

UNITED STATES DISTRICT COURT
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.

DEFENDANT ROBERT F. KENNEDY, JR.'S MOTION TO DISMISS

Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services, through the undersigned counsel and under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), moves to dismiss the Complaint and submits the following:

SYNOPSIS

The National Childhood Vaccine Injury Act of 1986 (the Vaccine Act), Pub. L. No. 99-660, 100 Stat. 3755, (codified as amended at 42 U.S.C. §§ 300aa-1 to -34 (1994)), established the National Vaccine Injury Compensation Program (the VICP) to ensure an adequate supply of vaccines and to 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. Through the VICP, individuals may petition the Court of Federal Claims to receive compensation

for vaccine-related injuries or death from specific vaccines. *See id.* §§ 300aa–10(a) and 300aa-11(a), (c)(1)(A). Not all vaccines and vaccine-related injuries are compensable and individuals cannot pursue claims regarding a new vaccine unless and until an excise tax is passed by Congress to establish compensatory funding for the new vaccine. The list of covered vaccines appears on the Vaccine Injury Table. Congress has not passed an excise tax for COVID-19 vaccines.

In her Complaint, Plaintiff Jeanne Materese alleges that she is unable to preserve a right to seek compensation for an injury she attributes to a COVID-19 vaccine. She asserts that an alleged failure by the Secretary of Health and Human Services (the Secretary) to timely comply with a statutorily imposed duty to add the COVID-19 vaccine to the Vaccine Injury Table is the reason she cannot seek compensation. Compl. ¶¶ 19-20, 22-23, 25, 27. She believes that this step is required before Congress can pass the requisite excise tax and that it will serve as notification for Congress to take action. *Id.* ¶¶ 25-26. She also believes that secretarial action at this juncture would preserve her access to a remedy that *may* come into effect *if* Congress enacts the requisite excise tax. *Id.* ¶¶ 9, 24, 26-27.

Plaintiff asks the Court to compel the Secretary to bypass the rulemaking process and add COVID-19 vaccines to the Vaccine Injury Table. She also seeks a declaration that misstates the statutory structure and the relationship between Congress and the Secretary regarding coverage of new vaccines. Furthermore, her requests overlook the fact that an alternative forum exists for individuals like herself who attribute injuries to COVID-19 vaccines.

As shown below, the Complaint should be dismissed. The Court lacks subject matter jurisdiction over the Complaint in its entirety because Plaintiff lacks standing to bring her claims: her alleged injury in fact is speculative and her claims are not redressable because they depend on the actions of non-parties. Indeed, another district court recently dismissed a similar lawsuit based on lack of standing. *See Brundage v. Kennedy*, Civil Action No. 25 - 119 (SLS), 2025 U.S. Dist. LEXIS 191813 (D.D.C. Sept. 29, 2025), *appeal docketed* (D.C. Cir. Jan. 12, 2026). As discussed below, *Brundage's* reasoning applies here. In addition, The Court lacks subject matter jurisdiction over Count IV because Plaintiff fails to meet the extraordinary standard for relief under the Mandamus Act. Count V should be dismissed because it requires the presence of a separate jurisdictional tether that does not exist.

BACKGROUND

A. Plaintiff's Alleged Injury

Plaintiff alleges that on an unspecified date prior to August 2021 she received a vaccination against COVID-19. Compl. ¶ 1. She also claims that on an unspecified date prior to 2021, the Centers for Disease Control and Prevention recommended COVID-19 vaccines for routine administration to children. *Id.* ¶ 22. Plaintiff attributes an alleged “severe platelet formation and blood clotting disorder,” that she states manifested in August 2021, to the COVID-19 vaccine that she received. *Id.* ¶ 1.

Plaintiff alleges that the Secretary is derelict in his duty under the Vaccine Act to add COVID-19 vaccines to the Vaccine Injury Table, which identifies the vaccines covered by the VICP. Compl. ¶¶ 19, 22-24. In an effort to seek compensation for her

alleged injury, she requests an order compelling the Secretary to add COVID-19 vaccines to the Vaccine Injury Table and also declaratory relief renouncing this alleged failure. *Id.* ¶¶ 10, 31, 55. Plaintiff believes the demanded revision to the Vaccine Injury Table will allow her to file a claim for harm attributable to any COVID-19 vaccine she received in the eight years immediately preceding the revision. *Id.* ¶¶ 20-21. By filing that claim, her logic goes, she will preserve access to a remedy that *may* come into effect *if* Congress enacts an excise tax to fund COVID-19 related vaccine claims. *Id.* ¶¶ 7, 20-21. She also claims that the alleged secretarial inaction means that Congress has not received a notification that would trigger it to consider passing the required excise tax. *Id.* ¶¶ 8, 25-26.

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 Vaccine Injury Table. *Id.* ¶¶ 32-37. In Count II, Plaintiff invokes the Administrative Procedure Act, 5 U.S.C. §§ 701-706, to seek the same relief. Compl. ¶¶ 38-44. In Count III, Plaintiff demands a declaration under the Declaratory Judgment Act, 28 U.S.C. § 2201, that misstates the statutory structure and the relationship between Congress and the Secretary regarding coverage of new vaccines. Compl. ¶¶ 45-55. In Count IV, Plaintiff pleads in the alternative that to the extent the Vaccine Act does not fully allow the remedy she requests, the Mandamus Act, 28 U.S.C. § 1361, provides the Court with jurisdiction to compel the Secretary to amend the Vaccine Injury Table. Compl. ¶¶ 56-60. Finally, in Count V, Plaintiff pleads in the alternative that to the extent the Vaccine Act does not fully allow the remedy she 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. ¶¶ 61-64.

B. The Vaccine Act

The Vaccine Act established a program to increase the safety and availability of vaccines through a streamlined compensation program. *See* 42 U.S.C. § 300aa–1. As part of this program, Congress established the VICP, through which individuals can petition the Court of Federal Claims to receive compensation for vaccine-related injuries or death from certain covered vaccines. *See id.* §§ 300aa–10(a) and 300aa-11(a), (c)(1)(A).

The Vaccine Act sets forth an initial version of the Vaccine Injury Table, *see id.* § 300aa-14(a), which lists the vaccines and vaccine-related injuries for which compensation was available at the inception of the VICP. The Vaccine Act also provides the process by which the Secretary can amend the Vaccine Injury Table to add vaccines and vaccine-related injuries for which compensation is available. *Id.* § 300aa-14(e). Specifically, 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). For each new vaccine, the Secretary initiates rulemaking to determine the parameters of coverage under VICP, *i.e.* 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.*

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. To that end, Congress established a funding structure for the VICP: the manufacturers, producers, or importers of covered vaccines are subject to an excise tax that provides funds to compensate successful petitioners and cover other program costs. *See id.* § 300aa-15(i)(2); 42 C.F.R. § 100.3(e)(8). The addition of a category of vaccines to the Vaccine Injury Table does not become effective (meaning that the Vaccine Act’s liability protections and VICP compensation is not available) unless and until the effective date of an excise tax enacted by Congress for that category of vaccine (unless Congress specifies an alternative effective date). The effective date of that tax triggers the Vaccine Act’s eight-year look back provision for VICP claims and also allows for claims based on subsequent injuries. *See* 42 C.F.R. § 100.3(e)(8); 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 Section 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 . . .”).

Under this structure, the Vaccine Act imposes two non-sequential requirements that must be met before an individual can seek compensation: a decision by the Secretary to include a vaccine on the Vaccine Injury Table (once the Secretary has determined that the CDC has recommended the vaccine for routine administration to children or to pregnant women) and the enactment of an excise tax to provide funds for compensation. Neither of these steps has occurred for COVID-19 vaccines, which makes them ineligible for the VICP.

HHS regulations and the history of the VICP make clear that Congress can enact an excise tax before the Secretary adds a vaccine to the Vaccine Injury Table and has done so before. Through Category XVII of the Vaccine Injury Table, HHS has ensured that categories of vaccines can be added to the Table quickly and prior to full rulemaking. Category XVII addresses the possibility that an excise tax will be passed after the CDC’s recommendation but before HHS undertakes rulemaking to add a new category of vaccines to the Table. It allows for coverage—meaning that petitioners may file petitions for compensation—once the Secretary publishes a notice of

coverage.¹ That notice informs the public of the date of coverage for the specified category of vaccines, which is “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).

For instance, in 2005, the Health Resources and Services Administration published a notice in the Federal Register announcing coverage of trivalent influenza vaccines under Category XVII. *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 recognized that the precursor for adding the trivalent influenza vaccine to the Vaccine Injury Table was satisfied (the Secretary had accepted CDC’s recommendation) and that Congress had enacted an excise tax. *Id.* The notice enabled individuals 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 Vaccine Injury Table through rulemaking. *Id.*² Similarly, in

¹ Category XVII covers “[a]ny 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.” 42 C.F.R. § 100.3(a). In contrast, Categories VII through XVI of the Vaccine Injury Table contain vaccines that have been added to the initial table with the effective dates of their inclusion. *See* 42 C.F.R. § 100.3(a) and (e)(2)-(7).

² Subsequently, the Secretary engaged in rulemaking to add trivalent influenza vaccines as a separate category on the Vaccine Injury 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).

1999, Congress enacted an excise tax for pneumococcal conjugate vaccines well in advance of a CDC recommendation or action by the Secretary. *See* Ticket to Work and Work Incentives Improvement Act of 1999, Pub. L. No. 106-170, § 523, 113 Stat. 1860, 1927 (1999); National Vaccine Injury Compensation Program: Addition of Pneumococcal Conjugate Vaccines to the Vaccine Injury Table, 66 Fed. Reg. 28166 (May 22, 2001). There is no particular order in which the two prerequisites for coverage under the VICP must be satisfied, but a claim for VICP compensation cannot be filed until Congress fulfils its role through enactment of an excise tax.

C. The Countermeasures Injury Compensation Program.

Although claims regarding COVID-19 vaccine injuries are currently ineligible for the VICP, they are eligible for compensation under a separate program operated by HHS, 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), which 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. *See generally id.* § 247d-6e; 42 C.F.R. § 110.10(a). The PREP Act's provisions come into effect when the Secretary 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). 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 countermeasures. *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 within the limitations period outlined above. *Id.* at 15,202, 15,203.

STANDARDS OF REVIEW

A motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1) may be facial or factual. *McElmurray v. Consol. Gov't of Augusta-Richmond Cty.*, 501 F.3d 1244, 1251 (11th Cir. 2007). In a facial attack, such as this one, the complaint's allegations are presumed true and the court is "required merely to look and see if the

plaintiff has sufficiently alleged a basis of subject matter jurisdiction.” *Stalley ex rel. United States v. Orlando Reg’l Healthcare Sys., Inc.*, 524 F.3d 1229, 1233 (11th Cir. 2008) (citations omitted).

Rule 12(b)(6) allows a complaint to be dismissed for failure to state a claim on which relief can be granted. Consideration of these motions is limited to the well-pleaded allegations, documents central to or referred to in the complaint, and matters judicially noticed. *See La Grasta v. First Union Securities, Inc.*, 358 F.3d 840, 845 (11th Cir. 2004) (internal citations omitted). Factual allegations as generally accepted as true and courts view the facts in a light most favorable to the plaintiff. *See Erickson v. Pardus*, 551 U.S. 89, 93-94 (2007). Legal conclusions, in contrast, “are not entitled to the assumption of truth.” *Ashcroft v. Iqbal*, 556 U.S. 662, 664 (2009). This is particularly so when a complaint includes legal conclusions that are presented as facts. *Davila v. Delta Air Lines, Inc.*, 326 F.3d 1183, 1185 (11th Cir. 2003). To survive a motion to dismiss, a complaint must include sufficient factual matter, accepted as true, to “state a claim to relief that is plausible on its face.” *Iqbal*, 556 U.S. at 678 (internal quotation marks and citations omitted). This plausibility standard is met when the plaintiff pleads enough factual content to allow the court “to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (internal citations omitted).

ARGUMENT

A. Plaintiff Lacks Standing To Bring Her Claims.

Plaintiff lacks standing because her alleged injury is too speculative and because a favorable decision would not redress the purported harm. The jurisdiction of federal

courts is limited to deciding “Cases” or “Controversies.” U.S. Const. art. III, § 2. The doctrine of standing is an expression of this limitation and is “perhaps the most important of the jurisdictional doctrines.” *Muransky v. Godiva Chocolatier, Inc.*, 979 F.3d 917, 924 (11th Cir. 2020) (internal citations omitted). The burden of demonstrating standing rests with the plaintiff. *Murthy v. Missouri*, 603 U.S. 43, 58 (2024). A plaintiff must satisfy three elements to establish standing. See *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). First, she must have “suffered an injury in fact,” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992), which requires a showing “that she has suffered, or will suffer, an injury that is concrete, particularized, and actual or imminent.” *Murthy*, 603 U.S. at 57 (internal citations omitted). Second, she must demonstrate that the injury “is fairly traceable to the challenged conduct of the defendant,” and, third, that it “is likely to be redressed by a favorable judicial decision.” *Spokeo*, 578 U.S. at 338. Plaintiff cannot satisfy either the first or the third elements of standing and her claims must therefore be dismissed.

1. Plaintiff Does Not Have an Injury in Fact Because Her Alleged Harm Is Speculative.

Plaintiff’s alleged injury in fact is too speculative to confer standing because her injury is not certainly impending. When, as is the case here, “a plaintiff seeks prospective relief,” she must “allege facts from which it appears there is a substantial likelihood that [s]he will suffer injury in the future.” *Mack v. USAA Cas. Ins. Co.*, 994 F.3d 1353, 1357 (11th Cir. 2021) (modified for clarity) (internal citations omitted). “To satisfy standing based on a threat of harm, [a plaintiff] must show that the harm is

‘certainly impending’ or that there is a ‘substantial risk’ of the harm.” *Nelson v. Experian Info. Sols., Inc.*, 144 F.4th 1356, 1356 (11th Cir. 2025) (quoting *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 414 and n.5 (2013)). A theory of harm that relies on a speculative chain of events is insufficient. *Id.*

Plaintiff’s theory of harm is that, by not acting, the Secretary has prevented her from filing a claim, which *might* ripen into financial relief *if* Congress separately passes an excise tax. She fears that if the Secretary delays amending the Vaccine Injury Table, the eight-year “look back” provision associated with an amendment would not encompass her alleged injury. Compl. ¶¶ 7, 21, 52. This theory is entirely speculative because the lack of an excise tax independently precludes her from seeking relief through the VICP. The only situation in which the addition of the COVID-19 vaccine to the Table would allow her to bring a VICP claim (and thus that the Secretary’s alleged failure to add the COVID-19 vaccine to the Table would prevent her from bringing a claim she otherwise could have brought) is if Congress enacts an excise tax. But it is entirely speculative whether, or when, Congress will do so. Her alleged injury is therefore not “certainly impending” so as to demonstrate an injury in fact.

The Supreme Court addressed the viability of speculative harm in *Clapper, supra*, when a group of plaintiffs sued to enjoin the government from implementing a law that permitted surveillance of non-U.S. citizens overseas. The plaintiffs reasoned that their overseas contacts were likely to be surveilled under the law and that the plaintiffs’ communications with those individuals would therefore also be captured by the surveillance. *See generally Clapper*, 568 U.S. at 401-02. The Court found that the

plaintiffs’ alleged injury was actually a “highly speculative fear” that relied on a minimum of five assumptions regarding how future events would play out. *Id.* at 410-14. It was therefore not sufficiently “imminent” to confer standing. *Id.* at 409-14. The Court reinforced the notion that “possible injury” is insufficient; the harm anticipated by a plaintiff “must be *certainly* impending.” *Id.* at 409.

Similarly, in *Nelson, supra*, the Eleventh Circuit employed the same rationale when it rejected the claims of a plaintiff who sued a credit reporting agency that failed to remove incorrect addresses associated with her from the agency’s files. 144 F.4th at 1353. The circuit found that an “increased risk of identity theft”—which assumed that (1) the agency would release the incorrect information, (2) the recipient of said information would, in turn, attempt to contact plaintiff at an incorrect address, and (3) malevolent third parties would thus be empowered to access information about her—was too speculative to confer standing. *Id.* at 1356-57.

So too here. Plaintiff’s alleged injury assumes that Congress will at some point pass an excise tax and empower individuals to seek compensation through the VICP for injuries attributed to COVID-19 vaccines. *See, e.g.*, Compl. ¶¶ 7 (stating that Plaintiff will be entitled to seek compensation “as soon as Congress imposes the statutory tax on COVID vaccines”); 26 (“Congress’ decision regarding funding for compensation claims . . . is the final step in the process of adding coverage for COVID vaccine injury claims to the VICP.”); 52; 55. As with *Clapper* and *Nelson*, a speculative chain of events (to wit, the entire legislative process) would need to occur before Plaintiff’s concerns about a “possible injury” transition to a “certainly impending”

harm. Not only must a member of Congress introduce a bill that proposes an excise tax on COVID-19 vaccines, but that bill must make it through the lengthy legislative process, a process under which most bills do not become law. *See, e.g., Coalition for Responsible Regulation, Inc. v. EPA*, 684 F.3d 102, 147 (D.C. Cir. 2012) (expressing “serious doubts as to whether, for standing purposes, it is ever ‘likely’ that Congress will enact legislation at all”), *rev’d in part on other grounds sub nom. Util. Air Regul. Grp. v. EPA*, 573 U.S. 302 (2014).

Plaintiff’s “chain of events reasoning [does not move] the needle from a hypothetical future harm to a certainly impending harm of” losing her ability to pursue compensation through the VICP. *See Nelson*, 144 F.4th at 1357 (modified for clarity). Similarly, Plaintiff’s reference to the Vaccine Act’s citizen-suit provision, Compl. ¶ 28 (citing 42 U.S.C. § 300aa-31(a)), is insufficient to confer standing or create an injury in fact. Nor is an alleged “statutory violation . . . enough to show an injury in fact.” *Muransky*, 979 F.3d at 924; *see also Spokeo*, 578 U.S. at 341 (rejecting the idea that a plaintiff “automatically satisfies the injury-in-fact requirement whenever a statute grants a person a statutory right and purports to authorize the person to sue to vindicate that right.”). Rather, a plaintiff must establish concrete harm resulting from the alleged statutory violation. *Nelson*, 144 F.4th at 1354; *see also 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). Having failed to establish an injury in fact that satisfies Article III’s standing requirement, Plaintiff’s claims are subject to dismissal for lack of jurisdiction.

2. Plaintiff's Alleged Injury is Not Redressable Because Relief Depends on the Actions of Non-Parties.

Even if Plaintiff were able to show an injury in fact, she still lacks standing because her injury is not redressable by this Court. “To satisfy Article III’s redressability requirement, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” *Berrocal v. AG*, 136 F.4th 1043, 1051-52 (11th Cir. 2025) (modified for clarity) (internal citations omitted). Significantly, “when a plaintiff’s theory of redressability depends on the possible future actions of nonparties, any persuasive effect a judicial order might have upon absent non-parties who are not under the defendant’s control, cannot suffice to establish redressability.” *Id.* (modified for clarity) (internal citations omitted). This Court cannot provide redress for Plaintiff’s injuries because even if the Court ordered the Secretary to add COVID-19 vaccines to the Vaccine Injury Table, the lack of an excise tax would independently preclude her from seeking relief under the VICP.

Plaintiff’s two theories as to why her alleged harm is redressable misread the law. Her contentions that an amendment to the Vaccine Injury Table would both (1) allow her to file a claim immediately, thereby preserving a right to compensation, and, (2) trigger an automatic notification to Congress, prompting it to act, are both incorrect. Beyond those errors, her theories depend on the actions of non-parties, specifically Congress. Her claims therefore do not satisfy the redressability element.

A revision to the Vaccine Injury Table would not allow Plaintiff to file a claim. That revision only takes effect, and thus authorizes the filing of claims, “upon the

effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the” Table. *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 Section 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 . . .”). As another district court recently found in dismissing a similar lawsuit for lack of standing, “[o]rdering the Secretary to add the COVID-19 vaccine to the Vaccine Injury Table would not permit [the plaintiff] to bring a VICP claim because Congress must still pass an excise tax on that vaccine.” *Brundage v. Kennedy*, 2025 U.S. Dist. LEXIS 191813 at *7-*8.

That tax has not been enacted. *See* Compl. ¶ 7. Because a revision to the Vaccine Injury Table would not take effect until the passing of an excise tax, claims filed in advance of that legislation would be void; they would not preserve any rights as there are not yet any rights to preserve. And contrary to Plaintiff’s suggestion, Compl. ¶¶ 8, 25, the Vaccine Act does not require the Secretary to notify Congress when he revises the Vaccine Injury Table. The Secretary is required to promulgate regulations, a process that provides notification to the public at large. The Act also requires the Secretary to notify the Advisory Commission on Childhood Vaccines—a federal advisory committee charged with various responsibilities relating to the VICP—when he intends to modify the regulations regarding vaccines already on the Vaccine Injury Table. *See* 42 U.S.C. § 300aa-14(c)-(d); 42 U.S.C. § 300aa-19. Congressional

notification is similarly not required if the Secretary adds a category of vaccines to the Table prior to rulemaking through a notice of coverage per 42 C.F.R. § 100.3(a)(XVII). 42 C.F.R. § 100.3(e). Thus, Plaintiff is incorrect to state that the Secretary's addition of a vaccine to the Table "operates as a recommendation to Congress" to enact an excise tax. Compl. ¶ 25.

Even if this Court could order the Secretary to recommend that Congress enact an excise tax, that would not redress Plaintiff's claimed injuries. It is Congress's prerogative to decide what legislation to enact. There is no "basis to conclude that granting the relief [Plaintiff] requests will have any effect on Congress's 'unfettered' discretion to impose an excise tax, nor do they provide a basis to 'predict' whether Congress's choice 'will be made in such manner as to . . . permit redressability of [Plaintiff's] injury.'" *Brundage*, 2025 U.S. Dist. LEXIS 191813 at *9 (quoting *Lujan*, 504 U.S. at 562).

Underpinning both of Plaintiff's theories is reliance on the independent actions of Congress, a non-party over whom neither the Court nor the Secretary has control. Speculation that a decision here would prompt Congress to act does not establish redressability. As explained above, standing is not satisfied if a plaintiff's theory of redressability depends on the possible actions of nonparties over whom the Court and the defendant lack control. *See Berrocal*, 136 F.4th at 1051-52; *see also Haaland v. Brackeen*, 599 U.S. 255, 294 (2023) ("[R]edressability requires that the court be able to afford relief through the exercise of its power, not through the persuasive or even awe-inspiring effect of the opinion explaining the exercise of its power."). Indeed, another

district court recently dismissed a nearly identical suit because of the lack of redressability. *See Brundage*, 2025 U.S. Dist. LEXIS 191813 at *7-*8 (holding that the plaintiff's injury was not redressable because he could not seek compensation until Congress passed an excise tax on COVID-19 vaccines). The allegations in the Complaint are therefore insufficient to establish Plaintiff's standing and dismissal is appropriate.

B. Count II Is Foreclosed by the Vaccine Act's Citizen-Suit Provision.

Assuming Plaintiff could show she had standing, her second count invoking the Administrative Procedure Act (the APA), 5 U.S.C. §§ 701-706, should be dismissed because Plaintiff may seek relief under the Vaccine Act, and the APA provides a cause of action only when there is no other adequate remedy available. Plaintiff asserts that judicial review of the Secretary's alleged failure is appropriate under 5 U.S.C. § 706(1), which allows a court to "compel agency action unlawfully withheld or unreasonably delayed." But that statute is unavailable because the citizen-suit provision included in the Vaccine Act provides an adequate remedy. Count II must therefore be dismissed regardless of Plaintiff's standing to bring suit.

In 42 U.S.C. § 300aa-31, the Vaccine Act includes a citizen-suit provision (there called "citizen's actions") permitting "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" the Vaccine Act. Plaintiff invoked that provision of the Vaccine Act in Count I of the

Complaint. The APA prohibits review of agency action or inaction when a plaintiff otherwise has access to an “adequate remedy in court.” 5 U.S.C. § 704.

As the Supreme Court has explained, where “Congress has provided special and adequate review procedures” concerning specific agencies or specific acts, the “general grant of review in the APA” does not “provide additional judicial remedies.” *Bowen v. Massachusetts*, 487 U.S. 879, 903 (1988). That is because Congress’s intent in including the limitation in Section 704 was “to avoid duplicating previously established statutory procedures for review of agency actions.” *Darby v. Cisneros*, 509 U.S. 137, 146 (1993).

Based on that guidance, courts regularly dismiss APA claims for lack of jurisdiction where a citizen-suit provision covers the challenged conduct. *See, e.g., Fla. Pub. Interest Research Group Citizen Lobby, Inc. v. EPA*, 386 F.3d 1070, 1080 n.15 (11th Cir. 2004) (discussing intersection of APA and citizen-suit provision of Clean Water Act); *Citizens for Const. Integrity v. United States*, 70 F.4th 1289, 1311-13 (10th Cir. 2023) (no jurisdiction to hear APA claim regarding Surface Mining Control and Reclamation Act when statute allowed for challenge in federal court); *Walsh v. United States*, 400 F.3d 535, 537 (7th Cir. 2005) (no jurisdiction to hear APA claim regarding Freedom of Information Act when statute included citizen-suit provision that allowed for injunctive relief). Those holdings include situations where an agency allegedly failed to meet a statutory obligation. *See, e.g., Hayes v. Whitman*, 264 F.3d 1017 (10th Cir. 2001); *Allegheny Cnty. Sanitary Auth. Bangor Borough Auth. v. United States EPA*, 732 F.2d 1167 (3d Cir. 1984).

Those decisions highlight that allowing APA claims for concerns covered by citizen-suit provisions would undermine special procedures, such as a mandatory notice in advance of filing suit, that Congress tailored to the needs of specific agencies and issues. *See, e.g., Brem-Air*, 156 F.3d 1005; *Allegheny Cnty.*, 732 F.2d at 1177. One such special procedure is present here. An individual must provide the Secretary with sixty days' written notice, and thus an opportunity to remedy an issue, prior to filing a citizen suit. 42 U.S.C. § 300aa-31. Plaintiff complied with those requirements. Allowing Plaintiff's APA claim would render that requirement obsolete.

Florida Home Builders Ass'n v. Norton, 496 F. Supp. 2d 1330 (M.D. Fla. 2007), does not alter this conclusion. That decision is not binding on this Court. *See Ga. v. President of the United States*, 46 F.4th 1283, 1304 (11th Cir. 2022). Nor does it have persuasive authority because it was premised on faulty reasoning. *Home Builders* relied on *Bennett v. Spear*, 520 U.S. 154 (1997), in finding that a failure to "conduct mandatory, nondiscretionary status reviews" is not a final agency action subject to Section 704. 496 F. Supp. 2d at 1335. But in *Bennett*, the Court engaged in a fact-specific analysis of the APA and the citizen-suit provision. 520 U.S. at 172-74. The Supreme Court could have, and did not, offer the broad conclusion adopted by *Home Builders*. *Bennett* found the Secretary of Interior's failure "to perform his duties as administrator of the" Endangered Species Act of 1973 actionable under the APA *only after* determining that the relevant citizen-suit provision was limited to substantive violations of the statute, not failures regarding implementation. 520 U.S. at 172-74.

Here, however, the citizen-suit provision specifically allows for actions regarding failures to perform any duty under the Vaccine Act. *See* 42 U.S.C. § 300aa-31. A proper application of the procedure used by *Bennett*, therefore, would result in the conclusion that Plaintiff's APA claim is not viable under Section 704.

C. The Mandamus Act Does Not Provide for Relief Here.

Plaintiff's attempt, Compl. ¶¶ 56-60, to invoke the Mandamus Act, 28 U.S.C. § 1361, is of no moment. Plaintiff has not met the requirements for such extraordinary relief. "The party seeking mandamus has the burden of demonstrating that his right to the writ is clear and indisputable." *Hakki v. Seciy*, 7 F.4th 1012, 1036-37 (11th Cir. 2021)). "[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). 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." *Cash v. Barnhart*, 327 F.3d 1252, 1258 (11th Cir. 2003) (quoting *Heckler v. Ringer*, 466 U.S. 602, 616 (1984)). "Mandamus relief is only appropriate when (1) a plaintiff has a clear right to the relief requested, (2) the defendant has a clear duty to act, and (3) no adequate alternative remedy is available." *Cash*, 327 F.3d at 1258.

Plaintiff has met none of the requirements for mandamus relief. As discussed in the previous sections, Plaintiff does not have a "clear right" to the relief she requests. *See supra* pp.11-18. Nor does the Secretary have a "clear duty to act." 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. ¶ 22. But 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 CICIP. *See id.* at 15,203. The CICIP is authorized to provide benefits to certain individuals or estates of individuals who sustain a 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. The CICIP has paid claims related to injuries from COVID-19 vaccines. *See Countermeasures Injury Compensation Program (CICIP) Data*, Health Res. & Servs. Admin., <https://www.hrsa.gov/cicp/cicp-data>; *see also Devita v. Sec’y of HHS*, 2025 U.S. Claims LEXIS 3969, *3 (Ct. Fed. Cl. Dec. 23, 2025) (noting that “claims for alleged injuries from COVID-19 countermeasures, including vaccines, may be compensable under the” CICIP). Although Plaintiff may be unable to pursue a CICIP claim based on the relevant limitations period, the CICIP is an adequate alternative remedy for pursuing compensation for injuries attributed to COVID-19 vaccination. Mandamus relief is therefore inappropriate and there is no jurisdiction over Count IV.

D. The All Writs Act Is Inapplicable.

In Count V, Plaintiff pleads in the alternative that to the extent her other counts do not provide the relief she 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. ¶ 62. 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 Vaccine Act. *Klay v. United Healthgroup, Inc.*, 376 F.3d 1092, 1099 (11th Cir. 2004). The All Writs Act “does not create any substantive federal 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 she requests, and her 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.

LOCAL RULE 3.01(G) CERTIFICATE

In accordance with Local Rule 3.01(g), the undersigned hereby certifies that the movant has conferred with counsel for Plaintiff. The parties do not agree on the resolution of the Motion. The meet and confer conference took place via Zoom on March 26, 2026.

Respectfully submitted,
April 13, 2026

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CERTIFICATE OF SERVICE

I hereby certify that on April 13, 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/ Shmuel Bushwick/s/

Trial Attorney