ORAL ARGUMENT NOT YET SCHEDULED

No. 26-5004

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

PAUL BRUNDAGE,
Plaintiff-Appellant

v.

ROBERT F. KENNEDY, JR.,
Secretary, United States Department
of Health and Human Services,
Defendant-Appellee

Appeal from the United States District Court
for the District of Columbia
Hon. Sparkle L. Sooknanan, No. 1:25-cv-00119-SLS

APPELLANT'S REPLY BRIEF

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August 14, 2026

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GLOSSARY OF ABBREVIATIONS

The Act	National Childhood Vaccine Injury Act of 1986
CDC	Centers for Disease Control and Prevention
The Note	42 U.S.C. § 300aa-14 Note
The Program	Vaccine Injury Compensation Program
The Table	Vaccine Injury Table
VICP	Vaccine Injury Compensation Program
PREP Act	42 U.S.C. § 247d-6d Public Readiness and Emergency Preparedness Act

SUMMARY OF ARGUMENT

The Secretary's arguments for denying Mr. Brundage standing under the Vaccine Act's citizen-suit provision are all based on false premises. Each requires concluding the Secretary has discretion regarding the deadline in 42 U.S.C. § 300aa-14(e)(2). He also relies on transposing Mr. Brundage's vaccine injury for the Secretary's deadline violation as the grounds of suit. Finally, his arguments depend on misreading the statute.

The Secretary's logic only works if 42 U.S.C. § 300aa-14 Note ("the Note") is construed as limiting §§ 300aa-14(e)(2), -16(b) and -31(a). Nowhere does the Secretary explain how these sections can be given effect if the Note is construed to bar Mr. Brundage from seeking relief. Mr. Brundage has explained that they cannot [Appellant's Br. at 22-34].

The responsive brief twists its logic past the breaking point to rebut Mr. Brundage's procedural right and savings clause standing. The Vaccine Injury Table ("Table") addition, which it elsewhere claims has "no legal effect," [Appellee's Br. at 29], suddenly conveys Mr. Brundage a substantive, yet somehow unredressable, right. Finally, it advances a tortuous misreading of the savings clause that renders Congress'

distinction of effective dates and revision dates pointless. These winding ways can be avoided by simply interpreting the deadline as a deadline.

Along the way, the Secretary argues that his interpretation's incompatibility with the statute matters not, because the District Court dismissed on standing, rather than the merits. [Appellee's Br. at 33-34]. This and his remaining arguments are simply extensions of an effort to "[misuse] the redressability requirement", *Diamond Alternative Energy, LLC v. EPA,* 606 U.S. 100, 120 (2025), to avoid judicial scrutiny.

Mr. Brundage has standing for the reasons given in his opening brief, and this Court should reverse the judgment.

ARGUMENT

The Secretary's arguments rely entirely upon two premises, without which he cannot prevail. Yet, these premises are unsupported either in law or fact. This reply will show the Secretary's inventive arguments collapse when tested against the Vaccine Act.

His first premise is that an excise tax must precede adding a vaccine to the Table. Although his brief correctly acknowledges that "the Act is silent as to whether the Secretary or Congress should act first," [Appellee's Br. at 5], his actual argument does not align with that

statement. Each argument for avoiding this suit to enforce straightforward provisions of the Vaccine Act depends on an assumption he has acknowledged is false.

The Secretary would thus divert this Court's attention from *his* obligation to instead focus on *Congress'* response to this case. [Appellee's Br. at 15 ("courts cannot presume to predict how legislators would respond")]. From there, the Secretary asks the Court to assess whether the order Mr. Brundage seeks would immediately authorize him to bring a VICP [Vaccine Injury Compensation Program] claim, rather than whether it would end the Secretary's delay. [Appellee's Br. at 15 ("plaintiff will remain ineligible for VICP compensation")]. These arguments invoke the Secretary's second faulty premise: that the injury Mr. Brundage seeks to redress is his vaccine injury.

The Secretary confuses the injuries at issue. As Mr. Brundage has explained, the vaccine injury's relevance is to establish that his harm is "sufficiently concrete and particularized to support Article III standing." [Appellant's Br. at 18]. The injuries "in this action," *Ctr. for a Sustainable Coast v. U.S. Army Corps of Eng'rs,* 100 F.4th 1349, 1358 (11th Cir. 2024), are those caused by the Secretary's disregard of his

statutory deadline: loss of the savings clause's protection; unlawful delay to compensation eligibility; and disregard for the procedure Congress established to expand VICP coverage. These injuries are described in Appellant's Br. at 16 – 22.

I. The Secretary's arguments depend on nonexistent discretion.

The Secretary does not state directly that he may ignore the deadline. His argument is this: his interpretation of the Note, his regulation,[1] and his current practice of waiting for Congress to enact an excise tax together empower him to ignore the deadline without accountability via a citizen-suit provision targeting his inaction. [*See* Appellee's Br. at 6, 16, 20, 22-23, 43-44]. In other words, *he* has decided Congress should first enact the tax, [*see* 42 C.F.R. § 100.3(e)(8)], and he need do nothing until it does.[2]

This argument requires construing the ministerial duty of a Table addition as a discretionary decision. Accepting it rejects the language of

[1] 42 C.F.R. § 100.3(e)(8)

[2] *Contrast* Appellee's Br. at 4-5 (Secretary is "authorized" to add vaccines) *with* 42 U.S.C. § 300aa-14(e)(2) ("When…the [CDC] recommends a vaccine…the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table").

§§ 300aa-14(e)(2) and -31, thereby eliminating the statutory two-year deadline, and limiting the cause of action Congress created.

A. The deadline admits no discretion.

The Secretary argues Mr. Brundage's deadline argument is wrong and that if Congress has not enacted an excise tax, the Secretary may disregard the deadline. [Appellee's Br. at 5 ("to add a vaccine to the Table…Congress must tax the vaccine").][3] This argument contradicts the plain and mandatory language of the Vaccine Act.

This Court must exercise its independent judgment when interpreting whether the Note, the regulation, and administrative practice give the Secretary the discretion he impliedly claims, and whether they render a court order to add a vaccine to the Table ineffectual. *See Loper Bright Enterprises v. Raimondo,* 603 U.S. 369, 392, 412 (2024) (courts independently decide "whether the law means what the agency says"). *Loper Bright*, 603 U.S. at 401, instructs that heightened scrutiny is warranted when reviewing the Secretary's

[3] The Secretary quotes *In re Gardasil Prods. Liab. Litig.,* 151 F.4th 178, 191-92 (4th Cir. 2025), which upheld a Table addition against a Presentment Clause challenge. *In re Gardasil,* 151 F.4th at 193. Because the deadline was not at issue, the description in that case is *dicta,* and not instructive here.

interpretation of his own authority and amenability to suit. Moreover, when the statutory text is unambiguous, as in § 300aa-14(e)(2), the Court's inquiry into its meaning ceases. *Kingdomware Technologies, Inc. v. United States,* 579 U.S. 162, 171 (2016). Congress gave "an exacting deadline," *In re Center for Biological Diversity,* 53 F.4th 665, 671 (D.C. Cir. 2022), not discretion. *See Anderson v. Yungkau,* 329 U.S. 482, 485 (1947) ("The word 'shall' is ordinarily 'the language of command'").

Assigning the Secretary an official, precise, and definite act, about which he has no discretion, created a ministerial duty. Courts may compel it, *Mississippi v. Johnson,* 71 U.S. 475, 498 (1866); *Kendall v. United States ex rel. Stokes,* 37 U.S. 524, 613-14 (1838), and Congress has authorized citizen enforcement of it, 42 U.S.C. § 300aa-31(a). Lacking discretion regarding the deadline, the Secretary's interpretations of the Act fail. His standing arguments, relying upon the premise that his statutory duty could be placed on hold until Congress passes an excise tax, must likewise fail.

B. The Secretary's practice does not justify disregarding the deadline.

Three of the nine vaccines added to the Table since 1993 were added before a corresponding excise tax was passed.[4] Only the most recent Table addition took longer than the statute's two-year maximum. *See* 78 Fed. Reg. 67369 (Nov. 12, 2013). A "practice" not followed a third of the time is hardly so established as to support disregarding a statutory mandate.

The first three Table additions preceded an excise tax.[5] In February 1995, the administration *requested* the excise taxes on the first two, based on the CDC recommendation and expected Table additions. Dep't of the Treasury, *General Explanations of the Administration's FY 1996 Revenue Proposals,* 11 (1995). Acting on CDC's recommendation, not a tax, was the practice of those "charged with setting [the amended Vaccine Act's] machinery in motion." *Int'l Broth. of Elec. Workers v. NLRB,* 814 F.2d 697, 714 (D.C. Cir. 1987) (quoting *Frazier v. MSPB,* 672 F.2d 150, 162 (D.C. Cir. 1982) and *Power*

[4] These additions are described in Amicus' Br. at 10-11.
[5] *Compare* 62 Fed. Reg. 7685,7866 (Feb. 20, 1997) *with* Taxpayer Relief Act of 1997, Pub. L. 105-34, 111 Stat. 788 § 904(b) (Aug. 5, 1997).

Reactor Dev. Co. v. Int'l Union of Elec., Radio & Mach. Workers, 367 U.S. 396, 408 (1961)). As such, the validity of the Secretary's later and contrary representations are questionable.

C. The Secretary's regulation cannot alter the deadline.

The Secretary cites 42 C.F.R. § 100.3(e)(8) as support that a Table addition only takes place after the excise tax. [Appellee's Br. at 20]. This argument fails because it requires giving effect to a regulation in a way that is contrary to the express, unambiguous terms of the Vaccine Act. *United States v. Larionoff,* 431 U.S. 864, 873 (1977). "A regulation which…operates to create a rule out of harmony with the statute, is a mere nullity." *Manhattan Gen. Equip. Co. v. Comm'r,* 297 U.S. 129, 134 (1936); *see also Utility Air Regul. Grp. v. EPA,* 573 U.S. 302, 325 (2014) (agency cannot rewrite unambiguous statutory terms).

The statute requires a Table addition within two years. 42 U.S.C. § 300aa-14(e)(2)(A). To the extent the Secretary's regulation purports to authorize waiting longer, it is invalid. *Larionoff,* 431 U.S. at 873; *Manhattan Gen. Equip. Co.,* 297 U.S. at 134.

II. Courts may neither eliminate the statutory deadline, nor narrow § 300aa-31(a), by construing the Note to eliminate judicial remedies for deadline violations.

The Secretary presents no alternative interpretation of the deadline or citizen-suit provisions. Nowhere outside his statement of the case do citations to § 300aa-14(e)(2) address the meaning of the fundamental text at issue in this case – the directive that "the Secretary shall, within 2 years of [CDC's] recommendation, amend the Vaccine Injury Table." He nowhere argues that "shall" means something other than "must."

Instead, he depends on the Note to render the deadline ineffective. However, it only ties the effective date of a Table addition to that of an excise tax. 42 U.S.C. § 300aa-14 Note. Using both his false premises, the Secretary stretches this provision to argue that only "legislation," [Appellee's Br. at 25], provides redress.

Effective redress for the Secretary's inaction, however, does not depend on Congress; it depends on whether a Court order at least partially advances Mr. Brundage's eligibility or savings clause rights, or compels a procedure Congress established for expanding VICP coverage. Because the Note does not conflict with the deadline, the

savings clause, or the citizen-suit provision, this Court must give them effect by allowing Mr. Brundage's suit to proceed.

A. Judicial compulsion remains available and effective redress.

The Secretary argues the Note eliminates all judicial remedies for his failure to timely add a vaccine to the Table. [*See* Appellee's Br. at 25]. This construction impermissibly modifies the cause of action Congress created in § 300aa-31(a). *See Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128 (2014) ("Just as a court cannot … recognize a cause of action that Congress has denied, it cannot limit a cause of action that Congress has created….") (internal citation omitted). Affirming the District Court would "render inutile [a cause] of action authorized by Congress through a decision that *no* remedy is available." *Franklin v. Gwinnett Cty. Pub. Sch.,* 503 U.S. 60, 74 (1992).

Moreover, Article III does not allow courts to abdicate their authority to award appropriate relief. *See Franklin,* 503 U.S. at 74. As the Supreme Court teaches:

> Congress had the power to command that act to be done; and the power to enforce the performance of the act must rest somewhere, or it will present a case which has often been

> said to involve a monstrous absurdity in a well-organized government, that there should be no remedy, although a clear and undeniable right should be shown to exist.

Kendall, 37 U.S. at 624. "Federal courts…have 'no more right to decline the exercise of jurisdiction which is given, than to usurp that which is not given.'" *Sprint Commc'ns, Inc. v. Jacobs*, 571 U.S. 69, 77 (2013) (quoting *Cohens v. Virginia,* 19 U.S. 264, 404 (1821)); *Leedom v. Kyne,* 358 U.S. 184, 190 (1958).

Construing the Vaccine Act to conclude that redress under § 300aa-31(a) requires legislative, rather than judicial, correction thus causes two Constitutional violations. It overrules Congress' creation of a cause of action by eliminating any remedy for violating the Table addition deadline. *See Franklin,* 503 U.S. at 74. It also causes an "injured party [to] be unable to bring his case before that tribunal to which the people of the United States have assigned all such cases." *Cohens,* 19 U.S. at 403-04.

A usual remedy for official inaction is the compulsion of action. *See Sierra Club v. Thomas*, 828 F.2d 783, 793 (D.C. Cir. 1987); *Pub. Citizen Health Research Grp. v. FDA,* 740 F.2d 21, 32 (D.C. Cir. 1984). While § 300aa-31 does not limit the remedies available, its limitation of

the cause of action to failures to act indicates that Congress considered compulsion appropriate and effective, if not the default remedy. This Circuit considers compulsion effective redress for a Cabinet member's failure to perform a statutory duty. *See PETA v. USDA,* 797 F.3d 1087, 1093 n.3 (D.C. Cir. 2015); *Haneke v. Sec'y of Health, Educ. & Welfare*, 535 F.2d 1291, 1296 (D.C. Cir. 1976).

The Secretary has not denied his power to amend the Table, the court's power to order him to do so, nor asserted that he could constitutionally disregard such an order. Absent such assertions, his redressability arguments are baseless: the order sought would create "a change in the legal status of the parties," which equals redressability. *Gutierrez v. Saenz,* 606 U.S. 305, 316 (2025).

B. The Secretary's cases concerning third parties and speculative redress are inapposite.

1. Mr. Brundage is an "object" of the forgone Table addition.

Assuming that the vaccine injury, rather than the overdue Table addition, is at issue, the Secretary selectively quotes *Lujan v. Defs. of Wildlife,* 504 U.S. 555 (1992), [Appellee's Br. at 21], for its discussion of

third-party choices and standing. The selection does not apply in Mr. Brundage's case, as the omitted start of the quoted paragraph shows:

> When the suit is one challenging the legality of government action or inaction, the nature and extent of facts that must be averred…in order to establish standing *depends considerably upon whether the plaintiff is himself an object of the action (or forgone action) at issue*. If he is, there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it.

Lujan, 504 U.S. at 561–62 (emphasis added). The Secretary appears to argue that, under the Vaccine Act, Congress regulates vaccine injury compensation directly despite its delegation of significant powers to him. In his reading, the vaccine-injured are not "objects" of a Table addition, though their rights depend on that action.

Yet the Secretary's Table amendments directly regulate the rights of vaccine-injured persons, by recognizing compensation rights for newly recommended vaccines and injuries. 42 U.S.C. §§ 300aa-11(c)(1), -13(a)(1)(A). Through the savings clause, those rights are preserved until they can be perfected in a Court of Federal Claims action. 42 U.S.C. § 300aa-16(b). Mr. Brundage is indisputably "an object of the…forgone" Table addition. *Lujan,* 504 U.S. at 561. There should be "little question

that the…inaction has caused him injury, and that a judgment … requiring the action will redress it." *Id.* at 561-62.

The Secretary's quotation from *Diamond Alternative Energy, LLC*, [Appellee's Br. at 21], is identically flawed. That court also limited its third-party discussion to situations where the plaintiff is not directly impacted by the government inaction at issue. *Diamond Alternative Energy,* 606 U.S. at 112.

2. Cases lacking an injury do not provide reliable redressability analysis.

Only one case cited by the Secretary to argue Mr. Brundage's redress is speculative contained a cognizable injury. The reasoning in the others does not transfer to Mr. Brundage's case, whose injuries-in-fact have not been disputed. [ECF 24 at 5].

The Secretary cites *DaimlerChrysler Corp. v. Cuno,* 547 U.S. 332 (2006), and *ASARCO, Inc. v. Kadish,* 490 U.S. 605 (1989), to argue that assessing the likelihood of future policy choices is speculative. [Appellee's Br. at 21-22]. Those cases were taxpayer challenges to a state tax credit, *DaimlerChrysler,* 547 U.S. at 342-43, and to a state mineral leasing statute, *ASARCO,* 490 U.S. at 614. In each, the Court found any injury insufficiently concrete or individualized, as well as

conjectural. *DaimlerChrysler,* 547 U.S. at 344; *ASARCO,* 490 U.S. at 613-14.

Analyses finding that redressability is conjectural are of little value when premised on injuries that are themselves speculative. Because redressability aligns injuries and remedies, *Diamond Alternative Energy,* 606 U.S. at 120, where a court has not been able to identify an injury, it has no reliable basis on which to assess redressability. The redressability discussions in the Secretary's cases are inherently *dicta*, with reasoning premised on supposition. Applying their logic to cases where the injuries are known, as here, should be done only with great caution.

Coalition for Responsible Regulation, Inc. v. EPA, 684 F.3d 102 (D.C. Cir. 2012) (per curiam), *rev'd in part, Utility Air Regul. Grp. v. EPA,* 573 U.S. 302 (2014), illustrates how redressability analysis is unreliable without an identified injury. There, a panel of this Court found no injury based on its statutory construction. *Coalition for Responsible Regulation,* 684 F.3d at 146. On appeal, the Supreme Court read the statute differently and granted part of the relief sought, without even discussing redressability. *Utility Air Regul. Grp. v. EPA,*

573 U.S. at 325. The Supreme Court must have found the discussion quoted by the Secretary [Appellee's Br. at 22] inapplicable to the injury it discerned.

3. Unlike in *US Ecology,* Mr. Brundage has not lost redressability.

US Ecology, Inc. v. U.S. Dep't of the Interior, 231 F.3d 20 (D.C. Cir. 2000), was decided solely on redressability, but its facts are distinguishable. Redressability existed when the case was filed, but was later lost. *See US Ecology,* 231 F.3d at 21-24 (discussing California's withdrawal from case). Because the original co-plaintiff was now opposed to its project, the remaining plaintiff could no longer establish a likelihood of redress. *See id.* at 25-26. The court's discussion noted a reluctance to find standing dependent on future policy decisions. *Id.* at 24; [Appellee's Br. at 22].

Mr. Brundage does not require Congress to change policy to achieve redress, however—longstanding Vaccine Act policy is that new vaccines should be covered, and injuries compensated, "as soon as possible." H.R. Rep. 99-908 at 20 (1986), *reprinted in U.S.C.C.A.N.* at 6361. Mr. Brundage requires nothing of Congress to establish redressability, *see* Part II.C, *infra.* For VICP eligibility he will require

an appropriation to the Trust Fund via an excise tax, consistent with established policy. *See* 42 U.S.C. § 300aa-14 Note; 26 U.S.C. §§ 4132, 9510. If mere lack of appropriations created a bar to judicial redress, courts would dismiss untold numbers of cases whenever a government shutdown occurs.

C. The Secretary fails to rebut that a Table addition provides Mr. Brundage partial relief.

In response to Mr. Brundage's argument that this Circuit's case law recognizes standing when relief is partial, or removes a categorical bar to the exercise of a right, the Secretary cites no cases of his own. He fails to distinguish Mr. Brundage's authorities establishing that the requested order provides partial relief under this Circuit's precedent. [Appellee's Br. at 25–33; Appellant's Br. at 41-48]. The Secretary's distinctions are rather premised entirely on his misapprehension of the harm. [Appellee's Br. at 25 ("traceable to lack of action by Congress")]. Nowhere does he discuss delay, timeliness or remedies for inaction.

1. *Duberry* controls this case.

This Court in *Duberry* rejected the same error, finding the District of Columbia:

> completely misapprehends the relief sought and obtained by Appellees in this litigation. Appellees are not seeking a declaration that they are entitled to carry firearms pursuant to LEOSA. Rather, they have sought to overturn the District's unlawful refusal to certify them as "qualified retired law enforcement officers," which is necessary in order for them to pursue the right to carry under LEOSA. Therefore, it does not matter whether Appellees have yet to obtain the identifications required by Section 926C(d).

Duberry v. D.C., 924 F.3d 570, 574 (D.C. Cir. 2019).

Likewise, Mr. Brundage does not seek an order that he may file a VICP claim. He seeks a belated Table addition. [ECF 1 at ¶ 5]. The argument that Congress must pass an excise tax before Mr. Brundage has standing to challenge the Secretary's inaction is identical to the one rejected in *Duberry*.

The Secretary also argues that the Table addition "defines" Mr. Brundage's right to compensation, rather than being a precondition to his exercising that right. [Appellee's Br. at 28]. Neither *Duberry* nor the statute support this contention. *Duberry* recognized that neither of the qualification criteria for carrying a firearm "defined" the right to do so. *Duberry,* 924 F.3d at 579-80. Neither do the criteria for determining the

effective date of a tax,[6] define Mr. Brundage's rights to a timely Table addition, preservation of his claim, or VICP eligibility.[7]

2. Partial redress exists under *Khodara* and *Swan*.

To escape this Circuit's partial relief precedents, the Secretary repeats the District Court's misreading of *Khodara Env't, Inc. v. Blakely,* 376 F.3d 187 (3d Cir. 2004), [Appellee's Br. at 26-27]. He cites the Third Circuit's references to a "regulatory obstacle" and "separate proceedings" when discussing the removability of an independent obstacle. [Appellee's Br. at 26-27]. These terms, however, describe the facts of that case rather than limit its rule. *Khodara,* 376 F.3d at 194-95. Moreover, the Secretary's arguments are inconsistent with *Khodara's* holding that but-for causation need not be shown for standing purposes: "it is well recognized that but-for causation is problematic in precisely the situation present here, *i.e.*, where an effect is 'causally over-determined,' *i.e.,* where there are multiple sufficient

[6] 42 U.S.C. § 300aa-14 Note
[7] VICP eligibility criteria are found in 42 U.S.C. § 300aa-11(c)(1). *Id.* § 300aa-11(b)(1)(A).

causes." *Id.* at 195.

The Secretary misunderstands *Swan v. Clinton,* 100 F.3d 973 (D.C. Cir. 1996); *Sierra Club v. U.S. Dep't of the Interior,* 899 F.3d 260 (4th Cir. 2018); and the word "partial." [Appellee's Br. at 25-26, 29]. These cases hold that partial redress suffices for standing purposes. *Swan,* 100 F.3d at 981; *Sierra Club,* 899 F.3d at 284. The Secretary argues that a Table addition would provide no relief because Mr. Brundage could not file a VICP claim until an excise tax passes. However, fulfilling *one* of the *two* steps required to acquire eligibility provides "partial" redress sufficient for standing. *Id.* at 285; *Partial, Black's Law Dictionary* (12th ed. 2024) ("Not complete; of, relating to, or involving a part rather than the whole").

D. The Secretary's arguments indicate that a Table addition would increase the likelihood of Congressional action and VICP eligibility.

Should this Court consider whether the requested order increases the likelihood of an excise tax, it should not accept the Secretary's scattered arguments that it would not. His arguments cite to the PREP

Act, which by its terms does not apply in this case;[8] impermissibly infer Congressional intent to deny a tax, based on unresolved VICP reform efforts;[9] explicitly argue that § 300aa-14(e)(2)(A) is surplusage;[10] and finally claim that his practice of ignoring Congress' command until a tax is enacted is actually Congress' preference.[11] Such flawed arguments cannot support his conclusion, especially considering the statutory purpose and posture here.

1. Courts do not presume Congress will fail to fund its programs.

At bottom, the Secretary asks this Court to presume that Congress would fail to appropriate money to the VICP Trust Fund for COVID vaccine injury claims even after the Secretary acknowledges they are coverable by placing the vaccine on the Table. However, courts require a clear expression of Congressional intent before assuming that

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[8] *Compare* [Appellee's Br. at 23-24, 30] *with* 42 U.S.C. § 247d-6d(h) ("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").
[9] *See* [Appellee's Br. at 30-31]; *Wilderness Soc. v. Morton*, 479 F.2d 842, 860 n.44 (D.C. Cir. 1973).
[10] [Appellee's Br. at 32 ("the Secretary's action has no effect at all unless Congress acts")].
[11] [Appellee's Br. at 32-33]. *Contra* 42 U.S.C. § 300aa-14(e)(2)(A).

an obligation created by statute will never be funded. *Cf. Maine Cmty. Health Options v. United States,* 590 U.S. 296, 317-19 (2020) (failure to appropriate does not support implying repeal of compensation right) (citing *United States v. Vulte,* 233 U.S. 509, 514-15 (1914) and *United States v. Langston,* 118 U.S. 389, 393-94 (1886)). Moreover, Congress has always taxed vaccines added by the Secretary. *See* Taxpayer Relief Act of 1997, Pub. L. No. 105-34, § 904, 111 Stat. 788, 873-74 (Aug. 5, 1997), and 62 Fed. Reg. 7685, 7688-89 (Feb. 20, 1997).

All net vaccine excise tax revenue is deposited into the Vaccine Injury Compensation Trust Fund. 26 U.S.C. § 9510(b)(1). Adding a taxable vaccine is thus as much an appropriation as a tax law. As with any appropriation, "the first step in the life cycle" lies with the agency. U.S. Gov't Accountability Off., GAO-16-464SP, *Principles of Federal Appropriations Law,* vol. 1, at 2-15 (4th ed. 2016). *See* Dep't of the Treasury, *supra,* at 11. These facts belie the Secretary's statements that his addition of a vaccine to the Table has no effect on a corresponding excise tax.

2. Ongoing reform efforts weigh in favor of redressability.

The Secretary overstates the facts by arguing that Congress has "declined" an excise tax. [Appellee's Br. at 16, 23, 39]. He asks the Court to infer that because modernization legislation including a COVID excise tax has not yet passed, any bill adding a COVID tax to the Trust Fund's appropriation is unlikely to pass–even after the Secretary adds the vaccine to the Table. [*See* Appellee's Br. at 23-24].

As this Court has noted, "it is hazardous to draw conclusions from congressional inaction." *Wilderness Soc. v. Morton*, 479 F.2d 842, 860 n.44 (D.C. Cir. 1973). In particular, proposals not receiving a floor vote, such as those in Appellee's Br. at 24, do not help discern any intent of Congress. *See Wilderness Soc.,* 479 F.2d at 860 n.44.

Instead, ongoing VICP reform efforts mean a court could find that a Table addition would make passage of the tax-appropriation likelier. *See Town of Barnstable v. F.A.A.,* 659 F.3d 28, 34 (D.C. Cir. 2011). This is partly because a Table addition clears a legislative path for a clean appropriation. Pending reforms include more consequential

provisions—those affecting manufacturer immunity[12] or the VICP limitations period,[13] for example. A Table addition would allow Congress to make a new Table effective quickly—without simultaneously requiring resolution of complex policy questions—through a clean amendment of 26 U.S.C. § 4132(a)(1).

III. Standing rulings cannot rely on improper construction.

The Secretary claims that because the District Court based its ruling on standing, Mr. Brundage cannot contest the impermissible construction that it relied on. [Appellee's Br. at 33-34 (claiming Plaintiff 'confuses standing with a cause of action')]. Unlike in *Common Cause v. FEC,* 108 F.3d 413, 419 (D.C. Cir. 1997), Mr. Brundage has demonstrated a discrete injury. Congressional intent to provide a remedy for Secretarial inaction is a fundamental flaw in the Secretary's interpretation. Statutory rights for redress against agencies are presumed to be judicially enforceable. *See Leedom v. Kyne*, 358 U.S. at 190. As in *Utility Air Regul. Grp.,* 573 U.S. at 325, standing here becomes apparent with proper statutory construction. *See also In re*

[12] LIABLE Act, H.R. 1432, 119th Cong. (2025).
[13] Vaccine Injury Compensation Modernization Act of 2026, H.R. 9672, 119th Cong. § 2(d) (2026).

Cheney, 406 F.3d 723, 729 (D.C. Cir. 2005) (jurisdictional question merged with merits).

IV. Mr. Brundage properly asserts a procedural injury.

The Secretary primarily opposes Mr. Brundage's procedural standing by arguing that a timely Table addition is a substantive, not procedural, right. [Appellee's Br. at 35-37]. This position contradicts his assertions elsewhere that the addition "has no effect at all." [*Id.* at 32]. If a Table addition "alters the rights and interests of the parties," [*id.* at 36-37, quoting *Citizens for Const. Integrity v. Census Bureau,* 115 F.4th 618, 626 (D.C. Cir. 2024)], then it provides Mr. Brundage redress even without relaxing the redressability standard. *Gutierrez v. Saenz,* 606 U.S. at 316; *see also Utah v. Evans,* 536 U.S. 452, 464 (2002) (citing cases).

Regardless, the Secretary's delay also violated Mr. Brundage's procedural right to have Congress' scheme for expanding coverage followed. *Cf. Ahmed v. Blinken,* 759 F. Supp. 3d 1, 8-9 (D.D.C. 2024) (delay causing both procedural and emotional harm). The Secretary acknowledges "there is no established test" for determining whether a right is procedural, quoting *Citizens for Const. Integrity,* 115 F.4th at

625-26. [Appellee's Br. at 36]. He also asserts, without support, that the Table addition and the excise tax are not connected. [*Id*. at 39]. The argument that Mr. Brundage's six-page assertion of a procedural right, [*Appellant's Br*. at 53-58], was "skeletal," [Appellee's Br. at 35-36], and thereby forfeited, is baseless.

In *Citizens for Const. Integrity,* 115 F.4th at 625-27*,* this Court ruled that challenging the *content* of the Census Report did not raise a procedural rights claim. That analysis does not apply here, because a ministerial deadline, unlike the content of a report, is "essentially procedural." *WildEarth Guardians v. Jewell,* 738 F.3d 298, 303 (D.C. Cir. 2013). The § 300aa-14(e)(2) deadline protects the right to timely compensation for injuries caused by newly recommended vaccines. It is thus designed to protect Mr. Brundage's concrete interest. *See Ctr. for Law & Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1157 (D.C. Cir. 2005).

Congress gave the Secretary a deadline to add recommended vaccines to the Table. The deadline applies independently of Congress. The Table addition is "connected to" the substantive result of expanded eligibility by operation of 42 U.S.C. §§ 300aa-11(b)(1)(A), 300aa-11(c)(1). *Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 184 (D.C. Cir. 2017).

That connection suffices for standing. *WildEarth Guardians,* 738 F.3d at 306.

V. The Secretary's attempts to avoid or rewrite the savings clause do not avail.

A. Mr. Brundage's Article III standing cannot be waived or forfeited.

To avoid this Court's consideration of Plaintiff's savings clause argument, the Secretary argues that it was forfeited by not expressly expounding it in the complaint or first response to the motion to dismiss. [Appellee's Br. at 41-42]. He would have this Court rewrite pleading standards and authorize courts to knowingly sustain jurisdictional error.

Mr. Brundage is not seeking to "expand the allegations of the complaint," as in *Runnemede Owners, Inc. v. Crest Mortg. Corp.,* 861 F.2d 1053, 1057 (7th Cir. 1988), or in *Arpaio v. Obama,* 797 F.3d 11, 21 (D.C. Cir. 2015). His theory is that pleaded in the complaint: the Secretary's deadline violation harms his rights under the Act. [ECF 1, ¶¶ 2-3, 6-7]. This theory is common to each right harmed, as is the relief: an order to the Secretary. [ECF 1, ¶ 5]. Such general allegations suffice to meet the modest pleading-stage burden, *Bennett v. Spear,* 520

U.S. 154, 168, 171 (1997), so Plaintiff need not rebut unknown redressability arguments in his complaint. *See Bennett,* 520 U.S. at 168; *cf. Gomez v. Toledo*, 446 U.S. 635, 639–40 (1980) (rebuttal of immunity not required in complaint).

The savings clause and procedural right arguments are just that—argument, which need not be alleged—illustrating how the order sought provides redress. They are not comparable to introducing new factual assertions of a "flood of unaccompanied minors," *Arpaio,* 797 F.3d at 21, or of a failed condition precedent, *Runnemede Owners,* 861 F.2d at 1057.

The Secretary asserts that Mr. Brundage improperly raised these arguments in his Rule 59(e) motion. [Appellee's Br. at 41-42]. Because the reconsideration decision is also a question of standing, this Court should review it *de novo. Teton Historic Aviation Found. v. U.S. Dept. of Defense,* 785 F.3d 719, 724 (D.C. Cir. 2015). In the alternative, this Court should find the District Court abused its discretion. "A district court by definition abuses its discretion when it makes an error of law." *Koon v. United States*, 518 U.S. 81, 100 (1996); *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.,* 839 F.3d 242, 249

(3d Cir. 2016) (on review standard for dismissal and denial of reconsideration).

Expanding on Mr. Brundage's standing theory in a reconsideration motion is allowed: "As a jurisdictional requirement, standing to litigate cannot be waived or forfeited." *Virginia House of Delegates v. Bethune-Hill*, 587 U.S. 658, 662–63 (2019). Pointing out clear jurisdictional error in a Rule 59(e) motion can save the parties and the courts the burdens of an unnecessary appeal or relitigating a new complaint. Moreover, to the extent the motion raised a question for the court as to specific factual support for redressability, then factual inquiry[14] or an opportunity to cure[15] is the proper course.

B. The Secretary's only textual argument is circular and inconsistent with the statute.

The Secretary also attempts to argue the District Court's ruling regarding the savings clause was correct on the merits. [Appellee's Br. at 42-46]. It cites to no canons of construction or case law, but does attempt a textual argument:

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[14] *Haase v. Sessions*, 835 F.2d 902, 906 (D.C. Cir. 1987).
[15] *See Foman v. Davis,* 371 U.S. 178, 182 (1962); *Customs Fraud Investigations, LLC,* 839 F.3d at 250.

> The "date of the revision of the Table," § 42 U.S.C. § 300aa-16(b), is the effective date of an excise tax on the added vaccine, because a "revision by the Secretary" under § 300aa-14(e)(2) has no effect until "the effective date of" an excise tax passed by Congress, *id.* § 300aa-14 note. Put differently, the Table is not revised until the vaccine is taxed.

[Appellee's Br. at 43]. Perhaps this interpretation is harmless in instances where the tax takes effect within 2 years of the CDC recommendation. In this case, however, it fails because any discretion the Secretary has, ends after two years. 42 U.S.C § 300aa-14(e)(2).

The Secretary attempts to equate "the date of the revision" with the "effective date". [Appellee's Br. at 43]. Yet this ignores that the reason for having an "effective date" is precisely to set a *different* date for applying the statute than the date the revision is final. *See Date, Black's Law Dictionary* (12th ed. 2024). He argues that before 1993—when it was up to Congress to amend the Table—the date of the revision could only be the effective date. [Appellee's Br. at 45].

This too misreads the Act. Before § 300aa-14(e)(2) was enacted, the "date of the revision of the table" referred to by the savings clause (§ 300aa-16(b)) would not be the effective date, but the date that an Act amending the statutory table was signed into law or enacted over a veto. *Gozlon-Peretz v. United States,* 498 U.S. 395, 404 (1991) ("It is well

established that…a law takes effect on the date of its enactment"). Thus, the usage of separate terms within § 300aa-16(b) reflects Congress' recognition of the opposite of the Secretary's conclusion: a Table revision could well occur on a different day than the effective date.

VI. The Secretary's remaining arguments lack merit.

A. The legislative "redress" the Secretary argues for would not relieve Mr. Brundage's injuries.

The Secretary argues that Mr. Brundage's injury "can only be redressed through the enactment of new legislation." [Appellee's Br. at 25]. This contention does not survive scrutiny. It relies on the Secretary's false premises to support an alternative path for relief that, when examined, proves empty.

The unstated corollary to this argument is that once a tax is passed, Mr. Brundage's injuries suddenly become redressable in court. However, the Secretary has not explained why, if Congress' action precedes Table additions, it imposed a deadline dating from a CDC recommendation[16] rather than from an excise tax. This inconsistency

[16] 42 U.S.C. § 300aa-14(e)(2),

with Congress' textual choice indicates his interpretation of the Act is flawed.

In addition to contradicting the statutory text, the Secretary's interpretation provides Mr. Brundage no redress. Passing an excise tax in no way relieves the harms caused by the Secretary's inaction: the vaccine remains off the Table; Mr. Brundage's VICP eligibility remains unlawfully delayed; the savings clause clock remains ticking; and the procedure for expanding coverage remains incomplete.

B. Defendant's argument that Congress is responsible for Mr. Brundage's injuries fails.

The Secretary's statement that the harm Mr. Brundage alleges is "attributable to Congress, not the Secretary" lacks merit. [Appellee's Br. at 19]. The District Court and, until now, the Secretary, considered Mr. Brundage's injuries sufficiently traceable to him, [*see* ECF 24 at 5], yet he now claims he is not the cause of Mr. Brundage's harm. [Appellee's Br. at 19]. His brief does not explain this theory, which must rely on his second false premise: that this suit concerns compensation under the Vaccine Act rather than timely administrative action.

Congress has not violated the Vaccine Act; the Secretary has. [Complaint, ¶ 2]. Congress determined that the Secretary should *not* be

allowed to delay coverage for persons injured by new vaccines. 42 U.S.C § 300aa-14(e)(2). Yet he has. [Complaint, ¶ 3]. The harms of that unlawful delay, rather than any action by Congress, underlie this suit. [Complaint, ¶¶ 2, 5-7]. Traceability was explained in Appellant's Br. at 21-22. There is no colorable argument that Congress is somehow responsible for the Secretary's dereliction of a Congressional command.

CONCLUSION

The Secretary's arguments against Mr. Brundage's standing to compel addition of the COVID vaccine to the Table are built on false premises. Because the Vaccine Act does not allow the Secretary to wait longer than two years to do so, and because Mr. Brundage's suit concerns the Secretary's failure to act rather than Mr. Brundage's vaccine injury, all the Secretary's arguments supporting the District Court's dismissal fail. Wherefore, Mr. Brundage requests this Court reverse the dismissal of his suit and remand for consideration on the merits.

Dated: August 14, 2026

Respectfully Submitted,

/s/Grant D. Godfrey

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CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This document complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B)(ii) because excluding the parts of the brief exempted by Fed. R. App. P. 32(f), it consists of 6,302 words.
2. This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced, serif typeface using Microsoft Word's 14-point Century Schoolbook font.

Dated: August 14, 2026

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CERTIFICATE OF SERVICE

I hereby certify that on August 14, 2026, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the CM/ECF system. Counsel in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Grant D. Godfrey
Grant D. Godfrey
Counsel for Plaintiff-Appellant

ORAL ARGUMENT NOT YET SCHEDULED

No. 26-5004

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

PAUL BRUNDAGE,
Plaintiff-Appellant

v.

ROBERT F. KENNEDY, JR.,
Secretary, United States Department
of Health and Human Services,
Defendant-Appellee

Appeal from the United States District Court
for the District of Columbia
Hon. Sparkle L. Sooknanan, No. 1:25-cv-00119-SLS

ADDENDUM TO APPELLANT'S REPLY BRIEF

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**Lead Counsel for Plaintiff-Appellant*

August 14, 2026

ADDENDUM TABLE OF CONTENTS

(iv) any other publicly or privately funded program.

(8) Noneconomic damages

In an action under subsection (d), any noneconomic damages may be awarded only in an amount directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff. For purposes of this paragraph, the term "noneconomic damages" means damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses.

(9) Rule 11 sanctions

Whenever a district court of the United States determines that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure in an action under subsection (d), the court shall impose upon the attorney, law firm, or parties that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which may include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorney's fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

(10) Interlocutory appeal

The United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction of an interlocutory appeal by a covered person taken within 30 days of an order denying a motion to dismiss or a motion for summary judgment based on an assertion of the immunity from suit conferred by subsection (a) or based on an assertion of the exclusion under subsection (c)(5).

(f) Actions by and against the United States

Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law, including any provision of chapter 171 of Title 28 (relating to tort claims procedure).

(g) Severability

If any provision of this section, or the application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of this section and the application of such remainder to any person or circumstance shall not be affected thereby.

(h) Rule of construction concerning National Vaccine Injury Compensation Program

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 subchapter XIX of this chapter.

United States Government Accountability Office
Office of the General Counsel

PRINCIPLES OF FEDERAL APPROPRIATIONS LAW

Chapter 2
The Legal Framework

Fourth Edition
2016 Revision

This document, in conjunction with GAO, *Principles of Federal Appropriations Law*, 4th ed., 2016 rev., ch. 1, GAO-16-463SP (Washington, D.C.: Mar. 2016), supersedes chapters 1, 2, and 3 of GAO, *Principles of Federal Appropriations Law*, 3rd ed., GAO-04-261SP (Washington, D.C.: Jan. 2004). Chapters 4 through 15 of the third edition of *Principles of Federal Appropriations Law,* in conjunction with GAO, *Principles of Federal Appropriations Law: Annual Update to the Third Edition*, GAO-15-303SP (Washington, D.C.: Mar. 2015), remain the most currently available material on the topics discussed therein. Both *Principles* and the *Annual Update to the Third Edition* are available at www.gao.gov/legal/redbook/redbook.html.

- Prompted by the growth of "backdoor spending,"[15] it enhanced the role of the Appropriations Committees in reviewing proposals for contract authority, borrowing authority, and mandatory entitlements. 2 U.S.C. § 651.

The 1974 legislation also imposed limitations on the impounding of appropriated funds by the executive branch. 2 U.S.C. §§ 681–688.

2. Executive Budgeting: the Budget and Accounting Act, 1921

With this as an historical backdrop, the first step in the life cycle of an appropriation is the long and exhaustive administrative process of budget preparation and review, a process that may well take place several years before the budget for a particular fiscal year is ready to be submitted to Congress. The primary participants in the process at this stage are the agencies and individual organizational units, which review current operations, program objectives, and future plans, and the Office of Management and Budget (OMB),[16] which coordinates and formulates a consolidated budget submission.

Throughout this preparation period, there is a continuous exchange of information among the various federal agencies, OMB, and the President, including revenue estimates and economic outlook projections from the Treasury Department, the Council of Economic Advisers, the Congressional Budget Office, and the Departments of Commerce and Labor.

The President must submit his budget request to Congress on or before the first Monday in February of each year, for use during the following

[15] The term "backdoor spending" is a collective designation for authority provided in legislation other than appropriation acts to obligate the government to make payments. The most common forms of backdoor spending are borrowing authority, contract authority, and entitlement authority. *See* GAO, *A Glossary of Terms Used in the Federal Budget Process*, GAO-05-734SP (Washington, D.C.: Jan. 2005). From the perspective of the appropriations committees, funding provided by these forms of authority causes their funding control to "sneak out" legislative "back doors."

[16] Part 1 of Reorganization Plan No. 2 of 1970 (84 Stat. 2085), designated the former Bureau of the Budget as OMB and transferred all the authority vested in the Bureau and its director to the President. By Executive Order No. 11541, July 1, 1970, the President in turn delegated that authority to the Director of OMB. OMB's primary functions include assistance to the President in the preparation of the budget and the formulation of the fiscal program of the government, supervision and control of the administration of the budget, centralized direction in executive branch financial management, and review of the organization and management of the executive branch.

fiscal year. 2 U.S.C. § 631.[17] Numerous statutory provisions, the most important of which are 31 U.S.C. §§ 1104–1109, prescribe the content and nature of the materials and justifications that must be submitted with the President's budget request. Specific instructions and policy guidance are contained in OMB Circular No. A-11.

3. Congressional Budgeting: the Congressional Budget Act of 1974

The next phase in the life cycle of an appropriation is sometimes referred to as "congressional budgeting." Under the Congressional Budget Act, Congress must agree on governmentwide budget totals. A timetable for congressional budget action is set forth in 2 U.S.C. § 631, with further detail in sections 632–656. Key steps in that timetable are summarized below.[18]

February 15. The Congressional Budget Office submits to the House and Senate Budget Committees its annual report required by 2 U.S.C. § 602(e). The report contains the Congressional Budget Office's analysis of fiscal policy and budget priorities.

Within 6 weeks after President submits a budget request, or at such time as may be requested by the Committee on the Budget. Each congressional committee with legislative jurisdiction submits to the appropriate Budget Committee its views and estimates on spending and revenue levels for the following fiscal year on matters within its jurisdiction. 2 U.S.C. § 632(d). The House and Senate Budget Committees then hold hearings and prepare their respective versions of a concurrent resolution, which is intended to be the overall budget plan against which individual appropriation bills are to be evaluated.

April 15. Congress completes action on the concurrent resolution, which includes a breakdown of estimated new budget authority and outlays for

[17] Section 1105(a) of title 31 of the United States Code states the requirement for a presidential budget submission slightly differently than 2 U.S.C. § 631: "On or after the first Monday in January but not later than the first Monday in February of each year, the President shall submit a budget of the United States Government for the following fiscal year."

[18] Some useful references discussing the congressional budget process are: GAO, *A Glossary of Terms Used in the Federal Budget Process*, GAO-05-734SP (Washington, D.C.: Sept. 2005), at Appendix I (Overview of the Development and Execution of the Federal Budget), Appendix II (Federal Budget Formulation and Appropriations Processes); GAO, *Budget Process: Evolution and Challenges,* GAO/T-AIMD-96-129 (July 11, 1996); and Committee on the Budget, United States Senate, *The Congressional Budget Process, An Explanation,* S. Print No. 105-67 (revised Dec. 1998).

General Explanations
of the
Administration's Revenue Proposals

Department of the Treasury
February 1995

REDUCE VACCINE EXCISE TAXES

Current Law

The Vaccine Injury Compensation Program provides compensation for individuals who suffer certain injuries following the administration of the following vaccines: diphtheria, pertussis, and tetanus (DPT); diphtheria and tetanus (DT); measles, mumps, and rubella (MMR); and polio. Compensation is paid from the Vaccine Injury Compensation Trust Fund (Vaccine Trust Fund), which is funded by net revenues from a manufacturer's excise tax on DPT, DT, MMR, and polio vaccines. The excise tax per dose is $4.56 for DPT, $0.06 for DT, $4.44 for MMR, and $0.29 for polio vaccines. A vaccine for measles only, mumps only, or rubella only is taxed at the full MMR rate.

The Vaccine Injury Compensation Program provides compensation for adverse reactions to a vaccine only if the vaccine is included in the Vaccine Injury Table prescribed by the Department of Health and Human Services and is subject to the vaccine excise tax.

Reasons for Change

The Vaccine Trust Fund is overfunded. At the end of FY 1994 the trust fund balance was $809 million and, at current tax rates, transfers to the trust fund will continue to exceed outlays by over $50 million per year. While the current trust fund balance is an appropriate reserve against any unexpected increase in awards, future transfers to the trust fund should be brought in line with expected outlays by a reduction in the tax.

It is expected that *haemophilis influenzae* type b (Hib) and hepatitis type B (Hep B) vaccines, which are now routinely recommended for administration to children, will be added to the Vaccine Injury Table before the end of 1995. Those vaccines should also be added to the list of taxed vaccines.

Proposal

The Administration will submit a proposal to restructure the vaccine excise taxes. Revenues from these taxes will be reduced to approximately half the amounts expected under current law.

Revenue Estimate (in billions of dollars)[1]

	Fiscal Years						
	1995	1996	1997	1998	1999	2000	Total
Reduce vaccine excise taxes	0	-0.1	-0.1	-0.1	-0.1	-0.1	-0.3

[1] Net of income tax offset.

I

119TH CONGRESS
1ST SESSION

H. R. 1432

To prohibit any Federal law from making the manufacturer of a COVID–19 vaccine immune from suit or liability, or limiting the liability of such a manufacturer, with respect to claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a COVID–19 vaccine, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 18, 2025

Mr. ROY (for himself, Mr. MASSIE, Mr. BRECHEEN, Mr. CLOUD, Mr. HIGGINS of Louisiana, Mr. CRANE, Mr. GOSAR, and Mr. PERRY) introduced the following bill; which was referred to the Committee on the Judiciary

---

A BILL

To prohibit any Federal law from making the manufacturer of a COVID–19 vaccine immune from suit or liability, or limiting the liability of such a manufacturer, with respect to claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a COVID–19 vaccine, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Let Injured Americans Be Legally Empowered Act'' or the ''LIABLE Act''.

SEC. 2. NO FEDERAL IMMUNITY FROM, OR LIMITATION ON, LIABILITY FOR MANUFACTURERS FOR LOSS CAUSED BY A COVID–19 VACCINE.

(a) IN GENERAL.—No Federal law, including sections 319F–3, 2111, and 2122 of the Public Health Service Act (42 U.S.C. 247d–6d, 300aa–11, 300aa–22), may make the manufacturer of a COVID–19 vaccine immune from suit or liability, or limit the liability of such a manufacturer, with respect to claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a COVID–19 vaccine.

(b) RULE OF CONSTRUCTION.—Nothing in this Act shall be construed to prohibit an individual from seeking compensation through the Countermeasures Injury Compensation Program under section 319F–4 of the Public Health Service Act (42 U.S.C. 247d–6e) or the National Vaccine Injury Compensation Program under subtitle 2 of title XXI of such Act (42 U.S.C. 300aa–10 et seq.).

(c) RELATION TO OTHER PROGRAMS.—An individual shall not be precluded from bringing a civil action for claims described in subsection (a) on the basis of such individual having sought or received compensation through the Countermeasures Injury Compensation Program

under section 319F–4 of the Public Health Service Act (42 U.S.C. 247d–6e) or the National Vaccine Injury Compensation Program under subtitle 2 of title XXI of such Act (42 U.S.C. 300aa–10 et seq.).

(d) DEFINITION.—The term ''COVID–19 vaccine'' means a vaccine licensed or otherwise authorized by the Food and Drug Administration to prevent, mitigate, or limit—

(1) the harm from COVID–19; or

(2) the transmission of SARS–CoV–2 or a virus mutating therefrom.

(e) RETROACTIVE APPLICABILITY.—This Act applies without regard to whether the adminstration or use of a COVID–19 vaccine occurs before, on, or after the date of enactment of this Act.

○

I

119TH CONGRESS
2D SESSION

H. R. 9672

To amend the Public Health Service Act to make updates to the Vaccine Injury Compensation Program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 14, 2026

Mr. DOGGETT (for himself and Mr. SMUCKER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Public Health Service Act to make updates to the Vaccine Injury Compensation Program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Vaccine Injury Compensation Modernization Act of 2026".

SEC. 2. CHANGES TO VACCINE INJURY COMPENSATION PROGRAM.

(a) SPECIAL MASTERS.—

(B) by inserting ", including recommendations on whether additional special masters are needed to ensure an expeditious and fair resolution of petitions or otherwise improve the Program" after "in the Program".

(b) RECOMMENDATIONS FROM CDC.—Section 2114(e)(2) of the Public Health Service Act (42 U.S.C. 300aa–14(e)(2)) is amended—

(1) in the matter preceding subparagraph (A)—

(A) by striking "routine administration to children" and inserting "administration to children, adults, or pregnant women"; and

(B) by striking "within 2 years of" and inserting "within 6 months of"; and

(2) in subparagraph (A), by striking "routine administration to children" and inserting "administration to children, adults, or pregnant women".

(c) INCREASE IN COMPENSATION.—

(1) COMPENSATION FOR DEATH.—Section 2115(a)(2) of the Public Health Service Act (42 U.S.C. 300aa–15(a)(2)) is amended to read as follows:

"(2) In the event of a vaccine-related death, an award of $600,000.".

(2) COMPENSATION FOR PAIN AND SUFFERING.—Section 2115(a)(4) of the Public Health Service Act (42 U.S.C. 300aa–15(a)(4)) is amended to read as follows:

"(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $600,000.".

(d) INCREASE STATUTE OF LIMITATIONS.—Section 2116(a)(2) of the Public Health Service Act (42 U.S.C. 300aa–16(a)(2)) is amended by striking "36 months" and inserting "5 years".

(e) PROGRAM INTEGRITY.—

(1) INCLUDING MEDICAL RECORDS IN PETITIONS.—Section 2111(a)(2)(A) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(2)(A)) is amended, in the matter preceding clause (i), by inserting "that includes the medical records and other information required under subsection (c) (including, if applicable, an identification of unavailable records and explanation of unavailability pursuant to subsection (c)(3))" after "unless a petition".

(2) DECISION TIMING FOR SPECIAL MASTERS.—Section 2112(d)(3)(A)(ii) of the Public Health Service Act (42 U.S.C. 300aa–12(d)(3)(A)(ii)) is amended by striking "the petition was filed" and inserting

Dated: November 4, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–27006 Filed 11–8–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Addition to the Vaccine Injury Table to Include All Vaccines Against Seasonal Influenza

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Through this notice, the Secretary of the U.S. Department of Health and Human Services (the Secretary) announces that all FDA-approved vaccines against seasonal influenza are covered under the National Vaccine Injury Compensation Program (VICP), which provides a system of no-fault compensation for certain individuals who have been injured by covered childhood vaccines. Prior to this publication, trivalent influenza vaccines were included under Category XIV on the Vaccine Injury Table (Table) and will continue to be listed in that category. This notice serves to include all vaccines against seasonal influenza (not already covered under Category XIV) as covered vaccines under Category XVII of the Table (new vaccines covered under the VICP). This notice ensures that petitioners may file petitions relating to all vaccines against seasonal influenza (not already covered under the VICP) with the VICP even before such vaccines are added as a separate and distinct category to the Table through rulemaking.

DATES: This notice is effective on November 12, 2013. As described below, all vaccines against seasonal influenza (except trivalent influenza vaccines, which are already covered under the VICP) will be covered under the VICP on November 12, 2013.

FOR FURTHER INFORMATION CONTACT: Vito Caserta, M.D., M.P.H., Acting Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number (301) 443–5287.

SUPPLEMENTARY INFORMATION: The statute authorizing the VICP provides for the inclusion of additional vaccines in the VICP when they are recommended by the Centers for Disease Control and Prevention (CDC) to the Secretary for routine administration to children. See section 2114(e)(2) of the Public Health Service (PHS) Act, 42 U.S.C. 300aa–14(e)(2). Consistent with section 13632(a)(3) of Public Law 103–66, the regulations governing the VICP provide that such vaccines will be included as covered vaccines in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines (42 CFR 100.3(c)(5)).

By way of background, trivalent influenza vaccines (meaning they each contain three vaccine virus strains which are thought most likely to cause disease outbreaks during the influenza season) are routinely given to millions of individuals in the United States each year. Trivalent influenza vaccines include an inactivated (killed) virus vaccine administered using a syringe as well as a live, attenuated product administered in a nasal spray. All trivalent vaccines have been covered under the VICP since July 1, 2005. On April 12, 2005, the Health Resources and Services Administration (HRSA) published a notice in the **Federal Register** announcing that such vaccines were covered under the category for new vaccines on the Table. See 70 FR 19092. Subsequently, the Secretary engaged in rulemaking to add trivalent influenza vaccines as a separate category on the Table (category XIV on the Table). See 76 FR 36367.

Since that time, quadrivalent influenza vaccines (meaning that they contain four vaccine virus strains which are thought most likely to cause disease outbreaks during the influenza season) have been approved by the Food and Drug Administration (FDA), and such vaccines are expected to be administered as an alternative to trivalent influenza vaccines during the upcoming and future flu seasons. On June 25, 2013, Public Law 113–15 was enacted, extending the applicable excise tax on trivalent influenza vaccines to also include any other vaccines against seasonal influenza. See Public Law 113–15 (amending 26 U.S.C. § 4132(a)(1)(N)).

The amendment included in Public Law 113–15 ensures that all FDA-approved seasonal influenza vaccines, including quadrivalent influenza vaccines, and other new seasonal influenza vaccines are covered under the VICP. Under the regulations governing the VICP, Category XVII of the Table specifies that ''[a]ny new vaccine recommended by CDC for routine administration to children, after publication by the Secretary of a notice of coverage'' is a covered vaccine under the Table (42 CFR 100.3(a), Item XVII). As explained in HRSA's notice of coverage with respect to the coverage of trivalent influenza vaccines, the CDC recommended in its May 28, 2004, issue of the Morbidity and Mortality Weekly Report (MMWR) that influenza vaccines be routinely administered to children between 6 and 23 months of age because children in this age group are at an increased risk for complications from influenza. That recommendation extends to seasonal influenza vaccines beyond trivalent vaccines. The latest CDC update of its annual influenza vaccination recommendation was published in the MMWR on September 20, 2013. MMWR 2013;62, No. 7. This report updated the 2012 recommendations by the CDC and its Advisory Committee on Immunization Practices regarding the use of influenza vaccines for the prevention and control of seasonal influenza. Routine annual influenza vaccination is recommended for all persons aged 6 months and older. For the 2013–14 influenza season, it is expected that trivalent live attenuated influenza vaccine (LAIV3) will be replaced by a quadrivalent LAIV formulation (LAIV4). Inactivated influenza vaccines (IIVs) will be available in both trivalent (IIV3) and quadrivalent (IIV4) formulations. No preferential recommendation was made for one influenza vaccine product over another for persons for whom more than one product is otherwise appropriate.

This notice serves to satisfy the regulation's publication requirement. Through this notice, all vaccines against seasonal influenza (beyond trivalent influenza vaccines, which are already covered under Category XIV on the Table) are included as covered vaccines under Category XVII of the Table (new vaccines).

Under section 2114(e) of the PHS Act, as amended by section 13632(a) of the Omnibus Budget Reconciliation Act of 1993, coverage for a vaccine recommended by the CDC for routine administration to children shall take effect upon the effective date of the tax enacted to provide funds for compensation with respect to the vaccine included as a covered vaccine in the Table. Under Public Law 113–15, the excise tax for vaccines against seasonal influenza (beyond trivalent influenza vaccines) ''shall apply to sales and uses on or after the later of: (A) The first day of the first month which begins more than 4 weeks after the date of the enactment of this Act [i.e., Pub. L. 113–

15]; or (B) the date on which the Secretary of Health and Human Services lists any vaccines against seasonal influenza (other than any vaccine against seasonal influenza listed by the Secretary prior to the date of the enactment of this Act) for purposes of compensation for any vaccine-related injury or death through the Vaccine Injury Compensation Trust Fund.'' Public Law 113–15, § 1. The law further provides that if the vaccines were sold before or on the effective date of the excise tax, but delivered after this date, the delivery date of such vaccines shall be considered the sale date. *Id.*

Under this statutory language, the effective date of the excise tax for seasonal influenza vaccines other than trivalent influenza vaccines is the later of August 1, 2013 (which is the first day of the first month beginning more than 4 weeks after the effective date of Public Law 113–15, which was June 25, 2013), or the date on which the Secretary publishes a notice of coverage under the VICP for seasonal influenza vaccines not previously covered under the VICP. This publication is the notice referred to in the latter requirement. Because this publication is made after August 1, 2013, the effective date of coverage for all vaccines against seasonal influenza (beyond trivalent influenza vaccines, which are already covered by the VICP) is the effective date of this publication, November 12, 2013.

Petitions filed concerning vaccine-related injuries or deaths associated with all vaccines against seasonal influenza vaccines must be filed within the applicable statute of limitations. The filing limitations applicable to petitions filed with the VICP are set out in section 2116(a) of the PHS Act (42 U.S.C. 300aa–16(a)). In addition, section 2116(b) of the PHS Act lays out specific exceptions to these statutes of limitations that apply when the effect of a revision to the Table makes a previously ineligible person eligible to receive compensation or when an eligible person's likelihood of obtaining compensation significantly increases. Under this provision, persons who may be eligible to file petitions based on the addition of a new category of vaccines under Category XVII of the Table may file a petition for compensation not later than 2 years after the effective date of the revision if the injury or death occurred not more than 8 years before the effective date of the revision of the Table (42 U.S.C. 300aa–16(b)). Thus, persons whose petitions may not be timely under the limitations periods described in section 2116(a) of the PHS Act, may still file petitions concerning vaccine-related injuries or deaths associated with seasonal influenza vaccines (with the exception of trivalent influenza vaccines that are already covered under the VICP) until November 12, 2015, as long as the vaccine-related injury or death occurred on or before November 12, 2021 (8 years prior to the effective date of the addition of non-trivalent seasonal influenza vaccines as covered vaccines).

The Table will be amended through subsequent rulemaking to include all vaccines against seasonal influenza in place of only trivalent influenza vaccines under Category XIV of the Table. Once that is done, the Table's coverage provisions (codified at 42 CFR 100.3(c)) will explain that trivalent influenza vaccines are included on the Table as of July 1, 2005, and that other seasonal influenza vaccines are included on the Table as of November 12, 2013.

Dated: November 5, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–26992 Filed 11–8–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Virology—A Study Section, October 03, 2013, 08:30 a.m. to October 04, 2013, 05:30 p.m., Embassy Suites Baltimore—Downtown, 222 St. Paul Place, Baltimore, MD which was published in the **Federal Register** on September 17, 2013, 78 FR 180 Pgs. 57169–57170.

The meeting will start on December 16, 2013 at 9:00 a.m. and end December 17, 2013 at 5:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: *November 5, 2013.*

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–26894 Filed 11–8–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Allergy and Infectious Diseases Special Emphasis Panel, October 10, 2013, 09:00 a.m. to October 10, 2013, 03:00 p.m., National Institutes of Health, 6700 B Rockledge Drive, 3137, Bethesda, MD, 20892 which was published in the **Federal Register** on September 16, 2013, 78 FR 56904.

The meeting notice is amended to change the date of the meeting from October 10, 2013 to December 5, 2013. The meeting is closed to the public.

Dated: November 5, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–26906 Filed 11–8–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; Heart, Lung, and Blood Program Project Review Committee.

Date: December 6, 2013.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jeffrey H Hurst, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7208, Bethesda,