional. If no petitioner has Article III standing, then this court has no jurisdiction to consider these petitions."). At a minimum, standing requires that the party invoking the court's authority "show [1] that he personally has suffered some actual and threatened injury as a result of the putatively illegal conduct of the defendant," . . . and [2] that the injury

"fairly can be traced to the challenged action" and [3] "is likely to be redressed by a favorable decision." *Valley Forge Christian Coll.*, 454 U.S. at 472 (internal citations omitted). The alleged injury in fact must be concrete and particularized and actual or imminent, not conjectural, hypothetical or speculative. *LPA Inc. v. Chao*, 211 F. Supp. 2d 160, 163 (D.D.C. 2002) (citing *Lujan*, 504 U.S. at 560–61; *Sierra Club v. EPA*, 292 F.3d 895, 898 (D.C. Cir. 2002); *Am. Petroleum Inst. v. EPA*, 216 F.3d 50, 63 (D.C. Cir. 2000)). If a plaintiff cannot meet all three prongs of this test, then the Court must dismiss the suit for lack of standing. *Id.* Standing must exist at the time litigation commences. *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000).

Plaintiff invokes a provision of the Vaccine Act that permits any person to "commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under th[e] [Act]," Compl ¶ 19 (citing 42 U.S.C. § 300aa-31(a)). However, a "citizen suit" provision such as the one invoked here "does not confer standing; it confers a right to sue upon parties who otherwise already have standing." *Common Cause v. FEC,* 108 F.3d 413, 419 (D.C. Cir. 1997). Thus, while the citizen suit provision of the Vaccine Act authorizes suits against the government for violations of the Vaccine Act, it does not dispense with the requirement that Plaintiff must demonstrate that he has standing to bring this action in federal court. *Coal. for Mercury-Free Drugs v. Sebelius*, 725 F. Supp. 2d 1, 8 (D.D.C. 2010) (citizen suit provision of Vaccine Act does not confer standing in the absence of satisfying the traditional standing requirements). Plaintiff's Complaint fails to establish that he has standing to bring the claim he asserts because he has not shown it is likely that his injury will be redressed by the relief he seeks.

The injury asserted in Plaintiff's Complaint is the present inability to pursue compensation under the VICP for the adverse reaction Plaintiff allegedly suffered after a COVID-19 vaccination. Compl. ¶¶ 1-3. Plaintiff attributes his inability to pursue a VICP claim to the failure of the Secretary to add the COVID-19 vaccine to the Vaccine Injury Table. Compl. ¶ 3. However, 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. A revision to the Table under § 300aa-14(e) does not take effect – *i.e.*, entitle a petitioner to pursue compensation for an alleged injury – until the effective date of that tax. 42 C.F.R. § 100.3(e)(8); Omnibus Budget Reconciliation Act of 1993, 107 Stat 312, 646 (stating that a revision to the Vaccine Injury Table under § 300aa-14(e) "shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table . . ."). That tax has not been enacted. Compl. ¶ 6. The power to raise revenue through taxes lies with Congress. *See* U.S. Const. Art. I, § 8 ("The Congress shall have Power To lay and collect Taxes"). It does not lie with the Secretary or the Court.

Plaintiff is incorrect that adding COVID-19 vaccines to the Table must occur before Congress can enact the corresponding excise tax; generally, the excise tax precedes including a new category of vaccines on the Table. Issuance of a notice of coverage (or amendments to the Table) generally follows both the CDC routine use recommendation *and* passage of the excise tax in large part to avoid confusion about whether particular categories of vaccine are actually covered under the Vaccine Act (affording vaccine manufacturers and administrators its liability protections and petitioners the ability to pursue compensation in the VICP). *See* National Vaccine Injury Compensation Program: Addition of Trivalent

Influenza Vaccines to the Vaccine Injury Table, 70 Fed. Reg. 19092 (Apr. 12, 2005) (notice of coverage for trivalent influenza vaccine issued following satisfaction of both prerequisites – CDC recommendation and excise tax enactment – for adding the vaccine to the Table). *Id.* This is important given that numerous provisions of the Vaccine Act (originally enacted before the statutory requirement for a corresponding excise tax) make clear that vaccines listed on the Table equate to vaccines covered under the Vaccine Act for both compensation and liability purposes. First, VICP eligibility depends upon receiving a vaccine listed on the Table. *See, e.g.*, 42 U.S.C. § 300aa-33(5) (defining "vaccine-related injury or death" in relation only to "one or more of the vaccines set forth in the Vaccine Injury Table"); 42 U.S.C. § 300aa-11(c)(1)(B)(i) (in order to have a vaccine-related injury or death eligible for compensation in the VICP, evidence must demonstrate that the injured/deceased person "received a vaccine set forth in the Vaccine Injury Table" (absent unusual circumstances involving contacts from the oral polio vaccine)). Further, the Vaccine Act's liability protections are available only for vaccines set forth in the Vaccine Injury Table. *See, e.g.*, 42 U.S.C. § 300aa-11(a)(2)(A) (prohibiting virtually all civil actions against vaccine administrators and manufacturers in state or federal courts for damages arising from *a vaccine-related injury or* death [defined in 42 U.S.C. § 300aa-33(5)] without first filing a VICP petition).

And even if Congress had already enacted a tax to provide compensation for the COVID-19 vaccination, and it is assumed all other requirements were met, it is not even clear from the Complaint that Plaintiff has established the basic thresholds to obtain compensation in the VICP. *See* 42 U.S.C. § 300aa–11(c)(1)(C)-(D)

Given this collection of prerequisites for Plaintiff's putative COVID-19 vaccine claim, it is not clear on the face of the Complaint that Plaintiff's present inability to bring a claim under the VICP is likely to be redressed by a favorable decision in this matter. *Valley*

Forge Christian Coll., 454 U.S. at 471. As a threshold matter, the requisite implementation of a tax to fund compensation for injuries related to the vaccine is not within the Secretary's (or the Court's) control. Plaintiff does not allege or suggest otherwise. Even if the enactment of a tax is assumed and COVID-19 vaccines were to become covered, Plaintiff offers no evidence to establish that his alleged injury would meet the requirements to satisfy a potential Table or non-Table claim.

Thus, at this point, Plaintiff can only speculate – as opposed to establish it is likely – that the relief he seeks will redress his injury. This is insufficient to establish Plaintiff's standing for the relief he seeks under the Vaccine Act.

B. Plaintiff's claim is not ripe for adjudication

Jurisdiction requires that a claim be ripe for decision. *Colorado Wild Horse & Burro Coal., Inc. v. Salazar*, 890 F. Supp. 2d 99, 102 (D.D.C. 2012). *See Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003) ("The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." (internal quotation marks and citations omitted)). Ripeness depends on "[1] the fitness of the issues for judicial decision and [2] the hardship to the parties of withholding court consideration." *Sheet Metal Workers Int'l Ass'n, Loc. 270, AFL-CIO v. N.L.R.B.*, 561 F.3d 497, 501 (D.C. Cir. 2009) (citing *Fed. Express Corp. v. Mineta*, 373 F.3d 112, 118 (D.C. Cir. 2004) (quoting *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 149 (1967))). When a court reviews claims for ripeness, such review is conducted based on the facts that existed at the time the complaint was filed. *Ctr. for Sci. in Pub. Int. v. Food & Drug Admin.*, No. CIV.A. 03-1962 (RBW), 2004 WL 2218658, at *3 (D.D.C. Sept. 17, 2004) (citations omitted).

Count I is premised upon the assertion that there is a "clear statutory requirement," Compl. ¶ 24, that the Secretary amend the Vaccine Injury Table to include the COVID-19

vaccine because more than two years have passed since the CDC recommended that the COVID-19 vaccine be administered to children on a routine basis. However, Plaintiff's complaint does not identify the date on which he alleges the CDC recommended that the COVID-19 vaccine be administered to children on a routine basis; nor does he identify the vehicle through which this recommendation was made. *See* Compl. ¶ 14. Thus, no facts have been pled to establish that at the time Plaintiff filed the complaint in this matter more than two years had passed since the CDC recommended that the COVID-19 vaccine be administered to children on a routine basis. In the absence of such facts, Plaintiff has not met his burden of proving subject matter jurisdiction because he has not established that his claim is ripe for adjudication.

Moreover, a claim is not ripe for adjudication if it "rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotation marks and citation omitted). As shown above, a prerequisite for adding the COVID-19 vaccine to the VICP and to the Vaccine Injury Table is the enactment of an excise tax by Congress. 42 C.F.R. § 100.3(e)(8); *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) ("[V]accines recommended by the CDC can be effectively added to the Table only if Congress, by separate legislation, enacts a separate excise tax on that vaccine to pay for compensation from the vaccine program."). The effective date of the tax enacted is the date a vaccine is covered for purposes of filing a claim in the VICP. 42 C.F.R. § 100.3(e)(8). Even if the Court was to order the Secretary to add the COVID-19 vaccine to the Vaccine Injury Table, Plaintiff would not be able to pursue a claim under the VICP because no corresponding excise tax has been enacted. *See, e.g.*, National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table—II, 62 Fed.

Reg. 7685, 7686 (Feb. 20, 1997) ("The tax for the hepatitis B, the Hib and the varicella vaccines has not been enacted yet; accordingly, claimants alleging an injury or death as a result of a hepatitis B, Hib, or varicella vaccination will not have a cause of action against the Secretary until the tax is enacted and become effective . . . As soon as the tax becomes effective, a petitioner may file a claim for an injury or death allegedly caused by these vaccines."). And even if the tax had been enacted and a notice of coverage published, Plaintiff's ability to pursue compensation under the VICP for his alleged injury would still be contingent on numerous other factors. *See* 42 U.S.C. § 300aa–11(c)(1)(C)-(D). Because the future actions necessary for Plaintiff to pursue a claim under the VICP for a COVID-19 vaccination "may not occur as anticipated, or indeed may not occur at all," Plaintiff's request is not ripe for adjudication under the Vaccine Act. *Texas*, 523 U.S. at 300.

II. Count II Fails To State A Claim For Relief Under the Mandamus Act

In Count II of the Complaint, Plaintiff pleads in the alternative that to the extent the Vaccine Act does not fully allow the remedy he requests, the Mandamus Act, *see* 28 U.S.C. § 1361, provides the Court with jurisdiction to order the Secretary to fulfill his obligations. Compl. ¶¶ 25-29. Mandamus relief should be denied here because Plaintiff has not met the requirements for such relief.

"[T]he remedy of mandamus is a drastic one, to be invoked only in extraordinary situations." *Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 34 (1980). Thus, it has long been settled that the Mandamus Act is a law of last resort, available "only if [the plaintiff] has exhausted all other avenues of relief and only if the defendant owes him a clear nondiscretionary duty." *Yee v. Jewell*, 228 F. Supp. 3d 48, 53 (D.D.C. 2017) (quoting *Heckler v. Ringer*, 466 U.S. 602, 616 (1984)). 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). "These three threshold requirements are jurisdictional; unless all are met, a court must dismiss the case for lack of jurisdiction." *Id.* (citation omitted). None of the three requirements for mandamus relief are met here.

Plaintiff's request rests upon the assertion that the Secretary's duty to amend the Vaccine Injury Table has been triggered because more than two years have passed since the CDC recommended that the COVID-19 vaccine be administered to children on a routine basis. Compl. ¶ 14. However, Plaintiff has pled no facts identifying the date on which this recommendation was made or the vehicle through which it was made. Thus, it is not clear on the face of the Complaint that 1) Plaintiff currently has an indisputable right to relief, or 2) a government official is currently violating a clear duty to act.

In addition, Congress and the Secretary have provided an adequate alternative remedy for COVID-19 vaccine injuries. In March 2020, the Secretary issued a declaration regarding the COVID-19 pandemic under the PREP Act. *See* Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 15201 (Mar. 17, 2020). A PREP Act declaration identifies certain countermeasures as "covered countermeasures," and under the PREP Act, "covered countermeasure" includes (1) a "biological product . . . that is authorized for emergency use," and (2) a "qualified, pandemic or epidemic product," including a "biological product . . . licensed . . . to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic." 42 U.S.C. §§ 247d-6d(i)(1)(A), (1)(C), (7)(A). The March 2020 PREP Act Declaration specifically identified "covered countermeasures" to include any "vaccine[] used to treat, diagnose, cure, prevent, or mitigate COVID-19." Declaration Under the Public Readiness

and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,202 (Mar. 17, 2020). Pursuant to this declaration, claims for alleged injuries from COVID-19 Covered Countermeasures may be compensable under the CICP. *See id.* at 15,203. The CICP is authorized to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of a Covered Countermeasure, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. *Id.* at 15,203. And the CICP has paid claims related to injuries from COVID-19 vaccines. *See Countermeasures Injury Compensation Program (CICP) Data*, Health Res. & Servs. Admin., https://www.hrsa.gov/cicp/cicp-data.

Thus, the CICP is an alternative, available remedy for pursuing compensation for injuries Plaintiff allegedly suffered because of receiving a COVID-19 vaccination.

III. Count III Asserted Under The All Writs Act Fails For Lack Of Subject Matter Jurisdiction

In Count III, Plaintiff pleads in the alternative that to the extent Counts I and II do not provide the relief he requests, Plaintiff is entitled to an order under the All Writs Act, 28 U.S.C. §1651, requiring the Secretary to comply with the Vaccine Act. Compl. ¶ 33. Plaintiff is incorrect.

The All Writs Act provides that federal courts "may issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law." 28 U.S.C. § 1651(a). By its terms, the authority to issue writs is confined to the issuance of process "in aid of" jurisdiction which is created by some other source and not otherwise enlarged by the Act. *In re Tennant,* 359 F.3d 523, 527 (D.C. Cir. 2004). The All Writs Act "is not itself a grant of jurisdiction." *Id.*

Plaintiff has no independent source of subject matter jurisdiction for a claim asserted under the All Writs Act. As shown above, Plaintiff lacks standing for the relief he requests, and his request is not ripe for adjudication. For these reasons, the Court lacks subject matter jurisdiction to grant Plaintiff relief under the All Writs Act.

CONCLUSION

For the reasons stated above, Plaintiff's claims should be dismissed.

Respectfully submitted,

May 5, 2025

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CERTIFICATE OF SERVICE

I hereby certify that I have this May 5, 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/ Glenn S. Greene /s/
Senior Trial Attorney