No. 20-_____

IN THE

# Supreme Court of the United States

ROBERT DAVID DUPUCH-CARRON
AND ELIZABETH JOANNA CARRON,

*Petitioners,*

*v.*

XAVIER BECERRA, SECRETARY OF
HEALTH AND HUMAN SERVICES,

*Respondent.*

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**ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

## PETITION FOR A WRIT OF CERTIORARI


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## QUESTIONS PRESENTED FOR REVIEW

1. Does the ordinary meaning of the words of section 11(c)(1)(B)(i)(III) of the National Childhood Vaccine Injury Act (the NCVIA or "Vaccine Act"), 42 USC § 300aa-11(c)(1)(B)(i)(III), require that a person who received a covered vaccine outside of the United States be a resident of the United States in order to be eligible to seek compensation under that section of the Vaccine Act?

2. Does the ordinary meaning of the words in section 11(c)(1)(B)(i)(III) of the National Childhood Vaccine Injury Act (the NCVIA or "Vaccine Act"), 42 USC § 300aa-11(c)(1)(B)(i)(III), require that a person who received a covered vaccine outside of the United States had been present in the United States "While living and breathing outside of his mother's body" before receiving that vaccine in order to satisfy Section 11(c)(1)(B)(i)(III)'s requirement that the person "returned to the United States not later than six months after the date of " the vaccination received outside of the United States?

## PARTIES TO THE PROCEEDING

The parties to this proceeding are:

Elizabeth Joanna Carron;

Robert David Dupuch-Carron;

and

Xavier Becerra, Secretary of Health and Human Services.

Elizabeth Joanna Carron and Robert David Dupuch-Carron filed the National Childhood Vaccine Injury Act claim that is the basis of this proceeding as the legal representatives of their minor son, A.R.D-C., and amended the caption of the case to reflect the fact that they brought the claim as the legal representatives of the estate of their minor son, A.R.D-C., after A.R.D-C's death. *See* 42 USC § 300aa-11(a)(1) and 42 USC § 300aa-15(a)(2).

## RELATED CASES

*Dupuch-Carron v. Sec'y of Health and Human Services*, No. 17-vv-1551, U. S. Court of Federal Claims, Office of Special Masters. Judgment entered September 13, 2019.

*Dupuch-Carron v. Sec'y of Health and Human Services*, No. 17-vv-1551, U. S. Court of Federal Claims. Judgment entered September 13, 2019.

*Dupuch-Carron v. Sec'y of Health and Human Services*, No. 20-1137, U. S. Court of Appeals for the Federal Circuit. Judgment entered August 11, 2020.

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## PETITION FOR A WRIT OF CERTIORARI

Robert David Dupuch-Carron and Elizabeth Joanna Carron respectfully petition for a writ of certiorari to review the order of the United States Court of Appeals for the Federal Circuit in this case.

## CITATIONS OF THE OPINIONS ENTERED IN THE CASE

1. The citation to the United States Court of Appeals for the Federal Circuit's Opinion is:

> *Dupuch-Carron v. Sec'y of Health and Hum. Servs.*, 969 F.3d 1318 (Fed. Cir. 2020).

The Opinion of the United States Court of Appeals for the Federal Circuit is Appendix A and is located at pages 1a through 30a of the Appendix.

2. The Order of the United States Court of Appeals for the Federal Circuit denying the Petitions for Panel Rehearing and Rehearing *En Banc* is unreported. It is Appendix D and is located at pages 78a through 79a of the Appendix.

3. The citation to the Memorandum Decision of Judge Richard A. Hertling, of the United States Court of Federal Claims, is:

> *Dupuch-Carron v. Sec'y of Health & Hum. Servs.*, 144 Fed. Cl. 659 (2019).

The Memorandum Decision of Judge Richard A. Hertling is Appendix B and is located at pages 31a through 49a of the Appendix.

4. The citation to the Decision of Special Master Thomas L. Gowen, of the United States Court of Federal Claims, Office of Special Masters, that dismissed the Petitioners' National Childhood Vaccine Injury Act claim is:

> *Dupuch-Carron v. Sec'y of Health & Hum. Servs.*, No. 17-1551V, 2019 WL 2263369, 2019 U.S. Claims LEXIS 578 (Fed. Cl. Spec. Mstr. Apr. 23, 2019).

The Decision of Special Master Thomas L. Gowan in Appendix C and is located at pages 50a through 77a of the Appendix.

## BASIS FOR JURISDICTION

The Petitioners ask the Court to review the Opinion and Judgment entered by the United States Court of Appeals for the Federal Circuit on August 11, 2020.

The Petitioners' Petitions for Panel Rehearing and Rehearing *En Banc* were denied by the United States Court of Appeals for the Federal Circuit on November 19, 2020.

This Court's March 19, 2020 order addressing the public health concerns related to COVID-19 extended the time within which a party may file a petition for writ of certiorari to 150 days from the date of the lower court's

judgment, order denying discretionary review, or order denying a timely petition for rehearing.

The Petitioners believe that 28 USC § 1254(1) confers the Court jurisdiction to review the Opinion and Judgment entered in this case on a writ of certiorari.

## STATUTORY PROVISIONS INVOLVED

The case involves section 11(c)(1)(B)(i)(III) of the National Childhood Vaccine Injury Act (the NCVIA or the "Vaccine Act"). 42 USC § 300aa-11(c)(1)(B)(i)(III). The relevant provisions of the statute read:

> (c) Petition content. A petition for compensation under the Program for a vaccine-related injury or death shall contain -
>
> (1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died -
>
> (A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,
>
> (B)
>
> (i) if such person received a vaccine set forth in the Vaccine Injury Table -

> (I) received the vaccine in the United States or in its trust territories,
>
> (II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or
>
> **(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination.**
>
> (ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen, . . . .

42 USC §§ 300aa-11(c)(1)(A) and (B) (emphasis added).

## STATEMENT OF THE CASE

This case presents the question of whether a child[1] who receives a vaccination covered by the National Childhood Vaccine Injury Act (the NCVIA or "Vaccine

1. Or the parents of a child who dies as a result of a vaccine related injury.

Act") is eligible to seek compensation through the National Vaccine Injury Compensation Program under section 11(c)(1)(B)(i)(III) of the Act, 42 USC § 300aa-11(c)(1)(B)(i)(III), if:

1) He was not a resident of the United States when he received the vaccination outside of the United States; and

2) His only pre-vaccination presence in the United States was as a child in utero when his mother visited the United States.

The Petitioners' son, A.R.D-C., developed a life-threatening autoimmune disease of the blood, hemophagocytic lymphohistiocytosis (HLH), two weeks after receiving eight vaccinations at his pediatrician's clinic in Nassau, The Bahamas, on July 23, 2016 and died as a result of a complication to the treatment that he received for that disease on December 24, 2017.

The Petitioners filed a claim for compensation through the National Vaccine Injury Compensation Program, 42 USC § 300aa-11 *et seq*, on A.R.D-C.'s behalf while he was alive and amended that claim to a claim for compensation for A.R.D-C.'s death after his death.

### 1. Facts Material to the Consideration of the Questions Presented

A.R.D-C. was born in Nassau, The Bahamas, on November 24, 2015. Before his birth, his mother, Elizabeth Carron, frequently visited the United States. She first learned that she was pregnant with A.R.D-C. at a doctor's visit in Coral Gables, Florida. She continued to visit the

United States during her pregnancy.

Robert David Dupuch-Carron was born in the United States. A.R.D-C'.s paternal grandmother owned a condominium in Coral Gables, Florida.

A.R.D-C. was healthy and developing normally until he received eight vaccines at his pediatrician's office in Nassau, The Bahamas, on June 23, 2016, at the age of 7 months. The vaccines that A.R.D-C. received on June 23, 2016 are listed in the "Vaccine Injury Table" of the NCVIA.

A.R.D-C. developed a fever on July 6, 2016. By July 9, 2016, A.R.D-C.'s fever had climbed to 107.1 degrees Fahrenheit and he had developed petechiae (small bruises) on his hands and legs. The fever and petechiae were the first symptoms of secondary hemophagocytic lymphohistiocytosis (HLH), an autoimmune disease of the blood that is fatal if not successfully treated.

A.R.D-C. was flown to Miami, Florida, for treatment of his illness on July 13, 2016 and was admitted to Miami Children's Hospital. A.R.D-C.'s doctors successfully treated his HLH, and he began outpatient recovery at his family's condominium in Coral Gables, Florida. A.R.D-C. spent most of the remainder of his life in the United States.

The treatment for HLH is chemotherapy that has many potential complications, including acute myeloid leukemia (AML). Unfortunately, in January of 2017, A.R.D-C. developed treatment related AML as a result of the chemotherapy. On August 17, 2017 he underwent an allogenic bone marrow transplant at John Hopkins

Children's Hospital in Baltimore, Maryland. On October 12, 2017, A.R.D-C.'s treatment related AML relapsed. A.R.D-C. died as a result of treatment related AML on December 24, 2017, in Baltimore, Maryland.

### 2. Basis for Federal Jurisdiction

Claims for compensation through the National Vaccine Injury Compensation Program are heard by the Office of Special Masters of the United States Court of Federal Claims. 42 USC § 300aa-12(a). If a party is unsatisfied with the decision of the special master deciding a case, the party can file a Motion for Review by a judge of the United States Court of Federal Claims. 42 USC § 300aa-12(e). The United States Court of Appeals for the Federal Circuit has jurisdiction to review the final judgement of the United States Court of Federal Claims under 42 USC § 300aa-12(f).

The Court of Federal Claims issued its final judgement in this case on September 13, 2019. The Petitioners (A.R.D-C.'s parents) filed their Notice of Appeal on November 7, 2019. That appeal was timely under 42 USC § 300aa-12(f).

## REASONS FOR GRANTING THE WRIT OF CERTIORARI

The Petitioners, Robert David Dupuch-Carron and Elizabeth Joanna Carron, have alleged that their son (A.R.D-C.) died as a result of an illness caused by the eight vaccines that he received when he was 7 months old. Although A.R.D-C. received the vaccines in The Bahamas, the vaccines were manufactured by manufacturers

located in the United States and covered by the National Childhood Vaccine Injury Act (the NCVIA or the "Vaccine Act").[2]

The Court of Appeals for the Federal Circuit denied the Petitioners eligibility to seek compensation for the death of their son though the National Childhood Vaccine Injury Act because: 1) Their son (A.R.D-C.) was not a resident of the United States when he received the vaccinations outside of the United States; and 2) Their son's (A.R.D-C.'s) only pre-vaccination presence in the United States was as a child in utero when his mother visited the United States.

Nothing in the ordinary meaning of the words of the NCVIA can be reasonably interpreted as restricting access to the National Vaccine Injury Compensation Program in this manner.

The statute allows a person who has received a vaccination covered by the NCVIA outside of the United States[3] to seek compensation through the National Vaccine Injury Compensation Program if that person was injured by a covered vaccine (or died as a result of injuries caused by a covered vaccine) and that person:

> **"received the vaccine outside the United States or a trust territory and the vaccine was**

2. The vaccines were covered by the NCVIA because they are listed in the Act's "Vaccine Injury Table." 42 USC § 300aa-14(a); 42 CFR § 100.3(a).

3. And the legal representatives of the estate of a person who dies as a result of an injury associated with a covered vaccine.

> **manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination."**

42 USC § 300aa-11(c)(1)(B)(i)(III) (emphasis added).

The Petitioners ask the Court to review the decision of the United States Court of Appeals for the Federal Circuit because: 1) The court of appeals' decision decided an important question of federal law that has not been but should be decided by this Court; and 2) The court of appeals' decision decided an important federal question in a way that conflicts with relevant decisions of the Court, specifically with this Court's decisions in *Sebelius v. Cloer*, 569 U.S. 369 (2013) and *Bostock v. Clayton County*, ___ U.S. ___, 140 S.Ct. 1731 (2020).

## I.

## The Ordinary Meaning of the Words of Section 11(c)(1)(B)(i)(III) of the NCVIA Does Not Limit Access to the National Vaccine Injury Compensation Program to *Persons Who Were Residents of the United States* When They Received a Covered Vaccine Outside of the United States

The NCVIA allows some persons who receive a covered vaccine outside of the United States to receive compensation through the Act. 42 USC § 300aa-11(c)(1)(B)(i)(III). The words of the Act explicitly set out the conditions under which a person who receives a vaccine outside of the United States can seek compensation under that section of the Act.

The words of the Act require that: 1) The vaccine that the person received "was manufactured by a vaccine manufacturer located in the United States;" and 2) The person "returned to the United States not later than 6 months after the date of the vaccination." 42 USC § 300aa-11(c)(1)(B)(i)(III). Nothing more.

The words of the Act do not require that the person who received a covered vaccine outside of the United States be a resident of the United States.

The decision of the United States Court of Appeals for the Federal Circuit *added a requirement* that the person who received a covered vaccine outside of the United States *be a resident of the United States* when he or she received the vaccine to Section 300aa-11(c)(1)(B)(i)(III). The court of appeals decision says:

> "We surmise that Congress, in enacting this section, intended to provide protection for persons who (1) previously resided in the United States, where they were subject to United States vaccination programs, (2) were temporarily away from the United States when they received the vaccination, and (3) 'returned to the United States' within six months with the intention of resuming residence therein."

969 F.3d 1318, 1332-1333 (Fed. Cir. 2020).

The residency requirement imposed by the court of appeals is based on the court of appeals' opinion of how Congress *should have* limited access to the Program. Nothing in the words of the statute can be reasonably interpreted as imposing a residency requirement.

The question of whether eligibility for compensation through the National Vaccine Injury Compensation Program under Section 300aa-11(c)(1)(B)(i)(III) of the NCVIA requires that persons who receive a covered vaccine outside of the United States be residents of the United States is an important question of federal law that has not been, but should be, settled by this Court. You should grant the petition for writ of certiorari to address that question.

An interpretation of the NCVIA that adds a requirement that is not set out in the words of the Act conflicts with this Court's decisions in *Bostock v. Clayton County,*___ U.S. ___, 140 S. Ct. 1731 (2020), and *Sebelius v. Cloer,* 569 U.S.369 (2013). You should grant the petition for writ of certiorari to resolve that conflict.

### A. The NCVIA Defines the Conditions Under Which a Person Who Receives a Covered Vaccine Outside of the United States Can Receive Compensation Through the Act

Section 300aa-11(c)(1)(B)(i)(III) of the NCVIA allows a person who may have been injured by a vaccine[4] that is listed on the Vaccine Injury Table to seek compensation under the Act if he or she:

> "(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer

4. The Vaccine Act also allows the legal representative of any person who has died as the result of the administration of a vaccine covered by the Act to seek compensation if the person who received the vaccine would have been eligible to seek compensation. 42 USC § 300aa-11(b) (1)(A).

> located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination."

42 USC § 300aa-11(c)(1)(B)(i)(III).

The words of the NCVIA require that a person who received a vaccine outside of the United States: 1) received a "vaccine manufactured by a vaccine manufacturer located in the United States;" and 2) "returned to the United States not later than 6 months after the date of vaccination." Nothing more.

The words of the NCVIA do not impose a residency requirement. Had Congress intended to include a residency requirement in Section 300aa-(c)(1)(B)(i)(III) it would have used words that explicitly imposed a residency requirement. For example, the words of Section 300aa-11(c)(1)(B)(i)**(II)** require that a person who receives a vaccine outside of the United States **be a citizen of the United States** and that the person received the vaccine while **"serving abroad as a member of the Armed Forces or otherwise as an employee of the United States** or a dependent of such a citizen." 42 USC § 300aa-11(c)(1)(B)(i)(II) (emphasis added).

The court of appeals' decision adds a specific and detailed residency requirement to Section 11(c)(1)(B)(i)(III) of the NCVIA. That requirement denies access to the National Vaccine Injury Compensation Program under Section11(c)(1)(B)(i)(III) to any person who: (1) Had not "previously resided in the United States, where they were subject to United States vaccination programs"; (2) Was not "temporarily away from the United States when they

received the vaccination" outside of the United States; or (3) Had not "'returned to the United States' within six months with the intention of resuming residency therein." *Dupuch-Carron v. Sec'y of Health and Hum. Servs*, 969 F.3d 1318, 1332-1333 (Fed. Cir. 2020).

The very specific residency requirements set out in the court of appeals' decision are not set out in the words of Section 11(c)(1)(B)(i)(III). They are not suggested by the legislative history of the NCVIA or any other extratextual source. They are, instead, based entirely on the court of appeal's subjective belief of who should be — and who should not be — eligible to seek compensation through the NCVIA.

### B. The Court of Appeals' Decision Conflicts with This Court's Decisions in *Bostock v. Clayton County* and *Sebelius v. Cloer* Because It *Adds* a Residency Requirement to Section 11(c)(1)(B)(i)(III) of the NCVIA

The court of appeals' imposition of a residency requirement was contrary to the United States Supreme Court's decisions in *Bostock v. Clayton County*, ___ U.S. ___, 140 S. Crt.1731 (June 15, 2020), and *Sebelius v. Cloer*, 569 U.S.369 (2013).

#### 1. *Bostock v. Clayton County.*

Your decision in *Bostock v. Clayton County*, ___ U.S. ___, 140 S. Crt.1731 (June 15, 2020), held that only the words of a statute are the law. Your opinion explained:

> "When the express terms of a statute give us one answer and extratextual considerations

> suggest another, it's no contest. *Only the written word is the law, and all persons are entitled to its benefit.*"

that:

> 'This Court normally interprets a statute in accord with the ordinary public meaning of its terms at the time of its enactment. After all, only *the words on the page constitute the law adopted by Congress and approved by the President.* If judges could add to, remodel, update, or detract from old statutory terms inspired only by extratextual sources and our own imaginations, we would risk amending statutes outside the legislative process reserved for the people's representatives."

and that:

> "This Court has explained many times over many years that, when the meaning of the statute's terms is plain, our job is at an end. *The people are entitled to rely on the law as written, without fearing that courts might disregard its plain terms based on some extratextual consideration.*"

*Bostock v. Clayton County*, ___ U.S. ___, 140 S. Crt.1731 at 1737, 1738, and 1749 (June 15, 2020) (emphasis added).

The court of appeals' decision **adds** to the words of the NCVIA, amending the Act outside the legislative process in a way which severely restricts the Act's application

to persons who receive covered vaccines outside of the United States.

Your decision in *Bostock* prohibits judges from adding requirements to a statute based on "extratextual sources" or their "own imaginations." By adding to the words of the NCVIA, the court of appeals' decision denied the Petitioners the right to rely on the law as written. Their claim for compensation through the NCVIA was denied because it did not meet the court of appeals' opinion of who should be eligible to seek compensation, not because their claim failed to meet the requirements **written by Congress.**

You should grant the petition for writ of certiorari to correct the court of appeals' error and articulate an interpretation of section 11(c)(1)(B)(i)(III) of the NCVIA that relies on the ordinary meaning of the words in the statute.

### 2. *Sebelius v. Cloer.*

The court of appeals' decision is also contrary to the clear rule of law set out in your decision in *Sebelius v. Cloer,* 569 U.S.369 (2013).

The words of the NCVIA allow a special master to award attorney's fees incurred in "any proceeding on" a "petition filed under Section 300aa-11" of the NCVIA. 42 USC § 300aa-15(e)(1)(3), 569 U.S. at 376. In *Cloer,* the Secretary of Health and Human Services argued that an award of attorney's fees was not available to an unsuccessful petitioner unless the petitioner had filed his or her claim within the Act's statute of limitations. 569 U.S. 369 at 371-372, 377.

In a unanimous decision, you rejected the Secretary's argument because the plain language of the NCVIA did not limit the award of attorney's fees to cases in which the petition had been filed within the Act's statute of limitations. 569 U.S.369 at 376-377.

The Court's opinion explained that:

> "Nothing in these two provisions [Sections 300aa-15(e)(1)(3) and 300aa-11] suggests that the reason for the subsequent dismissal of a petition, such as untimeliness, nullifies the initial filing of that petition. We have explained that '[a]n application is 'filed,' as that term is commonly understood, when it is delivered to, and accepted by, the appropriate court officer for placement into the official record. [citation omitted]. When this ordinary meaning is applied to the text of the statute, it is clear that an NCVIA petition which is delivered to the clerk of the court, forwarded for processing, and adjudicated in a proceeding before a special master is a 'petition filed under section 300aa-11.' 42 USC §300aa-15(e)(1). And so long as such a petition was brought in good faith and with a reasonable basis, it is eligible for an award of attorney's fees, even if it is ultimately unsuccessful. *Ibid.* If Congress had intended to limit fee awards to timely petitions, it could have easily done so. But the NCVIA instead authorizes courts to award attorney's fees for those unsuccessful petitions 'brought in good faith and [for which] there is a reasonable basis. *Ibid.*"

569 U.S. 369 at 376-377.

This Court held that adding the requirement that an unsuccessful petition be filed within the NCVIA's statute of limitations was inconsistent with both the NCVIA and the established rules of statutory construction. 569 U.S. 369 at 376-377, 380.

It might have seemed reasonable to require that an unsuccessful petition be filed within the statute of limitations in order to garner an award of attorney's fees. However, the words of the NCVIA did not impose that requirement. In *Cloer* this Court held that because the words of the NCVIA did not require that an unsuccessful petition be filed within the statute of limitations, Congress did not intend to impose that requirement.

That a residency requirement seemed reasonable to the court of appeals did not empower the court to add a residency requirement to Section 11(c)(1)(B)(i)(III). It was up to Congress to determine what requirements to include in the words of the law. If Congress had intended to limit eligibility to seek compensation under Section 11(c)(1)(B)(i)(III) to residents of the United States, **the words in Section 11(c)(1)(B)(i)(III) would have done so.**

You should grant the petition for writ of certiorari to correct the court of appeals' error and articulate an interpretation of section 11(c)(1)(B)(i)(III) of the NCVIA that does not require that a person who receives a vaccine outside of the United States be a resident of the United States in order to seek compensation through the NCVIA.

## II.

### The Ordinary Meaning of the Words of Section 11(c)(1)(B)(i)(III) of the NCVIA Does Not Limit Access to the National Vaccine Injury Compensation Program to Persons *Who Had Been Present in the United States "While Living and Breathing Outside Their Mother's Body"* Before They Received a Covered Vaccine Outside of the United States

Section 11(c)(1)(B)(i)(III) of the NCVIA allows persons who receive a covered vaccine outside of the United States to receive compensation through the Act if: 1) The vaccine that they received was manufactured by a vaccine manufacturer located in the United States; and 2) They "returned to the United States not later than 6 months after the date of the vaccination." 42 USC § 300aa-11(c)(1)(B)(i)(III).

The NCVIA does not specify what kind of *prior presence* in the United States is required to make a subsequent entry into the United States a "return" to the United States.

The United States Court of Appeals for the Federal Circuit held that a person could not "return" to the United States for the purposes of Section 11(c)(1)(B)(i)(III) unless he or she had been present in the United States "while living and breathing outside of his mother's body" before receiving the vaccination related to his or her injury. 969 F.3d at 1328.

The court of appeals' conclusion that a person who received a vaccination outside of the United States must

have been present in the United States while "outside of his mother's body" at some point prior to receiving that vaccination in order to qualify to seek compensation under section 11(c)(1)(B)(i)(III) is inconsistent with the words of the NCVIA and the two primary purposes for the NCVIA: stabilizing the vaccine market (by protecting vaccine manufacturers from civil liability for vaccine related injuries) and expediting compensation for persons who may have been injured by covered vaccines.

The question of whether eligibility for compensation through the National Vaccine Injury Compensation Program under Section 11(c)(1)(B)(i)(III) of the NCVIA requires that a person who receives a covered vaccine outside of the United States had been present in the United States "while living and breathing outside of his mother's body" at some point prior to receiving that vaccination is an important question of federal law that has not been, but should be, settled by this Court. You should grant the petition for writ of certiorari to address that question.

### A. Section 11(c)(1)(B)(i)(III) Does Not Limit the Kind of Pre-Vaccination Presence in the United States that Makes a Post-Vaccination Entry into the United States a "Return" to the United States.

Section 11(c)(1)(B)(i)(III) of the NCVIA allows persons who receive a vaccine listed in the Vaccine Injury Table to seek compensation through the Act if the person who received the vaccine outside of the United States satisfies the requirements of that section.

The NCVIA provides that a person can seek compensation if:

> "(i) **if such person received a vaccine set forth in the Vaccine Injury Table** -
>
> . . . .
>
> (III) **received the vaccine outside the United States** or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States **and such person returned to the United States not later than 6 months after the date of the vaccination."**

42 USC § 300aa-11(c)(1)(B)(i)(III) (emphasis added).

Section 11(c)(1)(B)(i)(III) does not require that the **person who "received the vaccine outside the United States"** had been previously present in the United States **as a "person."**

The ordinary meaning of the words in section 11(c)(1)(B)(i)(III) does not define — or limit — what kind of prior presence in the United States makes a post-vaccination entry into the United States a "return" to the United States.

### B. The Primary Purposes of the NCVIA Were to Stabilize the Market for Childhood Vaccines and to Compensate Persons Injured by Rare Vaccine Related Injuries

The NCVIA is a remedial statute, *Cloer v. Sec'y of Health and Hum. Servs.*, 675 F.3d 1358, 1362 (Fed. Cir.

2012), and as such should be interpreted in a manner which advances the remedial purpose of the statute. *Cloer v. Sec'y of Health and Hum. Servs.*, 675 3.3d at 1362, *see also Atchison, Topeka, & Santa Fe Ry. Co, v Buell*, 480 U.S. 557, 561-562 (1987).

The two primary purposes for the NCVIA were to stabilize the market for childhood vaccines by protecting vaccine manufacturers and administrators "located in the United States" from civil liability for vaccine related injuries and to compensate persons injured as a result of rare vaccine related injuries. *Sebelius v. Cloer*, 569 U.S. 369, 272 (2013); *Bruesewitz v Wyeth, LLC,* 562 U.S. 223, 228-230 (2011); *see also* H.R. Rep. No. 99-908, 99th Cong. 2d Sess., pt.1, pages 7, 12-13 (Sept. 26, 1986) *reprinted in* 1986 U.S. Code Cong. Admin. News 6344, pages 6348, 6353-54.

The legislative history of the NCVIA says that Congress meant it to create a "generous" compensation system, *Bruesewitz v. Wyeth*, 562 U.S. at 228-230, 238; H.R. Rep. No. 99-908, pages 3, 12, that would **divert persons injured by covered vaccines from product liability and medical malpractice litigation by awarding compensation to injured persons.** H.R. Rep. No. 99-908, page 13.

### C. The Court of Appeals Denied A.R.D-C. and His Parents Access to the NCVIA because A.R.D-C.'s Pre-Vaccination Presence in the United States Was as a Child Who Was In Utero when His Mother Visited the United States

The court of appeals held that A.R.D-C., and therefore his parents, were not eligible to seek compensation

because A.R.D-C. had not "returned to the United States" after his June 23, 2016 vaccinations.

This holding was based on two conclusions: 1) That A.R.D-C. was not a "person" as the term is used in the NCVIA when he was present in the United States while in utero; and 2) That in order to be eligible to seek compensation under Section 11(c)(1)(B)(i)(III) of the NCVIA a person who receives a vaccination outside of the United States must have been present in the United States **as a person** at some point before receiving that vaccination. 969 F.3d at 1328.

### D. The Court of Appeals' Interpretation of Section 11(c)(1)(B)(i)(III) is Inconsistent with the Ordinary Meaning of the Words of the NCVIA

The ordinary meaning of the words in the NCVIA does not limit eligibility to seek compensation under section 11(c)(1)(B)(i)(III) to persons who had been present in the United States while outside their mother's body before receiving that vaccination.

The words of the Act require that the person "received a vaccine outside of the United States" and that he or she received a vaccine "manufactured by a vaccine manufacturer located in the United States." If a person satisfies **those two requirements,** he or she is eligible to seek compensation under Section 11(c)(1)(B)(i)(III) if he or she returns to the United States not later than six months after receiving the vaccine.

The words of the NCVIA do not require that the person who "received the vaccine outside of the United

States" be "**a *person* who was present in the United States**" at some point before receiving the vaccine. The Act does not define — or limit — the kind of pre-vaccination presence required to satisfy Section 11(c)(1)(B)(i)(III).

The term "person" in Sections 11(c)(1)(B)(i) and in 11(c)(1)(B)(i)(III) is applied to the "*person who received a vaccine*" and the person who "*received the vaccine outside of the United States.*" It does not, therefore, apply to the person **before** receiving a vaccine.

### E. The Court of Appeals' Interpretation of Section 11(c)(1)(B)(i)(III) Undermines the Primary Purposes of the NCVIA

The two primary purposes for the NCVIA are to protect vaccine manufacturers and administrators "located in the United States" from civil liability for vaccine related injuries and to compensate persons injured as a result of rare vaccine related injuries. *Sebelius v. Cloer*, 569 U.S. at 272 (2013); *Bruesewitz v Wyeth, LLC*, 562 U.S. at 228-230 (2011). The legislative history of the NCVIA says that Congress meant it to create a "generous" compensation system that would divert persons injured by covered vaccines from product liability and medical malpractice litigation ***by awarding compensation to injured persons***. H.R. Rep. No. 99-908, pages 3, 7, and 12- 13.

The court of appeals' interpretation of Section 11(c)(1)(B)(i)(III) undermines both of these purposes by: 1) Expanding the exposure of "vaccine manufacturers located in the United States" to civil liability for vaccines administered outside of the United States; and 2)

Narrowing the population of vaccine-injured persons who are eligible to seek compensation.

### F. The Court of Appeals' Interpretation of Section 11(c)(1)(B)(i)(III) Is Inconsistent with Section 11(f) of the NCVIA

The court of appeals' interpretation of Section 11(c)(1)(B)(i)(III) is also at odds with the most recent amendment to the NCVIA — the "Maternal Immunization" provisions added to the NCVIA by the 21st Century Cures Act. 42 USC § 300aa-11(f).

#### 1. The maternal immunization provisions of the NCVIA recognize children who were in utero when their mothers received a vaccine as persons who received a vaccine

The maternal immunization provisions of the NCVIA explicitly recognize children who were in utero when their mothers received a covered vaccine as persons who received a vaccination for the purposes of the NCVIA. 42 USC § 300aa-11(f).

The maternal immunization provisions of the NCVIA serve the purposes of the original NCVIA by: 1) Protecting vaccine manufacturers from civil liability for vaccine related injuries which occur in utero; and 2) Providing compensation to children who were injured by vaccines while in utero. *See Rooks v. Sec'y of Health and Hum. Servs.,* 35 Fed. Cl. 1, 4-5, 9-10 (January 29, 1996); *Melton v. Sec'y of Health & Hum. Servs.*, 2002 U.S. Claims LEXIS 385 at *1-2, *5-9, 2002 WL 229781 (Fed. Cl. Spec. Mstr., July 3, 2002); and *Burch v. Sec'y of Health & Hum.*

*Servs.*, 2010 U.S. Claims LEXIS 154 at *4-5, *22-29, 2010 WL 1676767 (Fed. Cl. Spec. Mstr., April 9, 2010).

### 2. The court of appeals relied on the maternal immunization provisions of the NCVIA to deny A.R.D-C access to the National Vaccine Injury Compensation Program

The court of appeals relied on Section 11(f) — and the definition of "child" in 1 USC § 8 that is incorporated in it — for its conclusion that a child who is in utero when his or her mother visits the United States is not a "person" who is present in the United States and that a pre-vaccination in utero presence in the United States is insufficient to make a post-vaccination entry into the United States a "return" to the United States. 969 F.3d at 1325-1328

### 3. The court of appeals' reliance on Section 11(f) of the NCVIA and 1 USC § 8 to *limit* the access of the NCVIA was inconsistent with the plain language and purpose of Section 11(f) of the NCVIA and 1 USC § 8

The court of appeals reliance on Section 11(f) of the NCVIA and 1 USC § 8 to *limit* the access to the compensation provided by the NCVIA was inconsistent with the plain language and purpose of Section 11(f) of the NCVIA and inconsistent with 1 USC § 8.

Section 11(f) reads:

> **"(f) Maternal immunization.**
>
> (l) In general. Notwithstanding any other provision of law, for purposes of this subtitle

> [ 42 USCS §§ 300aa-10 et seq.], both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.
>
> (2) Definition. **As used in this subsection, the term 'child' shall have the meaning given that term by subsections (a) and (b) of [section 8 of title I, United States Code]**, except that, for purposes of this subsection, such section 8 shall be applied as if the term "include" in subsection (a) of such section were replaced with the term 'mean.' "

42 USC § 300aa-11(f) (emphasis added).

Section 1 of Title 8 of the United States Code defines the word "person" to "include every infant member of the species homo sapiens who is born alive at any stage of development." 1 USC § 8(a).

Section 8(c) specifies that:

> **"Nothing in this section shall be construed to** affirm, **deny,** expand, or contract **any legal status or right** applicable to any member of the species homo sapiens at any point prior to being 'born alive' as defined in this section."

1 USC § 8(c) (emphasis added).

The words of 1 USC Section 8 clearly say that its definition of "person" shall not be construed to deny "any legal status or right applicable to any member of the species homo sapiens at any point prior to being 'born alive' . . ."

The court of appeals disregarded the plain words of 1 USC § 8 — and, therefore, Section 11(f) of the NCVIA — when it denied A.R.D-C. access to the National Vaccine Injury Compensation Program because his pre-vaccination presence in the United States was while in utero.

### G. A.R.D-C. Was a "Person" When He Received His June 23, 2016 Vaccinations and When He Returned to the United States for Medical Care on July 13, 2016

A.R.D-C. had been "born alive" and was therefore a "person" under 1 USC § 8(a)'s definition when he received vaccines listed on the Vaccine Injury Table at his doctor's office in the Bahamas on June 23, 2016.

Section 11(c)(1)(B)(i)(III) of the NCVIA makes any "person" who receives a vaccine outside of the United States eligible for compensation if he or she returns to the Unites States no later than six months after receiving the vaccine.

A.R.D-C. was, therefore, a **person** who "received a vaccine outside of the United States" for the purposes of Section 11(c)(1)(B)(i)(III) of the NCVIA as of June 23, 2016. As a person who had received vaccines outside of the United States, all A.R.D-C. needed to do to be eligible

to seek compensation though the National Vaccine Injury Compensation Program was to "return to the United States not later than 6 months after receiving" those vaccines.

A.R.D-C. was flown to the United States for treatment of his vaccine-related illness on July 13, 2016. Under a correct interpretation of Section 11(c)(1)(B)(i)(III) that entry into the United States would have been enough to satisfy the requirement that he return to the United States.

Under the court of appeals' interpretation of Section 11(c)(1)(B)(i)(III) A.R.D-C.'s July 13, 2016 entry into the United States was not a "return" to the United States because he had not been in the United States **"as a person"** before receiving his June 23, 2016 vaccinations.

The court of appeals' interpretation of Section 11(c)(1)(B)(i)(III) disregarded the ordinary meaning of Section 11(c)(1)(B)(i)(III) — which required only that A.R.D-C. be a "person" when he received the vaccines outside of the United States. It also disregarded the clear prohibition in 1 USC § 8(c) against denying any legal status or right applicable to any member of the species homo sapiens at any point prior to being "born alive."

Whatever his legal status (that is, whether he was a "person" or not) A.R.D-C. was present in the United States before his June 23, 2016 vaccinations, so his July 13, 2016 trip to the United States was a "return" to the United States.

You should grant the petition for writ of certiorari to correct the court of appeals error and articulate an interpretation of Section 11(c)(1)(B)(i)(III) of the NCVIA that does not deny access to the National Vaccine Injury Compensation Program to children whose pre-vaccination presence in the United States was while in utero.

## CONCLUSION

You should grant this petition for a writ of certiorari in order to review the United States Court of Appeals for the Federal Circuit's decision and correct its erroneous interpretation of Section 11(c)(1)(B)(i)(III) of the National Childhood Vaccine Injury Act.

Respectfully submitted.

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# APPENDIX

**APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, DATED AUGUST 11, 2020**

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ROBERT DAVID DUPUCH-CARRON, ELIZABETH JOANNA CARRON, AS THE LEGAL REPRESENTATIVES OF THEIR MINOR SON, A. R. D-C.,

*Petitioners-Appellants,*

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

*Respondent-Appellee.*

2020-1137

Appeal from the United States Court of Federal Claims in No. 1:17-vv-01551-RAH, Judge Richard A. Hertling.

August 11, 2020, Decided

Before PROST, *Chief Judge*, CLEVENGER and STOLL, *Circuit Judges.*

*Appendix A*

CLEVENGER, *Circuit Judge.*

Appellants Robert David Dupuch-Carron and Elizabeth Joanna Carron, husband and wife, are the legal representatives of the estate of their deceased infant son, A.R. D-C. Appellants filed an action seeking compensation for injuries allegedly compensable under the National Vaccine Injury Compensation Act, 42 U.S.C. §§ 300aa-1 et seq. ("the Vaccine Act"). Appellants asserted standing to seek compensation pursuant to 42 U.S.C. § 300aa—11(c)(1)(B)(i)(III), which grants standing to a person who "received [a covered] vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination." On the parties' cross-motions for summary judgment, the Special Master ruled that Appellants are ineligible to seek compensation under the Vaccine Act, granted the Secretary of the Department of Health & Human Services' (the "Government" or "HHS") motion, and dismissed the petition. *See Dupuch-Carron v. Sec'y of Health & Hum. Servs.*, No. 17-1551V, 2019 U.S. Claims LEXIS 578, 2019 WL 2263369 (Fed. Cl. Apr. 23, 2019). Appellants filed a motion for review with the United States Court of Federal Claims ("the Claims Court") pursuant to 42 U.S.C. § 300aa-12(e). The Claims Court denied Appellants' motion for review. *See Dupuch-Carron v. Sec'y of Health & Hum. Servs.*, 144 Fed. Cl. 659 (2019). For the reasons discussed herein, we affirm.

*Appendix A*

**Background**

## I. Facts

Appellants were domiciled in Nassau, The Bahamas, for the entirety of the time period relevant to this case. Mrs. Carron is a citizen of the United Kingdom and avers that she is a "frequent visitor to the United States," spending "10 to 12 long weekends" in the country each year. *Dupuch-Carron*, 144 Fed. Cl. at 660. During a trip to Coral Gables, Florida from March 24 to April 3, 2015, Mrs. Carron visited an internist, who informed her that she was pregnant. After learning of her pregnancy, she claims to have traveled to the United States an additional four times while pregnant.

Mr. Dupuch-Carron was born in the United States. He appears to have grown up in The Bahamas but recalls "spen[ding] a great deal of time [in the United States] as a child during the summer holidays." *Id.* (alteration in original). Mr. Dupuch-Carron also avers that he is a "frequent visitor to the United States," spending "between 30 and 45 days in the United States on business" in a typical year. *Id.*

Mr. and Mrs. Dupuch-Carron's son, A.R. D-C., was born on November 24, 2015, at Doctors Hospital in Nassau, The Bahamas. He continued to live in Nassau for the first six months of his life. During that time, A.R. D-C. had unremarkable well-child visits at his pediatric center in Nassau, and was considered to be healthy and developing normally. He also received his first two sets of vaccinations in Nassau, with no apparent adverse consequences.

*Appendix A*

On June 23, 2016, during his six-month well-child visit to his pediatrician in Nassau, A.R. D-C. received his third set of vaccinations, which included the DTap, IPV, HIB, HBV, Prevnar, and rotavirus vaccinations. There is no dispute that the eight vaccines A.R. D-C. received during his June 23rd visit to the pediatrician are listed in the Vaccine Injury Table and were manufactured by companies with a presence in the United States.

On July 7, 2016 and July 9, 2016, A.R. D-C. presented at the pediatrician with complaints of a fever greater than 102 degrees Fahrenheit, crankiness, stuffy nose, rattling in his chest, occasional chesty coughs, reduced activity, vomiting, and diarrhea. A.R. D-C.'s parents brought him to the emergency room at Doctors Hospital in Nassau on July 10, 2016 with complaints of fever and vomiting for five days, irritability, and decreased appetite. The doctors determined he had thrombocytopenia and pancytopenia for which he received a blood transfusion, and febrile neutropenia for which he was given an intravenous antibiotic. On July 11, 2016, A.R. D-C. was transferred to the intensive care unit at Princess Margaret Hospital in Nassau, where a pediatric hematologist-oncologist recommended he be transferred to an institution "equipped to enable quick turn around and confirmation of the leukemia if present." *Dupuch-Carron*, 144 Fed. Cl. at 661.

Physicians in The Bahamas determined that A.R. D-C. would receive better treatment in the United States, and on July 13, 2016, A.R. D-C. was transferred by air ambulance to Nicklaus Children's Hospital in Miami, Florida, where he was diagnosed with hemophagocytic

lymphohis-tiocytosis ("HLH"). HLH is an autoimmune disease of the blood, fatal unless treated successfully. A.R. D-C. was treated at Nicklaus Children's Hospital until he was discharged on August 12, 2016, "on the condition he remain in Florida as an outpatient." *Id.*

A.R. D-C. received weekly treatment as an outpatient at Nicklaus Children's Hospital. A.R. D-C. was cleared to leave the United States over the Christmas season, so the family returned to The Bahamas. On February 28, 2017, A.R. D-C. was readmitted to Nicklaus Children's Hospital. He was diagnosed with acute myeloid leukemia ("AML"). A.R. D-C. underwent treatment, which included chemotherapy and radiation at Cincinnati Children's Hospital in Cincinnati, Ohio, as well as a bone-marrow transplant at Johns Hopkins Bloomberg Children's Hospital in Baltimore, Maryland.

On October 17, 2017, Appellants filed a petition under the Vaccine Act. On December 24, 2017, A.R. D-C. died from AML, and on March 26, 2018, Appellants filed an amended petition, alleging that the AML, which caused A.R. D-C.'s death, was a complication resulting from the treatment he had received for his vaccine-induced HLH.

## II. Procedural History

In Vaccine Act cases, the Claims Court and its special masters have jurisdiction over proceedings to determine if a petitioner under § 300aa–11 is entitled to compensation and the amount of such compensation. 42 U.S.C. § 300aa–12(a).

*Appendix A*

Prior to the filing of the amended petition, the Special Master in this case identified, as a threshold question, the issue of whether Appellants were eligible for compensation under the Vaccine Act because the vaccines were administered outside of the United States. The Special Master directed the parties to file cross-motions for summary judgment on that limited issue.

On March 26, 2018, concurrent with their filing of the amended petition, Appellants filed a Motion for Partial Summary Judgment on the limited issue of their eligibility under the Vaccine Act for compensation. Specifically, Appellants argued that A.R. D-C. "returned," under that term's plain meaning of "go back," to the United States within 6 months of receiving his vaccinations as required by 42 U.S.C. § 300aa–11(c)(1)(B)(i)(III). Appellants, citing the maternal immunization amendment to the Vaccine Act as support, argued that A.R. D-C.'s initial entrance into the United States occurred while *in utero*, and that A.R. D-C.'s "return" to the United States occurred when he traveled to Florida seeking medical treatment for HLH within 6 months of receiving his vaccinations.

On June 7, 2018, the Government filed a Cross-Motion for Summary Judgment on that threshold issue. The Government argued that "the recent maternal immunization amendment to the Vaccine Act establishes that a child *in utero* can 'receive' a vaccine but it does not establish that the child *in utero* was 'present' in the United States for purposes of a later 'return.'" *Dupuch-Carron*, 2019 U.S. Claims LEXIS 578, 2019 WL 2263369, at *5. Specifically, the Government argued that: (1) 42

U.S.C. § 300aa–11(c)(1)(B)(i)(III) requires that a "person" "return" to the United States within six months of receiving a vaccination; (2) A.R. D-C.'s "mother's entries into the United States while pregnant do not mean that [he] was 'present' [as a person] in the United States prior to birth"; and (3) "A.R. D-C. was not present in the United States at any time between his birth and his vaccinations." *Id.* (internal citations omitted). Thus, according to the Government, because A.R. D-C. had never previously been in the United States as a "person," as required by the statute, his "post-vaccination entry into the United States cannot constitute a 'return.'" *Id.*

The Government also argued that even if A.R. D-C. is recognized as a "person" who was present in the United States while *in utero*, A.R. D-C. did not "return[] to the United States," under a proper interpretation of the phrase, within six months after the date of vaccination. Specifically, the Government argued that a court does not construe statutes in a vacuum, and the words of a statute, such as "return," must be read in their context and with a view to their place in the overall statutory scheme. As support, the Government cited to the Claims Court's decision in *McGowan v. Secretary of the Department of Health & Hum. Services*, which found that because "the word 'return' relies on its context in order to impart a sense of permanence, the plain meaning rule is not dispositive." 31 Fed. Cl. 734, 738 (1994). Instead, according to the *McGowan* court, the phrase "returned to the United States" was limited to persons who had previously lived in the United States and returned within six months of vaccination with the intention to remain permanently in the United States from that point on. *See id.* at 734-40.

Appellants filed their Response and Reply on July 12, 2018. On April 23, 2019, however, the Special Master denied Appellants' Motion and granted the Government's Motion. First, the Special Master found that while "Congress did expressly amend the Vaccine Act to permit a cause of action alleging that a child was injured by transplacental exposure to a vaccine administered to his or her mother (but only after that child was born alive)," "this amendment did not change the definition of child or person," which is limited to live-born members of the species *homo sapiens*. *Dupuch-Carron*, 2019 U.S. Claims LEXIS 578, 2019 WL 2263369, at *6. Thus, according to the Special Master, "A.R. D-C., while living and breathing outside of his mother's body, was never present in the United States before his vaccinations or the onset of his severe illness" and "his entrance to the United States, while within six months after the vaccinations at issue, cannot be construed as a 'return.'" *Id.* Second, the Special Master found that even if A.R. D-C. was viewed to be a person upon being carried *in utero* into the United States, there was not sufficient evidence that he would have "returned to the United States" within six months, as that phrase was construed in *McGowan*. 2019 U.S. Claims LEXIS 578, [WL] at *10.

On May 23, 2019, Appellants filed a Motion for Review of the Special Master's decision, asking the Claims Court to review and reverse the Special Master's decision. In the Motion for Review, Appellants raised the following objection:

> The special master's conclusion that the petitioners were not eligible to seek compensation

> from the National Vaccine Injury Compensation Program because their son [A.R. D-C.]: 1) could not be viewed as a person who was present in the United States prior to his vaccinations; and 2) had not returned to the United States within six months after vaccinations was not in accordance with the law.

*Dupuch-Carron*, 144 Fed. Cl. at 662.

The Government filed its Response to Appellants' Motion for Review on June 20, 2019, arguing that the Special Master's decision on Appellants' eligibility to seek compensation under the Vaccine Act was correct. With the Claims Court's leave, Appellants filed their Reply on July 5, 2019. The Claims Court heard oral argument on Appellants' Motion for Review on September 5, 2019.

The Claims Court issued its opinion under seal on September 10, 2019 and reissued it for public availability on September 25, 2019. With respect to the first issue, the Claims Court found that "[t]he Vaccine Act considers a child whose mother receives a vaccine while the child is *in utero* to be a 'person,'" and therefore assumed without deciding, for the purposes of its analysis, that A.R. D-C. was a "person" under the relevant portions of the Vaccine Act, with a prior presence in the United States. *Dupuch-Carron*, 144 Fed. Cl. at 664 n.12. Thus, before the Claims Court, the case turned on the second issue raised by Appellants—whether A.R. D-C.'s arrival for medical treatment constituted "return" for the purposes of the Vaccine Act's exception to its requirement that claimants be vaccinated in the United States.

While the Claims Court declined to adopt the more narrow reading of the statute advanced in *McGowan*, it nevertheless found that, "[i]n light of the silence in the legislative record and the presumptions attendant to the task of statutory interpretation in this case, [there is] nothing to suggest that Congress meant to cover foreign nationals arriving in the United States for the purpose of seeking medical treatment when it used the word 'return' in the Vaccine Act." *Id.* at 666. Accordingly, "[b]ecause A.R. D-C.'s entry into the United States to receive medical treatment did not fall within the more specific meaning of 'return to the United States'" laid out by the Claims Court, the court held that A.R. D-C. had "not satisfied the requirements under 42 U.S.C. § 300aa–11(c)(1)(B)(i)(III)," *id.* at 667, and denied Appellants' Motion for Review.

This appeal followed.

**Discussion**

This court has jurisdiction to review the final judgment of the Claims Court under 42 U.S.C. § 300aa–12(f). In Vaccine Act cases, we review the Claims Court's decision *de novo*, "applying the same standard of review as the Court of Federal Claims applied to its review of the special master's decision." *Griglock v. Sec'y of Health & Hum. Servs.*, 687 F.3d 1371, 1374 (Fed. Cir. 2012) (citation omitted); *see also Paluck v. Sec'y of Health & Hum. Servs.*, 786 F.3d 1373, 1378 (Fed. Cir. 2015). "We owe no deference to the trial court or the special master on questions of law, but we uphold the special master's findings of fact unless they are arbitrary or capricious." *Lozano v. Sec'y*

*of Health & Hum. Servs.*, 958 F.3d 1363, 1368 (Fed. Cir. 2020) (citing *Griglock*, 687 F.3d at 1374). "Thus, although we are reviewing as a matter of law the decision of the Court of Federal Claims under a nondeferential standard, we are in effect reviewing the decision of the Special Master under the deferential arbitrary and capricious standard on factual issues." *Griglock*, 687 F.3d at 1374 (internal citations omitted).

The Vaccine Act gives the Claims Court (and its special masters) jurisdiction "over proceedings to determine if a petitioner under section 300aa-11 of this title is entitled to compensation under the [Vaccine Injury Compensation] Program and the amount of such compensation." *Martin ex rel. Martin v. Sec'y of Health & Hum. Servs.*, 62 F.3d 1403, 1406 (Fed. Cir. 1995) (quoting 42 U.S.C. § 300aa–12(a) (Supp. V 1993)). "Section 300aa–11, in turn, sets out the rules governing petitions for compensation." *Id.*

The Vaccine Act, 42 U.S.C. § 300aa–11(c)(1)(B)(i), delimits the categories of persons who may pursue a claim under it. Pursuant to the relevant provision, the person seeking compensation under the Act must show that he or she:

> (I) received the vaccine in the United States or in its trust territories,
>
> (II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of

> the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or
>
> (III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination . . .

42 U.S.C. § 300aa–11(c)(1)(B)(i).

Appellants do not claim that either 42 U.S.C. § 300aa–11(c)(1)(B)(i)(I) or § 300aa–11(c)(1)(B)(i)(II) is applicable to this case. Therefore, the question before the court, as it was before the Claims Court and Special Master, is whether 42 U.S.C. § 300aa–11(c)(1)(B)(i)(III) allows Appellants, under the specific facts of this case, to apply for compensation under the Vaccine Act.

Section 300aa–11(c)(1)(B)(i)(III) limits compensation under the Vaccine Act to (1) persons who (2) returned to the United States not later than 6 months after the date of the vaccination. Accordingly, we address whether: (1) A.R. D-C. was a "person" who had previously been in the United States in order for any subsequent travel there to constitute a "return"; and (2) A.R. D-C. "returned to the United States" within 6 months after the date of his vaccinations.

## I. A.R. D-C. Was Not a "Person" Who Had Previously Been to the United States

The Claims Court found that "[t]he Vaccine Act considers a child whose mother receives a vaccine while the child is *in utero* to be a 'person,'" *Dupuch-Carron*, 144 Fed. Cl. at 664 n.12, and therefore assumed without deciding, for the purposes of its analysis, that A.R. D-C. was a "person" under the relevant portions of the Vaccine Act, with a prior presence in the United States. We review the Claims Court's decision *de novo* and find, for the reasons discussed below, that it misinterpreted the relevant language of the Vaccine Act and thus impermissibly assumed that a child *in utero* is a "person" under 42 U.S.C. § 300aa–11(c)(1)(B)(i)(III).

It is undisputed that A.R. D-C. was born in The Bahamas, resided in The Bahamas uninterrupted for his first six months of life, received the vaccinations at issue in The Bahamas, and did not enter the United States as a live born child until nearly three weeks after vaccination for the purpose of medical treatment. Nevertheless, a "person" who receives a vaccination outside of the United States is eligible to seek compensation through the Vaccine Act under Section 300aa–11(c)(1)(B)(i)(III) if he "returned to the United States" not later than six months after the date of vaccination. *See* 42 U.S.C. § 300aa–11(c)(1)(B)(i)(III). Appellants concede that "[i]mplicit in the word 'returned' is a requirement that the *person* had been present in the United States at some time before the vaccination." Appellants' Br. 43 (italics added). Thus, in order to show that A.R. D-C. "returned to the United

States," Appellants must first show that their child, A.R. D-C., was a "person [that] had been present in the United States" at some time before the vaccination. According to Appellants, A.R. D-C.'s prior presence in the United States *in utero* satisfies the relevant statute.

The definition of "person" and "child" applicable to "any Act of Congress," including the Vaccine Act, is "every infant member of the species homo sapiens who is born alive at any stage of development." 1 U.S.C. § 8(a). Though they acknowledge the definition's applicability, Appellants point out that 1 U.S.C. § 8(c) states, "[n]othing in this section shall be construed to affirm, deny, expand, or contract any legal status or legal right applicable to any member of the species homo sapiens at any point prior to being 'born alive.'" *See* Oral Arg. at 28:33-30:04, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=20-1137.mp3. And, based on the text of the Vaccine Act in view of cases involving transplacental exposure to a vaccine, and decisions interpreting the Social Security Act, Appellants argue that an unborn fetus is a "person" having an independent and legally significant presence under the Vaccine Act that cannot be denied or contracted by 1 U.S.C. § 8(a). *Id.* We disagree.

Appellants first allege that "[t]wo decisions from the Court of Federal Claims and a third from a special master have held that a child in utero is a 'person' for the purposes of the Vaccine Act." Appellants' Br. 46-47. In *Rooks v. Sec'y of Dep't of Health & Hum. Servs.*, *Melton v. Sec'y of Dep't of Health & Hum. Servs.*, and *Burch v. Sec'y of Dep't of Health & Hum. Servs.*—the opinions cited

by Appellants—the Claims Court and Special Masters were presented with the question of whether a child, whose mother received a vaccine while it was *in utero*, can be deemed to have also "received" the vaccine, such that they can petition for compensation under the Vaccine Act once born. *See Rooks v. Sec'y of Dep't of Health & Hum. Servs.*, 35 Fed. Cl. 1, 4 (1996) (stating "this case deals with the special master's legal determination of the meaning of 'received' under the Vaccine Act" and finding "that the potential to 'receive' a vaccine while in utero exists"); *Burch v. Sec'y of Dep't of Health & Hum. Servs.*, No. 99-946V, 2010 U.S. Claims LEXIS 154, 2010 WL 1676767 (Fed. Cl. Spec. Mstr. Apr. 9, 2010); *Melton v. Sec'y of Dep't of Health & Hum. Servs.*, No. 01-105V, 2002 U.S. Claims LEXIS 21, 2002 WL 229781 (Fed. Cl. Spec. Mstr. Jan. 25, 2002). These cases do not state or imply, however, that those *in utero* are themselves "persons" that have a separate legal presence while traveling abroad for purposes of determining eligibility to seek compensation through the Vaccine Act.

Appellants nevertheless allege that the 21st Century Cures Act's (the "Cures Act") amendment to the Vaccine Act,[1] which reflects those earlier decisions, "recognized and ratified the conclusion that a child in utero is a person for the purposes of the Vaccine Act." Appellants' Br. 51.

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1. In 2016, the 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033, 1152 (Dec. 13, 2016), amended the Vaccine Act to provide that "[a] covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child . . . who was *in utero* at the time such woman was administered the vaccine."

First, the Cures Act's amendment to the Vaccine Act—42 U.S.C. § 300aa–11(f)—did not amend the subsection concerning extraterritorial application of the Vaccine Act at issue here. Second, rather than make explicit the principle that a child *in utero* is a "person" for all purposes of the Vaccine Act, the statute makes clear that those whose mother received a vaccine while they were *in utero* do not have a cognizable claim under the Vaccine Act until they become a "person"—*i.e.* , "a member of the species homo sapiens who is born alive at any stage of development." *See* 42 U.S.C. § 300aa–11(f)(1); 1 U.S.C. § 8(a).

The amendment, which addresses "Maternal immunization," states:

> (1) In general
>
> Notwithstanding any other provision of law, for purposes of this part, both a woman who received a covered vaccine while pregnant and any child ***who was*** in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.
>
> (2) Definition
>
> As used in this subsection, the term "child" shall have the meaning given that term by subsections (a) and (b) of section 8 of Title 1,

> except that, for purposes of this subsection, such section 8 shall be applied as if the term "include" in subsection (a) of such section were replaced with the term "mean".

42 U.S.C. § 300aa–11(f) (emphasis added).

Appellants and the Claims Court have both interpreted 42 U.S.C. § 300aa–11(f)(1) as suggesting that a "child in utero" is a "person." *See Dupuch-Carron*, 144 Fed. Cl. at 664 n.12; Appellants' Reply Br. 16. They are mistaken. The first paragraph states that both a woman who received a covered vaccine and a child, who was previously *in utero* at the time such woman received the vaccine, are "persons" deemed to have received the vaccine. 42 U.S.C. § 300aa—11(f)(1). The second paragraph states that the term "child" shall retain the meaning given that term by subsections (a) and (b) of section 8 of Title 1. *Id.* As mentioned above, 1 U.S.C. § 8(a) states that "the words 'person', 'human being', 'child', and 'individual', shall [mean][2] every infant member of the species homo sapiens who is born alive[3] at

2. In accordance with 42 U.S.C. § 300aa–11(f)(2), "the term 'include' in subsection (a) of" 1 U.S.C.A. § 8 has been "replaced with the term 'mean.'"

3. "[T]he term 'born alive', with respect to a member of the species homo sapiens, means the complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion." 1 U.S.C. § 8(b).

any stage of development." 1 U.S.C. § 8(a). Thus, unlike other federal legislation in which Congress has explicitly bestowed special legal status upon children *in utero*,[4] 42 U.S.C. § 300aa–11(f) makes clear that the words "person" or "child," included therein, retain their 1 U.S.C. § 8(a) definition. Accordingly, only once it is born may a child whose mother received a vaccine while they were *in utero* be considered a "person" that has received the vaccine.

Appellants also argue that decisions addressing the status of a child *in utero* in the context of surviving child benefits under the Social Security Act support their claim that A.R. D-C. was present in the United States before birth under the Vaccine Act. The cases cited by Appellants dealt with the issue of whether an applicant met the statutory requirements to be considered a "child" of a deceased wage earner for purposes of child support under the Social Security Act. *See, e.g., Wagner v. Finch*, 413 F.2d 267, 268-69 (5th Cir. 1969) ("The crucial issue remaining is whether or not this child, conceived outside of marriage and born after her father's death, may nevertheless be deemed to be her father's child under 42 U.S.C.A. 416(h)(3) of the Act."). Section 8(a) of Title 1

4. For example, the Unborn Victims of Violence Act, 18 U.S.C. § 1841, applies to injurious acts committed against a child *in utero*, but, unlike 42 U.S.C. § 300aa–11(f), specifically includes its own definition of "unborn child" that does not incorporate or refer to the "born alive" language from 1 U.S.C. § 8's definition of "person" or "child" applicable to the Vaccine Act. *See* 18 U.S.C. § 1841(d) (2018) ("As used in this section, the term 'unborn child' means a child *in utero*, and the term 'child *in utero*' . . . means a member of the species homo sapiens, at any stage of development, who is carried in the womb.").

limits the term "child," as used in all acts of Congress, to those born alive. As Appellants previously pointed out, however, this definition should not be construed to affirm, deny, expand, or contract any legal status or legal right applicable to any member of the species homo sapiens at any point prior to being "born alive." 1 U.S.C. § 8(c). As such, it cannot abridge any legal status afforded to unborn children under the Social Security Act, which has its own, separate, definition of "child" that does not include any requirement that they be "born alive." *See* 42 U.S.C. § 416(e). As discussed above, no similar legal right applicable to fetuses exists under the Vaccine Act. For at least these reasons, we agree with the Government that the Social Security Act and its implementing regulations are entirely distinct and separate from the Vaccine Act, and the interpretation of the Social Security Act's language has no bearing on the language included in the Vaccine Act.

For the foregoing reasons, we hold that 1 U.S.C. § 8's definition of "person" applies to that term as it is used in the Vaccine Act. Accordingly, we find that the Claims Court's assumption that A.R. D-C. was a "person" with a prior presence in the United States was legally improper, and agree with the Special Master that A.R. D-C., while living and breathing outside of his mother's body, was never present in the United States before his vaccinations and, thus, that his entrance to the United States cannot be construed as a "return."

## II. A.R. D-C. Had Not "Returned to the United States" Within the Meaning of the Vaccine Act

Even if A.R. D-C. could be recognized as a "person" who was present in the United States before vaccination, and the Claims Court's assumption was correct, the parties still disagree as to whether A.R. D-C. "returned to the United States" within six months of his vaccinations. § 300aa–11(c)(1)(B)(i)(III). The Claims Court denied Appellants' Motion for Review after finding "nothing to suggest that Congress meant to cover" those, like A.R. D-C., who only travel to "the United States for the purpose of seeking medical treatment when it used the word 'return' in the Vaccine Act." *Dupuch-Carron*, 144 Fed. Cl. at 666. For the reasons discussed herein, we agree.

The scope of the Vaccine Act does not, generally, extend beyond the borders of the United States. The Act itself refers to a "national" vaccine injury compensation program, and 42 U.S.C. § 300aa–11(c)(1)(B)(i)(I) broadly provides that anyone, including temporary visitors, who received a scheduled vaccine "in the United States or in its trust territories," are eligible to seek compensation under the Act. The legislative history, moreover, does not address any concern for the continued supply of vaccines outside the United States or the compensation of non-residents of the United States, save for two exceptions. *See McGowan*, 31 Fed. Cl. at 739. First, families of citizens who were employees of the United States or members of the armed forces can petition for compensation under the Vaccine Act, even if the vaccine was received outside the United States or its territories. 42 U.S.C. § 300aa–11(c)(1)

(B)(i)(II). Second, as noted above, anyone who received a vaccine made in the United States and who subsequently returned to the United States not later than six months after the vaccination can petition for compensation under the Vaccine Act. 42 U.S.C. § 300aa–11(c)(1)(B)(i)(III). These exceptions, by their wording, apply only to those who previously had some degree of presence in the United States prior to leaving and, in the case of § 300aa–11(c)(1)(B)(i)(III), "returned."

On appeal, as below, Appellants argue that both the Special Master and the Claims Court inappropriately interpreted the word "return" because "[t]he relevant language of the Vaccine Act is not ambiguous," and the Special Master and Claims Court's interpretations of "return" do not comport with the "ordinary meaning" of the word (*i.e.* "to come or go back to"). *Dupuch-Carron*, 144 Fed. Cl. at 664; *see also, e.g.*, Appellants' Br. 18. Appellants contend that failing to apply the "ordinary meaning" of the word is inconsistent with the Supreme Court's unanimous holding in *Sebelius v. Cloer*, which stated that "[u]nless otherwise defined, statutory terms are generally interpreted in accordance with their ordinary meaning." 569 U.S. 369, 376-77, 133 S. Ct. 1886, 185 L. Ed. 2d 1003 (2013) (quoting *BP Am. Prod. Co. v. Burton*, 549 U.S. 84, 91, 127 S. Ct. 638, 166 L. Ed. 2d 494 (2006)).[5] Therefore, Appellants argue, under the plain meaning of the unambiguously used definition of "return," they should be allowed to maintain their claim.

5. On June 17, 2020, counsel for Appellants also submitted a Citation of Supplemental Authority pursuant to Fed. R. App. P. 28(j), which cited, as support, the Supreme Court's decision in *Bostock v. Clayton County*, 590 U.S. __, 140 S. Ct. 1731, 207 L. Ed. 2d 218 (2020).

Before the Claims Court, the Government did not dispute Appellants' understanding of the "plain meaning" of "return," but instead argued that because such an interpretation, under the Vaccine Act, would lead to "absurd results," the plain meaning rule should not apply and that the court must look to the context surrounding the phrase "returned to the United States." According to the Government, as construed in *McGowan*, 31 Fed. Cl. at 740,[6] "return" does not mean a temporary visit, but an arrival "with the intention to remain permanently from that point on." *Dupuch-Carron*, 144 Fed. Cl. at 664.

The Claims Court declined to adopt the reading of the statute advanced by the Government, in reliance on *McGowan*, that "return" must include an intent to establish permanent residence in the United States. Nonetheless, the Claims Court found that "the term

6. The decisive issue in *McGowan* was the meaning of the word "return" in the relevant provision of the Vaccine Act. 31 Fed. Cl. at 738. The petitioner, who was born in the United States, received two vaccinations in Canada, where she resided and where her father was receiving medical training. *Id.* at 736. Within six months of her August 20, 1965 vaccination, the petitioner entered the United States to visit her maternal grandparents. *Id.* On October 1, 1990, the petitioner filed an application for compensation under the Vaccine Act, arguing that she suffered encephalopathy as a result of her August 20, 1965 measles vaccine. *Id.* As framed by the Claims Court, the question "regarding the definition of 'return' is whether there is a sense of permanence inherent in the word." *Id.* The Claims Court found that simple dictionary definitions of "return" "shed little light on the issue," *id.*, and, after canvassing the legislative history of the Vaccine Act, held "[a]n injured person who does not intend to return to live in the United States should not be able to petition for a claim," *id.* at 739.

'return' must be limited by its context to avoid absurd results," and held that more is needed than the transient presence allowable under Appellants' overbroad reading of the word "return." *Id.* at 666. On appeal, the Government, dropping its reliance on *McGowan*, argues that the Claims Court is correct. We agree.

Applying the broadest meaning to the phrase "returned to the United States," as argued by Appellants, invites absurd results inconsistent with the statute's context. Take, for example, a French citizen, resident in France, who flew from Paris, France to Tokyo, Japan with a one-day stopover in New York, who then returned to France and received a vaccination. The fact that within six months of the vaccination, the French citizen again stopped for a day in New York on his way to Tokyo, Japan would permit him to submit a Vaccine Act claim under Appellants' broad reading of the statute. Both the Supreme Court and this court, however, have repeatedly held over the years that "[i]f a literal construction of the words of a statute be absurd, the act must be so construed as to avoid the absurdity." *Holy Trinity Church v. United States*, 143 U.S. 457, 460, 12 S. Ct. 511, 36 L. Ed. 226 (1892); *see also Cloer*, 569 U.S. at 377 n.4 (avoiding statutory interpretation that would produce an "absurd result"); *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 252, 130 S. Ct. 1324, 176 L. Ed. 2d 79 (2010) (declining to "adopt a view of the statute that . . . would produce an absurd result"); *Pub. Citizen v. U.S. Dep't of Justice*, 491 U.S. 440, 454, 109 S. Ct. 2558, 105 L. Ed. 2d 377 (1989) ("Where the literal reading of a statutory term would 'compel an odd result,' we must search for

other evidence of congressional intent to lend the term its proper scope." (quoting *Green v. Bock Laundry Mach. Co.*, 490 U.S. 504, 509, 109 S. Ct. 1981, 104 L. Ed. 2d 557 (1989))); *Haggar Co. v. Helvering*, 308 U.S. 389, 394, 60 S. Ct. 337, 84 L. Ed. 340, 1940-1 C.B. 237 (1940) (explaining that a reading of a statute that "would lead to absurd results is to be avoided when [it] can be given a reasonable application consistent with [its] words and with the legislative purpose"); *Pitsker v. Office of Pers. Mgmt.*, 234 F.3d 1378, 1383 (Fed. Cir. 2000) (finding Office of Personnel Management's statutory interpretation violated "the canon of statutory construction that an interpretation that causes absurd results is to be avoided if at all possible"); *Timex V.I., Inc. v. United States*, 157 F.3d 879, 887 (Fed. Cir. 1998) (finding that where "statutory construction frustrates Congress's intent, encourages undesirable behavior, and produces absurd results," it should "be avoided, not rubber-stamped").

When construing a statutory term or phrase to avoid an absurd result, or when the term or phrase is "ambiguous," it "must be read in [its] context and with a view to [its] place in the overall statutory scheme." *Colonial Press Int'l, Inc. v. United States*, 788 F.3d 1350, 1357 (Fed. Cir. 2015) (quoting *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809, 109 S. Ct. 1500, 103 L. Ed. 2d 891 (1989)); *see also Wassenaar v. Office of Pers. Mgmt.*, 21 F.3d 1090, 1092 (Fed. Cir. 1994) (stating that "[a] reading of [a statute] which would lead to absurd results is to be avoided when [it] can be given a reasonable application consistent with [its] words and legislative purpose"). Indeed, with respect to the language at issue in this case,

Appellants' counsel acknowledged at oral argument that "the factual context of the person's prior presence in the United States and subsequent return is relevant." *See* Oral Arg. at 4:25-43, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=20-1137.mp3. ("It's necessary to understand whether or not there was a return."); *see also id.* at 5:53-6:35 (counsel for Appellants equating "return" with "go back" and acknowledging that "go back" can be ambiguous). Accordingly, the phrase "returned to the United States" must be read in its context and with a view to its place in the overall statutory scheme.

The phrase "returned to the United States," itself, is not addressed in any of the legislative history concerning the Vaccine Act. Thus, the purpose of Congress' enactment of the Act must be understood to guide the court's understanding of the phrase. *See Amendola v. Sec'y of Dep't of Health & Hum. Servs.*, 989 F.2d 1180, 1182 (Fed. Cir. 1993).[7] In *Amendola*, this court found that "the motivating factor behind enactment of the [Vaccine Act] was the desire to protect the vaccine supply by shielding manufacturers from exposure to liability resulting from the small but nevertheless statistically significant incidence of unavoidable injury or death from widespread use of the vaccine." *Id.* at 1186.

7. In *Amendola*, this court found that because the Vaccine Compensation Act is a "complex piece of legislation" incorporating its "legislative purpose," "the meaning of any particular phrase or provision," included therein, "cannot be securely known simply by taking the words out of context and treating them as self-evident." *Amendola*, 989 F.2d at 1182.

While protection of the United States vaccine supply was the motivating factor, however, the Vaccine Act's limited legislative history makes clear that Congress had two goals in its enactment. As the Claims Court correctly noted in *McGowan*, and is not disputed by the parties here:

> The first goal was to "offer fair compensation to victims" injured in connection with childhood vaccination programs. H.R. 1780, 99th Cong., 1st Sess. (1985); S. 827, 99th Cong., 1st Sess. (1985); H.R. Rep. No. 908, 99th Cong., 2d Sess., pt. 1, at 7 (1986), U.S. Code Cong. & Admin. News 1986, pp. 6287, 6348. The second was to insure the "continued supply of vaccines that are vital to the public health." H.R. 1780; S. 827; H.R. Rep. No. 908. This second goal is linked only to the supply of vaccines in the United States.

*Id.* at 738-39.

Interpreting the Vaccine Act in view of these goals, the *McGowan* court held that 42 U.S.C. § 300aa–11(c)(1)(B)(i)(III) applies "only to those who previously had lived in the United States," *id.* at 739, and "return[ed] to the United States within six months of the vaccination date, with the intention to remain permanently from that point on," *id.* at 740.

Relying on *McGowan*, the Special Master in this case dismissed Appellants' claim after finding that there was no evidence that A.R. D-C. would have established a permanent presence in this country. As the Claims

Court found, however, upon review of the Special Master's decision, while *McGowan*'s permanent residence requirement was too restrictive, more is required of a "return" than a temporary visit for medical treatment. We agree with the Claims Court that the permanent residence requirement is overly restrictive. We nonetheless agree with the *McGowan* court that some residence is required both before leaving and upon "return[] to the United States" under 42 U.S.C. § 300aa–11(c)(1)(B)(i)(III).

One of the goals of the Vaccine Act was to provide compensation to those injured in connection with childhood vaccination programs. Congress specifically noted that vaccination programs are facilitated by state and local distribution of vaccines, and at the time of the Act's passage, state laws mandated that "virtually all" children be vaccinated "as a condition for entering school." H.R. Rep. No. 99-908, 99th Cong., 2d Sess., pt. 1, at 4-7 (1986). It is doubtful that the United States or any state or local government would have authority to impose vaccination requirements outside of its own borders (with the exception of persons applying to immigrate to the United States). Allowing those currently living outside the United States, who have not previously lived in the United States, and who were not injured in connection with United States vaccination programs, to receive compensation under the Vaccine Act would not serve the legislative goal of providing compensation to those injured in connection with those childhood vaccination programs.

With respect to Congress's other goal of stabilizing the vaccine market, Congress undoubtedly intended to reduce liability for vaccine manufacturers by limiting civil

actions against them from those covered by the Vaccine Act. *See* 42 U.S.C. § 300aa–11(a)(2)-(3); *see also* 42 U.S.C. § 300aa–11(a)(9) ("This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program."). Congress, through the Vaccine Act, has explicitly mandated that "[i]f a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action." 42 U.S.C. § 300aa–11(a)(2)(B). The Vaccine Act, however, does not, nor can it, prevent civil actions against vaccine manufacturers in other countries. Thus, allowing residents of other countries, who have not previously resided in the United States and do not plan on residing in the United States, and were not injured in connection with United States vaccination programs, to receive compensation under the Vaccine Act would not serve the goal of immunizing United States vaccine manufacturers from suit; those foreign residents could sue in foreign courts not similarly prevented from hearing these cases.[8]

If Congress wished to provide such broad immunity as argued by Appellants, it is hard to see why Congress

8. With regard to pending civil actions, the Vaccine Act manifests a legislative intent to prevent double compensation. *See* 42 U.S.C.A. § 300aa–11(a)(7) (providing that a damage award, either by settlement or court action, precludes a Vaccine Act petition); § 300aa–11(c)(1)(E) (providing that petitioner must aver in the petition that he has not previously collected a damage award either by settlement or court action). We agree with the *McGowan* court that logic dictates that Congress would not allow the opportunity for double compensation when the petitioner could be compensated outside of the United States. *See McGowan*, 31 Fed. Cl. at 740 n.3.

disallowed claims by persons who never entered the United States or entered the United States at some point before vaccination but did not return again within six months. We surmise that Congress, in enacting this section, intended to provide protection for persons who (1) previously resided in the United States, where they were subject to United States vaccination programs, (2) were temporarily away from the United States when they received the vaccination, and (3) "returned to the United States" within six months with the intention of resuming residence therein.

We hold that because A.R. D-C.'s entry into the United States to receive medical treatment does not fall within the more narrowly construed meaning of "returned to the United States" that the Vaccine Act's broader context demands, Appellants have not satisfied the requirements of 42 U.S.C. § 300aa–11(c)(1)(B)(i)(III).

## Conclusion

Appellants are not eligible to seek compensation from the Vaccine Program under 42 U.S.C. § 300aa–11(c)(1)(B)(i)(III). First, A.R. D-C., while living and breathing outside of his mother's body, was never present in the United States before his vaccinations such that his entrance to the United States for medical treatment could be construed as a "return." Second, even if A.R. D-C. was a "person" with a prior presence in the United States as a result of his *in utero* travel, he never resided in the United States nor intended to upon his "return." Thus, we hold that A.R. D-C. did not "return[] to the United States"

within the meaning of the Vaccine Act. Accordingly, the Claims Court's Order denying Appellants' Motion for Review is affirmed.

**AFFIRMED**

COSTS

The parties shall bear their own costs.

## APPENDIX B — OPINION OF THE UNITED STATES COURT OF FEDERAL CLAIMS, FILED SEPTEMBER 10, 2019

UNITED STATES COURT
OF FEDERAL CLAIMS

No. 17-1551V

ROBERT DAVID DUPUCH-CARRON
AND ELIZABETH JOANNA CARRON,
AS THE LEGAL REPRESENTATIVES
OF THEIR MINOR SON, A.R. D-C.,

*Petitioners,*

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

*Respondent.*

Filed under seal: September 10, 2019
Reissued for Public Availability:
September 25, 2019 [1]

1. Pursuant to Vaccine Rule 18(b), this opinion was initially filed on September 10, 2019, and the parties were afforded 14 days to propose redactions. The parties did not propose any redactions. Accordingly, this opinion is reissued in its original form for posting on the Court's website.

*Appendix B*

Statutory interpretation; National Vaccine Injury Compensation Act, 42 U.S.C. §§300aa-1 et seq.; the Vaccine Act; 42 U.S.C. § 300aa-11(c)(1)(B)(i); Return

**MEMORANDUM OPINION**

***HERTLING*, Judge**

The petitioners, Robert David Dupuch-Carron and Elizabeth Joanna Carron, husband and wife, are the legal representatives of the estate of their deceased son, A.R. D-C. They filed this action seeking compensation for injuries allegedly compensable under the National Vaccine Injury Compensation Act, 42 U.S.C. §§ 300aa-1 et seq. ("the Vaccine Act"). On the parties' cross-motions for summary judgment, the Special Master ruled that the petitioners are ineligible to receive compensation under the Vaccine Act, granted the respondent's motion, and dismissed the petition. *See Dupuch-Carron v. Sec'y of Health & Human Servs.*, 2019 WL 22663369 ("*Dupuch-Carron*"). The petitioners filed this motion for review pursuant to 42 U.S.C. § 300aa-12(e).

## I. Facts

A brief recitation of the facts provides necessary context.[2]

2. Because the Special Master granted summary judgment, he necessarily determined that no material facts were in dispute. As the undisputed facts have not changed, the Court's recitation of the background facts herein draws from the Special Master's opinion in *Dupuch-Carron*.

*Appendix B*

The petitioners were domiciled in Nassau, The Bahamas, for the entirety of the time period relevant to this case. Ms. Carron is a citizen of the United Kingdom and avers that she is a "frequent visitor to the United States," spending "10 to 12 long weekends" in the country each year. During a trip to Coral Gables, Florida from March 24 to April 3, 2015, Ms. Carron visited an internist, who informed her that she was pregnant. After learning she was pregnant with A.R. D-C, she claims to have traveled to the United States an additional four times over the course of her pregnancy.

Mr. Dupuch-Carron was born in the United States. His citizenship is not noted in the record. He appears to have grown up in The Bahamas but recalls "spen[ding] a great deal of time [in the United States] as a child during the summer holidays." Mr. Dupuch-Carron avers that he is a "frequent visitor to the United States," spending "between 30 and 45 days in the United States on business" in a typical year.

A.R. D-C was born on November 24, 2015, at Doctors Hospital in Nassau, The Bahamas. He continued to live in Nassau for the first six months of his life. During his first six months, A.R. D-C had unremarkable well-child visits at Precious Posterity Pediatric Centre in Nassau, and was considered to be healthy and developing normally. He also received his first two sets of vaccinations in Nassau, apparently with no adverse consequences.

On June 23, 2016, during his six-month well-child visit to his pediatrician in Nassau, A.R. D-C received his third set of vaccinations, which included the DTap, IPV,

HIB, HBV, Prevnar, and rotavirus vaccinations. There is no dispute that the eight vaccines A.R. D-C received during his June 23rd visit to the pediatrician are listed in the Vaccine Injury Table and were manufactured by companies with a presence in the United States.

On July 7, 2016 and July 9, 2019, A.R. D-C presented at the pediatrician with complaints of a fever greater that 102 degrees Fahrenheit, crankiness, stuffy nose, rattling in his chest, occasional chesty coughs, reduced activity, vomiting, and diarrhea. On July 10, 2016, A.R. DC's parents brought him to the emergency room at Doctors Hospital in Nassau with complaints of fever and vomiting for five days, irritability, and decreased appetite. The doctors determined he had thrombocytopenia[3] and pancytopenia[4] for which he received a blood transfusion, and febrile neutropenia[5] for which he was given an intravenous antibiotic. On July 11, 2016, A.R. D-C was transferred to the intensive care unit at Princess Margaret Hospital in Nassau, where a pediatric hematologist—oncologist recommended he be transferred to an institution "equipped to enable quick turn around and confirmation of the leukemia if present."[6]

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3. Thrombocytopenia is defined as a "decrease in the number of platelets." *Dorland's Illustrated Medical Dictionary* 1069 (32nd ed. 2012) ("*Dorland's*") at 1922.

4. Pancytopenia is defined as a "deficiency of all cellular elements of the blood." *Dorland's* at 1368.

5. Neutropenia is "an abnormal decrease in the number of neutrophils in the blood, with the absolute neutrophil count being less than 1500/$\mu$L." *Dorland's* at 1272.

6. Leukemia is "a progressive, malignant disease of the blood-forming organs, characterized by distorted proliferation and

Physicians in The Bahamas determined that A.R. D-C would receive better treatment in the United States, and on July 13, 2016, A.R. D-C was transferred by air ambulance to Nicklaus Children's Hospital in Miami, Florida, where he was diagnosed with hemophagocytic lymphohistiocytosis ("HLH").[7] HLH is an autoimmune disease of the blood, fatal unless treated successfully. A.R. D-C was treated at Nicklaus Children's Hospital until he was discharged on August 12, 2016, "on the condition he remain in Florida as an outpatient."

A.R. D-C continued weekly treatment with Dr. Maggie Fader as an outpatient at Nicklaus Children's Hospital. A.R. D-C was cleared to leave the United States over the Christmas season, so the family returned to The Bahamas. On February 28, 2017, A.R. D-C was readmitted to Nicklaus Children's Hospital. He was diagnosed with acute myeloid leukemia ("AML").[8] A.R. D-C underwent treatment, which included chemotherapy[9] and radiation[10]

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development of leukocytes and their precursors in the blood and bone marrow." *Dorland's* at 1026.

7. Hemophagocytic lymphohistiocytosis is "any of several closely related disorders involving both lymphocytosis and histiocytosis, with excessive hemophagocytosis in the lymphoreticular system or the central nervous system." *Dorland's* at 1085.

8. Acute myeloid leukemia, also known as acute myeloblastic leukemia or acute myelogenous leukemia, is "a common kind of acute myelogenous leukemia, in which myeloblasts predominate." *Dorland's* at 1026.

9. Chemotherapy is "the treatment of a disease by chemical agents." *Dorland's* at 341.

10. Radiation is "energy transmitted by waves through space or through some medium; usually referring to electromagnetic radiation when used without a modifier." *Dorland's* at 1570.

at Cincinnati Children's Hospital in Cincinnati, Ohio, as well as a bone-marrow transplant at Johns Hopkins Bloomberg Children's Hospital in Baltimore, Maryland.

On October 17, 2017, the petitioners filed a claim under the Vaccine Act. On December 24, 2017, A.R. D-C died from AML, and on March 26, 2018, the petitioners filed an amended petition, alleging that the AML, which caused A.R. D-C's death, was a complication resulting from the treatment he had received for his vaccine-induced HLH.

## II. Procedural History

Prior to the filing of the amended petition, the Special Master had identified as a threshold question the issue of whether the petitioners were eligible for compensation under the Vaccine Act because the vaccines were administered outside of the United States. The Special Master directed the parties to file cross-motions for summary judgment on that limited issue.

On March 26, 2018, concurrent with their filing of the amended petition, the petitioners filed their Motion for Partial Summary Judgment on the limited issue of their eligibility under the Vaccine Act for compensation. On June 7, 2018, the respondent filed its Cross-Motion for Summary Judgment on that threshold issue. Petitioners filed their Response and Reply on July 12, 2018. On April 23, 2019, the Special Master denied the petitioners' Motion and granted the respondent's.

On May 23, 2019, the petitioners filed a Motion for Review of the Special Master's decision, asking this Court

to review and reverse the Special Master's decision. In their Motion for Review, the petitioners raise the following single numbered objection:

> The special master's conclusion that the petitioners were not eligible to seek compensation from the National Vaccine Injury Compensation Program because their son [A.R. D-C]: 1) could not be viewed as a person who was present in the United States prior to his vaccinations; and 2) had not returned to the United States within six months after vaccinations was not in accordance with the law.

The respondent filed its Response to the petitioners' Motion for Review on June 20, 2019, arguing that the Special Master's decision on the petitioners' eligibility to seek compensation under the Vaccine Act was correct. With the Court's leave, the petitioners filed their Reply on July 5, 2019. The Court heard oral argument on the petitioners' Motion for Review on September 5, 2019.

## III. Standard of Review

Under the Vaccine Act, this Court may review a Special Master's decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)-(2). The Court may: "(A) uphold the findings of fact and conclusions of law . . ., (B) set aside any findings of fact or conclusion of law . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . ., or, (C) remand the petition to the special master for further action in accordance with the court's direction." *Id.* § 300aa-12(e)

(2)(A)-(C). Findings of fact and discretionary rulings are reviewed under an "arbitrary and capricious" standard, while legal conclusions are reviewed *de novo. Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992); *see also Doyle ex rel. Doyle v. Sec'y of Health & Human Servs.*, 92 Fed. Cl. 1, 5, n.8 (2010).

The sole issue in this case is whether the petitioners, who are not domiciled in the United States, and whose son received the allegedly injurious vaccines outside of the United States, are eligible to bring a claim under the Vaccine Act. This question requires the Court to interpret the relevant provisions of the Vaccine Act. As a question of law, an issue of statutory interpretation is subject to *de novo* review. *Black v. Sec'y of Health & Human Servs.*, 33 Fed. Cl. 546, 549 (1995) (collecting cases).

## IV. Discussion

### A. Relevant Statutory Provisions

The Vaccine Act, 42 U.S.C. § 300aa-11(c)(1)(B)(i), delimits the categories of persons who may pursue a claim under it. Pursuant to the relevant provision, the party seeking compensation under the Act must show that he:

> (I) received the vaccine in the United States or in its trust territories;
>
> (II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen

> of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen; or
>
> (III) received the vaccine outside of the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States *and such person returned to the United States not later than 6 months after the date of the vaccination.*

*Id.* (emphasis added).

The petitioners do not claim that either 42 U.S.C. § 300aa-11(c)(1)(B)(i)(I) or § 300aa-11(c)(1)(B)(i)(II) is applicable to this case. Therefore, the question before the Court is whether 42 U.S.C. § 300aa-11(c)(1)(B)(i)(III) allows the petitioner, under the specific facts of this case, to receive compensation under the Vaccine Act.

### B. The *McGowan* Decision

*McGowan v. Secretary of the Department of Health & Human Services* is the only relevant judicial precedent. 31 Fed. Cl. 734 (1994). In *McGowan*, the petitioner, who was born in the United States, received two vaccinations in Canada, where she resided and where her father was receiving medical training. *Id.* at 736. Within six months of her August 20, 1965 vaccination, the petitioner entered the United States to visit her maternal grandparents.

*Id.* She received her second vaccine in Canada in late December 1965. *Id.* In April 1967, the petitioner and her parents returned permanently to the United States. *Id.*

On October 1, 1990, the petitioner filed an application for compensation under the Vaccine Act, arguing that she suffered encephalopathy as a result of her August 20, 1965 measles vaccine.[11] *Id.* The Special Master dismissed the petitioner's claim, finding that she had failed to prove, by a preponderance of the evidence, that she had returned to the United States within six months of her August 20, 1965 measles vaccination. *Id.* On review, this Court sustained the Special Master's decision, holding that the "petitioner has failed to 'return' within the meaning of 42 U.S.C. § 300aa-11(c)(1)(B)(i)(III) and fails to meet the jurisdictional requirements of the Vaccine Act." *Id.* at 740.

Just as in this case, the decisive issue in *McGowan* was the meaning of the word "return" in the relevant provision of the Vaccine Act. 31 Fed. Cl. at 738. As framed by the Court, the question "regarding the definition of 'return' is whether there is a sense of permanence inherent in the word." *Id.* There, as here, the "[p]etitoner argue[d] that a return is completed with the initial entry," while the respondent contended that "a 'return' requires at least an intention to remain, from that moment on, as a permanent resident of the United States." *Id.*

The *McGowan* Court found that the simple dictionary definitions of "return" "shed little light on the issue." *Id.*

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11. Encephalopathy is defined as "any degenerative disease of the brain." *Dorland's* at 614.

Instead, the Court canvassed the legislative history of the Vaccine Act to determine the legislative purpose behind its enactment. The Court identified two goals underlying the Act's implementation. The first was "to 'offer fair compensation to victims' injured in connection with childhood vaccination programs[.]" *Id.* (quoting H.R. 1780, 99th Cong., 1st Sess. (1985); S. 827. 99th Cong., 1st Sess. (1985); H.R. Rep. No. 99-908 pt. 1 at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6367). The second was "to insure the 'continued supply of vaccines that are vital to the public health.'" *Id.* at 739 (quoting same).

In interpreting 42 U.S.C. § 300aa-11(c)(1)(B)(i)(III), the *McGowan* Court held "[a]n injured person who does not intend to return to live in the United States should not be able to petition for a claim." 31 Fed. Cl. at 739. The Court further held that "[t]o rule that 'return' means simply to physically enter the United States is to invite absurd scenarios." *Id.* (citing *Hellebrand v. Sec'y of Dep't of Health & Human Servs.*, 999 F.2d 1565, 1570-71 (Fed. Cir. 1993)) ("[A] court should seek to avoid construing a statute in a way which yields an absurd result and should try to construe a statute in a way which is consistent with the intent of Congress."). Ultimately, the Court held that "[a]s Congress meant that 'return' would mean a permanent return, an injured person must return to the United States within six months of the vaccination date, with the intention to remain permanently from that point on, in order to be able to participate in the compensation program." *Id.* at 740.

### C. Analysis

The crux of the petitioners' claim at this stage of the case centers on whether A.R. D-C "returned" to the United States within six months of his receipt of the vaccine, pursuant to 42 U.S.C. § 300aa-11(c)(1)(B)(i)(III).[12] The petitioners argue that the Special Master inappropriately interpreted the word "return" because "[t]he relevant language of the Vaccine Act is not ambiguous," and the Special Master's interpretation of "return" does not comport with the "ordinary meaning" of the word. In making that argument, the petitioners point to the Oxford English Dictionary, which defines "return" as "to come or go back to a place or person." *Id.; see also Return*, OXFORD ENGLISH DICTIONARY (2d ed. 1989). The petitioners contend that failing to apply the "ordinary meaning" of the word is "clearly inconsistent with the Supreme Court's unanimous holding in *Sebelius*

12. The petitioners also raise the argument that a child *in utero* is a "person" for the purposes of the Vaccine Act. The Vaccine Act considers a child whose mother receives a vaccine while the child is *in utero* to be a "person" for the purposes of the Vaccine Act. 42 U.S.C. § 300aa-11(f)(1) ("[F]or the purposes of this subpart, both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such a woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine."). While the Court need not decide the question, it assumes, for the purposes of its analysis, that A.R. D-C was a "person" under the relevant portions of the Vaccine Act, with a prior presence in the United States. The sole issue requiring analysis to resolve the case is whether A.R. D-C's arrival in Miami for medical treatment constituted a "return" to the United States within six months of his vaccination.

*v. Cloer." See Sebelius v. Cloer*, 569 U.S. 369, 376-77, 133 S. Ct. 1886, 185 L. Ed. 2d 1003 (2013) ("As in any statutory construction case, this Court proceeds from the understanding that '[u]nless otherwise defined, statutory terms are generally interpreted in accordance with their ordinary meaning.'") (quoting *BP America Production Co. v. Burton*, 549 U.S. 84, 91, 127 S. Ct. 638, 166 L. Ed. 2d 494 (2006)). Therefore, the petitioners argue, under the plain meaning of the unambiguously used definition of "return," they should be allowed to maintain their claim.

The respondent rejects the petitioners' interpretation of "return," instead arguing that, under the Vaccine Act, as construed in *McGowan*, 31 Fed. Cl. at 740, "return" does not mean a temporary visit, but an arrival "with the intention to remain permanently from that point on." The respondent relies on the Court's decision in *McGowan* in making that argument.[13] While the respondent does not reject the petitioners' understanding of the "plain

13. The respondent also argues that, because A.R. D-C was born in The Bahamas and never lived in the United States after birth, he could not "return" to the United States. Thus, the respondent posits that A.R. D-C's first entry into the United States occurred on July 13, 2016, when he arrived for medical treatment. The respondent similarly rejects the petitioners' argument that A.R. D-C's mother's occasional visits during her pregnancy were sufficient to establish that he was "present" in the United States for the purpose of the Vaccine Act. While these arguments were raised by the respondent, the Court does not believe it necessary to address whether A.R. D-C's *in utero* visits constituted presence in the United States, because such a determination would, in and of itself, not be dispositive of the case. Instead, the Court's decision turns on whether A.R. D-C's arrival in the country for medical treatment constituted a "return" sufficient to satisfy the Vaccine Act, assume the *in utero* visits were A.R. D-C's initial entries into the country.

meaning" of "return," the respondent argues that, to qualify for Vaccine Act compensation, a "return" necessarily requires a sense of permanence. Because the word 'return' relies on its context in order to impart a sense of permanence, the respondent argues, the plain meaning rule is not dispositive.

Thus, this case turns on whether A.R. D-C's arrival for medical treatment constitutes "return" for the purposes of the act's exception to its requirement that claimants be vaccinated in the United States.

As in any case involving statutory interpretation, the Court's analysis must begin with the words employed by the legislature. *See, e.g., Lewis v. United States*, 445 U.S. 55, 60, 100 S. Ct. 915, 63 L. Ed. 2d 198 (1980) ("[I]n any case concerning the interpretation of a statute the 'starting point' must be the language of the statute itself."); *see also Reiter v. Sonotone Corp.*, 442 U.S. 330, 337, 99 S. Ct. 2326, 60 L. Ed. 2d 931 (1979) ("As is true in every case involving the construction of a statute, our starting point must be the language employed by Congress."). Such an inquiry requires that the Court analyze the legislature's words in accordance with both their ordinary meaning and within the context of the statutory scheme surrounding their implementation. No single word or phrase should be wrenched from its context and interpreted in a vacuum. *See Holihan v. Secretary of HHS*, 45 Fed. Cl. 201, 205 (1999) ("A statute is to be read as an undivided whole, not a collection of disparate clauses."). To do so would defeat the purpose of the judicial enterprise, which is to interpret the law applicable to a particular case in accordance with what the legislature wrote as a whole.

As to the ordinary meaning of "return," this Court agrees with *McGowan* that dictionary definitions of the word shed little light on what the word means in the Vaccine Act. *See* 31 Fed. Cl. at 738. While this Court does not necessarily agree with *McGowan* that a "return" must be permanent, *id.* at 740, this Court recognizes that applying the broadest meaning to the term as argued by the petitioners invites absurd results inconsistent with the statute's context. *See id.* at 739. For instance, if a French citizen, resident in France, vacationed in the United States, then returned to France and received a vaccination there, the fact that one week later, the French citizen stopped in New York to change planes on his way to Mexico would permit him to submit a Vaccine Act claim under the petitioners' broad reading of "return." It is inconceivable that Congress's use of the term "return" in the Act was meant to extend the benefits of the Vaccine Injury Compensation Program to this scenario. That application produces an absurd result even if "return" might ordinarily be used this way in other contexts. *See United States v. Kirby*, 74 U.S. 482, 486-87, 19 L. Ed. 278 (1868) ("All laws should receive a sensible construction. General terms should be so limited in their application as not to lead to injustice, oppression, or an absurd consequence."). What counts as a "return" for the Vaccine Act must have some limit, but the term's range of ordinary meanings requires the Court to look to context for further clues.

The context surrounding the term "return" suggests that "return" means something more than a nonresident prior visitor's temporary entry for medical treatment. The term is used in a gatekeeping provision that waives the

government's sovereign immunity, and without any explicit language calling for the Vaccine Act's extraterritorial application.

First, the Federal Circuit has described the section containing the statutory provision at issue, 42 U.S.C. § 300aa-11, as a "gate-keeping" provision, which a petitioner must satisfy to maintain a Vaccine Act claim. *Amendola v. Secretary, HHS*, 989 F. 2d 1180, 1182 (Fed. Cir. 1993). Indeed, 42 U.S.C. § § 300aa-11(c)(1)(B)(i)(III), operates as a limitation on coverage.

Second, the Vaccine Act operates as a limited waiver of sovereign immunity. Therefore, its provisions must be given a "strict and narrow construction." *Holihan*, 45 Fed. Cl. at 207; *see also Grice v Sec'y of Health & Human Servs.*, 36 Fed. Cl. 114, 120 (1996) ("[T]he Vaccine Act is a limited waiver of sovereign immunity."). Moreover, when Congress waives sovereign immunity, any ambiguities in the statute must be resolved in favor of the federal government as the sovereign. *Holihan*, 45 Fed. Cl. at 208. Thus, it would be inconsistent with the purpose of 42 U.S.C. § § 300aa-11(c)(1)(B)(i)(III) to accept the petitioners' unlimited reading of "return," expanding the Vaccine Act's waiver of sovereign immunity to claims from individuals with no or few meaningful ties to the United States.

Third, there is no indication in the statute that Congress intended to apply the Vaccine Act outside of the United States.[14] Unless Congress is explicit in seeking to

14. The Vaccine Act makes clear that it covers vaccines provided in the United States, and vaccines administered abroad to United

extend the extraterritorial effect of a legislative act, the presumption must be that a statute only has domestic application. *Kiobel v. Royal Dutch Petroleum Co.*, 569 U.S. 108, 115, 133 S. Ct. 1659, 185 L. Ed. 2d 671 (2013); *Morrison v. Nat'l Austl. Bank Ltd.*, 561 U.S. 247, 255, 130 S. Ct. 2869, 177 L. Ed. 2d 535 (2010); *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 454, 127 S. Ct. 1746, 167 L. Ed. 2d 737 (2007); *E.E.O.C. v. Arabian Am. Oil Co.*, 499 U.S. 244, 248, 111 S. Ct. 1227, 113 L. Ed. 2d 274 (1991).[15] The Court has canvassed the entire statutory text and legislative history of the Vaccine Act. There is not a single hint that Congress was thinking about compensating individuals vaccinated outside of the United States who lacked ties to the country.

Moreover, the Vaccine Injury Compensation Program's funding structure, set out in the Vaccine Act, also suggests that Congress did not explicitly seek for the Act to have extraterritorial application. Congress funded the Vaccine Program through an excise tax of seventy-five cents ($0.75) per sale of a taxable vaccine that is manufactured or produced in the United States, or enters the United States "for consumption, use, or warehousing." 26 U.S.C. §§ 4132, 4131(b)(1). Vaccines sold or re-sold "for

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States citizens. 42 U.S.C. § 300aa-11(c)(1)(B)(i)(I), (II). This context in which Congress actually restricted the remedies in the Vaccine Act to some Americans receiving vaccines abroad supports the inference that Congress had in mind United States persons as it thought about the potential beneficiaries of the Vaccine Act.

15. *Kiobel*, for example, applied the presumption against extraterritorial effect to a statute enacted in 1789; *a fortiori* the presumption also applies to a statute enacted in 1986.

export . . . to a foreign country" are exempt from the tax. *See* INTERNAL REVENUE SERV., *Pub. 510: Excise Taxes* (rev. Mar. 2018; last visited Sept. 5, 2019) http://www.irs.gov/publications/p510. Thus, the Vaccine Injury Compensation Program is funded by excise taxes on domestic manufacturers and producers, suggesting that Congress intended to limit that Program to domestic claims, with limited exceptions. Here again, an expansive definition of "return" could work against one of the key goals underlying the Vaccine Act, ensuring the supply of vaccines, by expanding the potential class of beneficiaries without adequate financial support for the program.

In sum, the term "return" must be limited by its context to avoid absurd results. The Act's waiver of sovereign immunity is strictly and narrowly construed—a principle with which the Court must assume Congress was familiar when it enacted the Vaccine Act. Nothing in the Act or its legislative history overcomes the presumption against extraterritoriality, and the coverage-expanding results of the petitioners' interpretation are inconsistent with the Act's funding and coverage-limiting provisions. The petitioners' unlimited reading of the word "return" must be rejected.

Because of the quality of medical care available in this country, foreign nationals from countries with fewer medical resources often avail themselves of advanced or specialized treatment in the United States. Congress would have been familiar with this phenomenon.[16]

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16. For example, several years before Congress considered the Vaccine Act, the former Shah of Iran sought medical treatment in

In light of the silence in the legislative record and the presumptions attendant to the task of statutory interpretation in this case, the Court finds nothing to suggest that Congress meant to cover foreign nationals arriving in the United States for the purpose of seeking medical treatment when it used the word "return" in the Vaccine Act.

This holding is narrower than the rule adopted in *McGowan*. The Court declines to adopt the reading of the statute advanced by the respondent, in reliance on *McGowan*, that "return" must include an intent to establish permanent residence in the United States because it is broader than necessary to resolve this case.

## V. Conclusion

Because A.R. D-C's entry into the United States to receive medical treatment did not fall within the more specific meaning of "return to the United States" that the Vaccine Act's broader context demands, he has therefore not satisfied the requirements under 42 U.S.C. § 300aa-11(c)(1)(B)(i)(III). The Court has no choice but to deny the petitioners' Motion for Review.

/s/ Richard A. Hertling
**Richard A. Hertling**
**Judge**

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the United States, triggering strong reactions in Iran, including the seizure of the U.S. Embassy and the taking of hostages.

**APPENDIX C — OPINION OF THE UNITED STATES COURT OF FEDERAL CLAIMS, FILED APRIL 23, 2019**

UNITED STATES COURT
OF FEDERAL CLAIMS

No. 17-1551V

ROBERT DAVID DUPUCH-CARRON AND ELIZABETH JOANNA CARRON, AS THE LEGAL REPRESENTATIVES OF THE ESTATE OF THEIR MINOR SON, A.R.D-C.,

*Petitioners,*

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

*Respondent.*

April 23, 2019, Filed

PUBLISHED

Special Master Gowen

Eligibility for Compensation; "Person"; "Returned".

*Appendix C*

**DECISION**[2]

Robert David Dupuch-Carron and Elizabeth Joanna Carron ("petitioners," or "father" and mother") are the legal representatives of the estate of their minor son, A.R.D-C. The family is domiciled in The Bahamas. Ms. Carron carried A.R.D-C. *in utero* upon five visits to the United States. On November 24, 2015, A.R.D-C. was born in The Bahamas. On June 23, 2016, A.R.D-C. received DTaP, IPV, HIB, HBV, Prevnar, and rotavirus vaccines at his pediatrician's office in The Bahamas. He remained in The Bahamas until July 13, 2016, when he was transported to the United States for treatment for secondary hemophagocytic lymphohistiocytosis ("HLH"). A.R.D-C. later developed secondary complications and passed away in the United States on December 24, 2017. On October 7, 2017, petitioners initiated a claim within

2. Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), because this opinion contains a reasoned explanation for the action in this case, I am required to post it on the website of the United States Court of Federal Claims. The court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. **This means the opinion will be available to anyone with access to the Internet**. Before the opinion is posted on the court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). An objecting party must provide the court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the court's website without any changes**. *Id.*

the National Vaccine Injury Compensation Program, alleging that A.R.D-C.'s March 26, 2016 vaccines caused his injuries and death.[3] Petition (ECF No. 1); *see also* Amended Petition filed March 26, 2018 (ECF No. 15).

Ripe for adjudication is whether petitioners' claim is eligible under 42 U.S.C. § 300aa-11(c)(1)(B)(III), which provides that the vaccination(s) at issue must be received by a "person" who then "returns" to the United States within six months. Petitioners contend that this threshold eligibility requirement is fulfilled on the grounds (1) that A.R.D-C. was a "person" upon entering the United States while *in utero* and that (2) A.R.D-C. "returned" to the United States within six months under a plain meaning of that quoted word. Petitioners' Motion for Summary Judgment ("Pet. Mot.") (ECF No. 11); Pet. Reply (ECF No. 21); *see also* Pet. Exhibits ("Exs.") 1-16. Respondent challenges both contentions. Respondent's Cross-Motion for Summary Judgment ("Resp. Mot.") (ECF No. 18).

After carefully analyzing and weighing all of the evidence presented in this case in accordance with the applicable legal standards, I hereby **DENY** petitioners' motion for summary judgment and **GRANT** respondent's motion for summary judgment, finding that the petition is not eligible under 42 U.S.C. § 300aa-11(c)(1)(B)(III). Accordingly, petitioners may not proceed in seeking compensation from this Program and their petition is dismissed.

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3. The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 *et seq.* (hereinafter "the Vaccine Act" or "the Act").

*Appendix C*

## I. Summary of Relevant Facts[4]

### A. Family's Connections to the United States

The Dupuch-Carron family — the father Mr. Dupuch-Carron, the mother Ms. Carron, the paternal grandmother Ms. Eileen Dupuch-Carron, and A.R.D-C. during his life — were domiciled in Nassau, The Bahamas. Additionally, the grandmother, through a company established by her parents, Sir Etienne Dupuch and Lady Marie Dupuch, also owns a condominium in Coral Gables, Florida. Pet. Ex. 16 ¶ 5. She is a "frequent visito[r] to the United States," "spend[ing] 10 to 12 long weekends in the United States a year." *Id.* ¶ 4.

The father was born in the United States. Pet. Ex. 16 ¶ 5. He recalls "spen[ding] a great deal of time here as a child during the summer holidays with his grandparents." *Id.* Mr. Carron is a "frequent visitor to the United States," spending "between 30 and 45 days in the United States on business" in a typical year. *Id.* ¶ 3.

The mother is a citizen of the United Kingdom and a resident of The Bahamas. Pet. Ex. 11 at 7. Her pregnancy with A.R.D-C. was confirmed by an internist in Coral Gables, Florida during a visit to the United States from March 24, 2015 to April 3, 2015. Pet. Ex. 11 at 12-22; Pet. Ex. 10 ¶ 31. While pregnant, she made four additional

4. In order to reach this decision, I fully reviewed the entire record. This section is a summary of the facts deemed most relevant to the present limited issue: as a threshold matter, whether petitioners are eligible to receive compensation from the Vaccine Program.

visits to the United States: from April 9, 2015 to April 11, 2015; from July 1, 2015 to July 3, 2015; from August 12, 2015 to August 14, 2015; and from September 18, 2015 to October 5, 2015. Pet. Ex. 11 at 12-22; Pet. Ex. 10 ¶ 31. The father avers that "[B]efore [A.R.D-C.'s] illnesses and death, [the mother] probably spent more time in the United States than I." Pet. Ex. 16 ¶ 4.

### B. A.R.D-C.'s Early Life, Vaccines at Issue, and Entry to the United States

A.R.D-C. was born on November 24, 2015, at Doctors Hospital in Nassau, The Bahamas. Pet. Ex. 2. "During his first six months," A.R.D-C. lived with his mother, father, and grandmother in Nassau, The Bahamas. Pet. Ex. 16 ¶ 2.

A.R.D-C. had unremarkable well-child visits at Precious Posterity Pediatric Centre in Nassau, The Bahamas on November 30, 2015; December 22, 2015; January 26, 2016; February 26, 2016; April 14, 2016; and April 25, 2016. Pet. Ex. 3 at 2-12, 19.

On June 23, 2016, A.R.D-C. presented to the same practice for his six-month well-baby visit. He received the DTaP, IPV, HIB, HBV, Prevnar, and rotavirus vaccines at issue in this case. *Id.* at 13-14, 19.

On July 7, 2016, and again July 9, 2016, the parents brought A.R.D-C. to the same pediatric practice for complaints of fever greater than 102 degrees Fahrenheit, crankiness, stuffy nose, rattling in chest, occasional chesty coughs, reduced activity, vomiting, and diarrhea. *Id.* at

15-16. A.R.D-C. was assessed with "likely viral illness, [rule out] sepsis" and discharged home with Cardec drops. *Id.* at 16.

On July 10, 2016, the parents brought A.R.D-C. to the emergency room at Doctors Hospital in Nassau, The Bahamas for complaints of fever for five days, vomiting for five days, irritability, and decreased appetite. Pet. Ex. 4 at 2. He was found to have thrombocytopenia,[5] pancytopenia[6] for which he was given a blood transfusion, and febrile neutropenia for which he was given intravenous Zosyn, an antibiotic.[7] Pet. Ex. 4 at 4, 12; Pet. Ex. 5 at 7.

On July 11, 2016, A.R.D-C. was transferred to the intensive care unit at Princess Margaret Hospital in Nassau, The Bahamas. Pet. Ex. 5. Repeat bloodwork showed worsened neutropenia. *Id.* at 7. He was diagnosed with "febrile neutropenia with pancytopenia" with the need to rule out leukemia, bacterial sepsis, and viral infection. *Id.* A pediatric hematologist-oncologist recommended that A.R.D-C. should be transferred to an institution that was "equipped to enable quick turn around and confirmation of the leukemia if present" and was able to provide immunophenotyping, cytogenetic evaluation,

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5. Thrombocytopenia is "a decrease in the number of platelets." *Dorland's Illustrated Medical Dictionary* (32nd ed. 2012) [hereinafter "*Dorland's*"] at 1922.

6. Pancytopenia is "deficiency of all cellular components of the blood." *Dorland's* at 1368.

7. Neutropenia is "an abnormal decrease in the number of neutrophils in the blood." *Dorland's* at 1272.

and reliable blood bank support. *Id.* Those capabilities were "unavailable" or "limited" in The Bahamas. *Id.*

On July 12, 2016, The Bahamas issued a passport to A.R.D-C. Pet. Ex. 11 at 3. That same day, the United States granted him a visa. The purpose for entering the United States was "medical." *Id.* at 4-5.

On July 13, 2016, A.R.D-C. was transferred by air ambulance to Nicklaus Children's Hospital in Miami, Florida, where his diagnosis was modified to hemophagocytic lymphohistiocytosis ("HLH").[8] He was treated for that condition until discharge on August 12, 2016. Pet. Ex. 6 at 12-13.

The mother recalls that A.R.D-C. was discharged "on the condition he remain in Florida as an outpatient." Pet. Ex. 10 ¶ 18. "Instead of traveling back home to The Bahamas, we took up residence in our family's apartment in Coral Gables." *Id.* A.R.D-C. continued to see hematologist-oncologist Dr. Maggie Fader as an outpatient of Miami Children's Hospital on a weekly basis. *Id.* ¶ 19. The family was "finally given permission to leave the USA on Christmas Eve 2016 provided [they] come back to Miami Children's Hospital for monthly visits to Dr. Maggie Fader." *Id.* A.R.D-C. was able to return briefly to The Bahamas from December 24, 2016 to January 24,

8. Hemophagocytic lymphohistiocytosis is "any of several closely related disorders involving both lymphocytosis and histiocytosis, with excessive hemophagocytosis in the lymphoreticular system or the central nervous system; they are usually seen in children secondary to infection and are often fatal; they can also be secondary to rheumatologic or other conditions or can be familial." *Dorland's* at 1085.

2017, and again from January 29, 2017 to February 20, 2017. Pet. Mot. Memorandum ("Mem.") at 3.

A.R.D-C. spent the remaining ten months of his life in the United States in connection with his medical treatment. On February 28, 2017, he was readmitted to Nicklaus Children's Hospital in Florida due to a rash that had spread over his body which was diagnosed as myeloid sarcoma. Pet. Ex. 7 at 6; Pet. Ex. 10 at ¶ 21. A.R.D-C. underwent a bone marrow aspiration and was diagnosed with treatment-related acute myeloid leukemia. *See* Pet. Ex. 7; Pet. Ex. 10 at ¶ 22. A.R.D-C. underwent further treatment, including chemotherapy and radiation, primarily at Miami Children's. He was also evaluated at Cincinnati Children's Hospital in Ohio and underwent extensive treatment including a bone marrow transplant at Johns Hopkins Bloomberg Children's Hospital in Maryland. Pet. Ex. 10 at ¶ 26. Sadly, on December 24, 2017, A.R.D-C. died from treatment-related acute myeloid leukemia at Johns Hopkins. Pet. Ex. 15.

## II. DISCUSSION

### A. Introduction

The threshold issue to be resolved is whether A.R.D-C. can be deemed to have "returned" to the United States within six months after receiving the vaccines giving rise to this claim, pursuant to 42 U.S.C. § 300aa-11(c)(1)(B)(III), as required to be eligible to receive compensation under the Vaccine Act.

*Appendix C*

The Vaccine Act was established to compensate vaccine-related injuries and deaths. 42 U.S.C. §300aa-10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" *Rooks v. Sec'y of Health & Human Servs.*, 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rept. No. 99-908, 99th Cong., 2d Sess. at 3 (reprinted in 1986 U.S.C.C.A.N. at 6287, 6344)).

The Vaccine Act provides that a "person" is eligible to seek compensation in the Program upon establishing certain requirements including receipt of a vaccine listed on the Vaccine Injury Table and the showing of a sufficiently severe injury. Additionally, the person must establish that he or she:

> (I) received the vaccine in the United States or its trust territories,
>
> (II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or
>
> *(III) received the vaccine outside the United States or a trust territory and the vaccine*

> *was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination.*

42 U.S.C. § 300aa-11(c)(1)(B) (emphasis added).

The Federal Circuit described the various subsections of 42 U.S.C. § 300aa-11 as "gate-keeping" provisions. *Amendola v. Sec'y of Health & Human Servs.*, 989 F.2d 1180, 1182 (Fed. Cir. 1993). If a petitioner is unable to satisfy the requirements of these gatekeeping provisions, "any injury caused by [the vaccine's] administration is not compensable, and the injured party has no cognizable claim under the Vaccine Act." *Scanlon v. Sec'y of Health & Human Servs.*, 114 Fed. Cl. 135, 141 (2013).

It is clear that that A.R.D-C. did not receive the vaccines at issue in the United States or its trust territories, as required to be eligible to receive compensation under subsection (I). It is also clear that he received the vaccines outside the United States and its trust territories, however, there is no evidence that he is a dependent of a United States citizen who was serving abroad as a member of the Armed Forces or otherwise as an employee of the United States.

The only remaining subsection is (III). There is no dispute that the vaccines at issue were made by "vaccine manufacturer[s] located in the United States" and that they were administered to A.R.D-C. outside of the United States. Pet. Exs. 12-14; Pet. Mot. Mem. at 5-8;

Resp. Mot. at 4. It is undisputed that A.R.D-C. came to the United States for medical treatment twenty (20) days after receiving the vaccines at issue. However, A.R.D-C.'s eligibility to seek compensation under this subsection remains to be determined. First, it refers to a "person." This raises the question of whether under the Act's meaning, A.R.D-C. was a "person" when he was carried *in utero* to the United States. After his birth, he did not enter the United States until after the vaccinations when he entered for medical treatment. Additionally, even if it is accepted that A.R.D-C. was a "person" while *in utero*, the further question is whether he "returned" under the Vaccine Act.

**B. "Such *person* returned to the United States"**

Petitioners argue that A.R.D-C. returned to the United States after his vaccinations because he previously entered the country five times while *in utero*. "As a matter of law, a child who is *in utero* is a person for the purposes of the National Vaccine Injury Compensation Program." Pet. Mot. Mem. at 13, citing *Rooks*, 35 Fed. Cl. 1 (holding that a vaccination given to a pregnant woman can be "received" by a child *in utero*); *Burch v. Sec'y of Health & Human Servs.*, No. 99-946V, 2010 U.S. Claims LEXIS 154, 2010 WL 1676767 (Fed. Cl. Spec. Mstr. April 9, 2010) (same); *Melton v. Sec'y of Health & Human Servs.*, No. 01-105V, 2002 U.S. Claims LEXIS 21, 2002 WL 229781 (Fed. Cl. Spec. Mstr. Jan. 25, 2002) (same). In 2016, Congress expressly amended the Vaccine Act to recognize this principle:

(11) Petitions for Compensation...

> (f) Maternal immunization.
>
> (1) Notwithstanding any other provision of law, for the purposes of this subpart, both a woman who received a covered vaccine while pregnant and *any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.*
>
> (2) Definition. As used in this subsection, the term "child" shall have the meaning given that term by subsections (a) and (b) of Section 8 of Title 1...

42 U.S.C. § 300aa-11[9] (emphasis added), cited in Pet. Mot. Mem. at 13.

> "Child" is defined:
>
> (a) In determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative

9. As amended by the wide-ranging 21st Century Cures Act, P.L. 114-255, December 13, 2016, 130 Stat. 1033. The 21st Century Cures Act also amended the Vaccine Injury Table "to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women" and amended the Vaccine Act to provide that "A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child... who was *in utero* at the time such woman was administered the vaccine." *Id.*

> bureaus and agencies of the United States, the words "person", "human being", "child", and "individual", shall include every infant member of the species homo sapiens who is born alive at any stage of development.
>
> (b) As used in this section, the term "born alive", with respect to a member of the species homo sapiens, means the complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion. (c) Nothing in this section shall be construed to affirm, deny, expand, or contract any legal status or legal right applicable to any member of the species homo sapiens at any point prior to being "born alive" as defined in this section.

1 U.S.C. § 8.

Respondent contends that the recent maternal immunization amendment to the Vaccine Act establishes that a child *in utero* can "receive" a vaccine but it does not establish that the child *in utero* was "present" in the United States for purposes of a later "return." Resp. Mot.

at 5, n. 4. In this case, respondent argues that the mother's entries into the United States while pregnant do not mean that A.R.D-C. was "present" in the United States prior to birth. Furthermore, A.R.D-C. was not present in the United States at any time between his birth and his vaccinations. His first entry into the United States was after he was born in The Bahamas and received the vaccines at issue in The Bahamas, for treatment of his post-vaccination injury on July 13, 2016. "As a matter of logic," that post-vaccination entry into the United States cannot constitute a "return." Resp. Mot. at 5; *id.*, n. 4.[10]

I agree with respondent. Congress did expressly amend the Vaccine Act to permit a cause of action alleging that a child was injured by transplacental exposure to a vaccine administered to his or her mother (but only after that child was born alive). This cause of action was previously in question and not expressly recognized under the Act. *See, e.g.*, *Rooks*, 35 Fed. Cl. 1; *Burch*, 2010 U.S. Claims LEXIS 154, 2010 WL 1676767; *Melton*, 2002 U.S. Claims LEXIS 21, 2002 WL 229781 (all analyzing this issue). However, this amendment did not change the definition of child or person under any other sections of the law — such as the section requiring that a "person"

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10. Strangely, petitioners' reply provides: "Respondent apparently *concedes* that these [*in utero*] visits establish [A.R.D-C.'s] 'entry' into the United States and 'presence' in the United States as a visitor." Pet. Resp. at 11 (emphasis added, citing Resp. Mot. at 5 and *id.*, n. 4. This does not seem correct. My understanding is that respondent *does not* accept that the visits to the United States while A.R.D-C. was *in utero* count for determining whether A.R.D-C. could later "return."

"return" to the United States to be eligible to file a claim.

Congress did not amend the Vaccine Act to expand who constitutes a person who can be deemed a person for purposes for later "return" to the United States. Additionally, the applicable definition of "person" specifies that it shall not be construed to "affirm, deny, expand, or contract any legal status or legal right applicable to any member of the species homo sapiens at any point prior to being 'born alive' as defined therein." 1 U.S.C. § 8. If Congress wished to amend that section of the Act, it could have done so. Without express expansion by Congress, the Court is not inclined to make that finding. As such, the amendment to the Vaccine Act does not appear to establish that a pregnant woman's presence in the United States creates a separate presence of the fetus in the United States before birth.

In this case, A.R.D-C., while living and breathing outside of his mother's body, was never present in the United States before his vaccinations or the onset of his severe illness which necessitated his subsequent entry for medical treatment. Thus, his entrance to the United States, while within six months after the vaccinations at issue, cannot be construed as a "return."

**C. "Such person *returned* to the United States"**

Even if A.R.D-C. is recognized as a "person" who was present in the United States before vaccination, the parties still disagree whether A.R.D-C. did "return to the United States not later than six months after the date of vaccination." § 300aa-11(c)(1)(B)(III).

"Return" is not defined in the Vaccine Act. Petitioners argue that the analysis should start and end with the plain meaning. They cite the Supreme Court's decision in *Sebelius v. Cloer* for the proposition that: "As in any statutory interpretation case, [the Court starts,] of course, with the statutory text, and proceeding from the understanding that unless otherwise defined, statutory terms are generally interpreted in accordance with their ordinary meaning." *Sebelius v. Cloer*, 569 U.S. 369, 376, 133 S. Ct. 1886, 185 L. Ed. 2d 1003 (2013) (analyzing the ordinary meaning of "filed" in the Vaccine Act). Petitioners argue that similarly, here, the "common, ordinary, and accepted meaning" of "return" should be applied. Pet. Mot. Mem. at 8-9, citing *Cloer*, 569 U.S. at 376-80; *Nuttall v. Sec'y of Health & Human Servs.*, No. 7-810V, 2015 U.S. Claims LEXIS 117, 2015 WL 691272, *10 (Fed. Cl. Spec. Mstr. Jan. 20, 2015); *Waddell v. Sec'y of Health & Human Servs.*, No. 10-316V, 2012 U.S. Claims LEXIS 1237, 2012 WL 5504421, *8 (Fed. Cl. Spec. Mstr. Sept. 19, 2012). Petitioners cite several dictionary definitions which provide that "return" means simply to "go back" to a place or person. Pet. Mot. Mem. at 9 (internal citations omitted). Neither respondent or this Court has located alternative definitions for the word "return."

However, those definitions submitted by petitioners are still non-specific. "Return" is used in a variety of contexts and the sense of permanence depends on the subject of the return. Here, the Vaccine Act's requirement that a person "returned to the United States" might be understood to be limited to scenarios such as where a person who previously lived in the United States was travelling or working for a limited period of time in a foreign country, where he or she received a vaccine, then "returned" to the United States intending to remain indefinitely. But if "return" is read more broadly, a person who entered the United States once for any length of time and for any purpose (such as tourism, visiting family, medical treatment, or business) returned to his or her country of residence where he or she received a vaccine, and who entered the United States again for any length of time and for any purpose within six months of the vaccination could be deemed to "return" and therefore be eligible to file a petition under the Vaccine Act. This reading seems overly broad.

In this sense, the meaning of "return" is ambiguous. *See McGowan v. Sec'y of Health & Human Servs.*, No. 90-2446V, 1994 WL 879451 (Fed. Cl. Spec. Mstr. May 10, 1994), *mot. for rev. denied*, 31 Fed. Cl. 734, 738 (1994) (reasoning that dictionary definitions "shed little light" and "[s]ince the word "return" relies on its context in order to impart a sense of permanence, the plain meaning rule is not dispositive")[11]; *Sutherland Statutes and Statutory*

11. Both parties note that *McGowan* is the only case analyzing the requirement that a person "return to the United States not later than six months after the date of vaccination" under Vaccine Act

*Construction* (7th ed. 2018) (hereinafter "*Sutherland's*") at § 45:2, The problem of ambiguity ("Modern courts typically frame the issue by stating that ambiguity exists when a statute is capable of being understood by reasonably well-informed persons in two or more different senses.").

In *Cloer*, the Supreme Court noted that where the words of the Vaccine Act are "unambiguous," the plain

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Section 11(c)(1)(B)(III). Pet. Mot. Mem. at 9-11; Resp. Mot. at 5-8; Pet. Resp. at 9-10. *McGowan* concerned a child who was born in the United States in 1964, then moved to Canada where her father was undergoing medical training. While in Canada, she received a measles vaccination and developed convulsions. The child continued to live in Canada apart from intermittent trips to visit her grandparents who were living in the United States — including at least one trip within six months of the vaccination at issue. The child and her parents did not return to live permanently in the United States until over two years after the vaccination, in 1967. The special master dismissed the claim and the Court of Federal Claims affirmed, both holding that the word "returned" was not addressed in the legislative history but was limited to persons who had previously lived in the United States and returned within six months of vaccination with the intention to remain permanently from that point on. *See* 31 Fed. Cl. at 734-740.

Of course, opinions of special masters and the U.S. Court of Federal Claims constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. United States*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 U.S. Claims LEXIS 73, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

meaning governs. However, where there is more than one meaning, certain canons and policy arguments come into play. 569 U.S. at 380-81. As noted by respondent, the Vaccine Act is a limited waiver of sovereign immunity which should be given a "strict and narrow construction." Any ambiguity must be construed "in favor of the sovereign." *Holihan v. Sec'y of Health & Human Servs.*, 45 Fed. Cl. 205, 207 (1999), cited in Resp. Mot. at 8

While interpretation of statutory text, including the Vaccine Act, should begin with the plain meaning it should not produce absurd results. *Cloer*, 133 S. Ct. at 1894, n. 4; *see also Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1570-71 (Fed. Cir. 1993); *McGowan*, 31 Fed. Cl. at 739 ("To rule that 'return' means simply to physically enter the United States is to invite absurd scenarios").

As respondent notes, a court does "not construe statutes in a vacuum, and 'the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'" Resp. Mot. at 7, citing *Colonial Press Int'l v. U.S.*, 788 F.3d 1350, 1356 (Fed. Cir. 2015) (quoting *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809, 109 S. Ct. 1500, 103 L. Ed. 2d 891 (1989)). When interpreting a statute, a court is "not guided by a single sentence or number of sentences but look[s] to the provisions of the whole law, and to its object and policy." Resp. Mot. at 7, citing *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 34, 110 S. Ct. 929, 108 L. Ed. 2d 23 (1990).

Congress had two main goals upon passing the Vaccine Act. The first was to stabilize the national

vaccine market. *Cloer*, 569 U.S. at 372 (stating that the Act was passed in response to an increase in vaccine-related tort litigation); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228-29, 131 S. Ct. 1068, 179 L. Ed. 2d 1 (2011) (recounting that an increasing number of vaccine product liability suits, associated with the withdrawal of several manufacturers and vaccine shortages within the United States) (internal citations omitted); *McGowan*, 31 Fed. Cl. at 738-39. Petitioners assert that: "A person who is [allegedly] injured by a vaccine manufactured by 'a vaccine manufacturer located in the United States' can sue the manufacturer in a traditional negligence or product liability action in the country where the vaccine was administered." Pet. Resp. at 8. "Such suits would create the same kind of expenses, liability concerns, and disruption of the vaccine market as those arising from vaccinations administered in the United States." *Id.* Bringing "some of those cases," those filed by prior visitors to the United States who enter again within six months, would "protect vaccine manufacturers located in the United States from vaccine-injury liability and stabilize the vaccine market." *Id.* Congress undisputedly intended to reduce liability for those manufacturers. However, if Congress wished to provide such broad immunity as argued by the petitioners, it is hard to see why Congress disallowed claims by persons who never entered the United States or entered the United States at some point before vaccination but did not return again within six months. Congress only made eligible those persons who had previously entered the United States and entered again within six months after vaccination. It seems more likely that Congress, in enacting this section, intended

to provide protection for persons who were temporarily away from the United States but who returned within six months after vaccination with an intent to stay.[12]

Congress's second expressed goal was to compensate individuals suffering injury following vaccination. *Cloer*, 569 U.S. at 372 ("Congress enacted the NVCIA to... expedite compensation to injured parties"); *Bruesewitz*, 562 U.S. at 226-29 ("to facilitate compensation"); *McGowan*, 31 Fed. Cl. at 738 ("to "offer fair compensation to victims"). In the legislative history, Congress specifically noted that vaccination programs are facilitated by state and local distribution of vaccines. Additionally, at the time of the Act's passage, state laws mandated that "virtually all" children be vaccinated "as a condition for entering

12. A further limitation is found in how the Vaccine Program is funded. Upon passing the Vaccine Act, Congress decided that it would be funded by an excise tax on the vaccines covered. Originally, taxes were set at different rates to reflect "the currently accepted views regarding the relative reactogenicity of [different] vaccines." The number of doses of each vaccine distributed in the United States was used to estimate the revenues generated per year. H.R. 99-908 at *34. In 1997, the funding scheme changed to a uniform tax of seventy-five cents ($0.75) levied on "any taxable vaccine sold by the manufacturer, producer, or importer thereof." 26 U.S.C. § 4131; I.R.C. § 4131. "The manufacturer is liable for the tax," which "attaches when the title to the article sold passes from the manufacturer to the buyer." However, an exemption applies for sale or resale "for export ... to a foreign country." *See also* Internal Revenue Service, *Publication 510: Excise Taxes (rev. Mar. 2018)*, available at http://www.irs.gov/publications/p510. Manufacturers do not pay the excise tax on vaccines exported for use outside of the United States, suggesting that claims for those vaccines should not be liberally accepted.

school." H.R. Rep. No. 99-908 at *4-7.[13] The legislative history is generally focused on public health within the United States.

Petitioners characterize this purpose of compensation broadly as "humanitarian."[14] Pet. Resp. at 7. This interpretation is overly broad. Congress did not evince any concern about persons possibly injured by vaccines outside of and without any connection to the United States and it is doubtful that the United States or any state or local government would have authority to impose vaccination requirements outside of its own borders (with the exception of persons applying to immigrate to the United States).

Petitioners also argue that this "humanitarian" purpose would also be served by allowing claims by "repeat visitors" to the United States, particularly those

13. While the legislative history addresses primarily programs and laws requiring vaccination of children, states also require vaccination of certain adults such as employees in healthcare facilities in the United States. *See* Centers for Disease Control and Prevention, *Vaccination Laws*, available at https://www.cdc.gov/phlp/publications/topic/vaccinationlaws.html (last accessed April 12, 2019).

14. *See e.g.*, *Oxford Dictionary*, https://en.oxforddictionaries.com/definition/humanitarian (humanitarian (adj.): "concerned with or seeking to promote human welfare... denoting an event or situation which causes or involves widespread human suffering, especially one which requires the large-scale provision of aid'); *Oxford Advanced Learner's Dictionary* at https://www.oxfordlearnersdictionaries.com/us/definition/english/humanitarian 2 ("concerned with reducing suffering and improving the conditions that people live in").

reentering the United States for medical treatment because "a Program award lessens the financial burden on the vaccine-injure person and their family." Pet. Resp. at 7. It is true that the Program compensates eligible petitioners for unreimbursed expenses. However, a not insignificant number of people come from other countries to the United States for more sophisticated medical care, as in this case. *See* Pet. Ex. 5 at 7 (recommending that A.R.D-C. be transferred from a hospital in The Bahamas to another institution that was better equipped to diagnose and treat his condition). There is no indication that Congress would permit compensation to persons coming to the United States for medical treatment, but *only* if they had entered this country prior to vaccination *and* returned within six months.

Related to this same goal, petitioners argue that allowing claims by "repeat visitors" who seek treatment in the United States "also lessens the financial burden on [the] healthcare provider[s]" therein. Pet. Resp. at 7-8. However, this argument is unavailing because for the majority of healthcare services, the providers are not paid by individuals, but by private insurance companies as well as federal and state health benefits programs. The Vaccine Program is a secondary payer of medical expenses. It is not subject to liens from private insurance carriers or federal medical insurance programs such as Medicare — but only subject to liens from state Medicaid programs. § 300aa-15(g) - (h).

In addition to the goals of stabilizing the vaccine market and compensating for post-vaccination injuries, Congress also recognized that the federal government

has historically had the "responsibility to prevent the spread of infectious diseases from other countries into the United States and between States within its own borders." H.R. Rep. 99-908 at 5; *see also Griffin v. Sec'y of Health & Human Servs.*, No. 13-280V, 2014 U.S. Claims LEXIS 271, 2013 WL 1653427, *7 (Fed. Cl. Spec. Mstr. April 4, 2014) (connecting this goal to the Vaccine Act's provisions making eligible United States citizens who are vaccinated while serving abroad in the military or otherwise employed by the United States, and the provision regarding persons receiving vaccinations and then "return[ing]" within six months), *mot. for rev. denied*, 124 Fed. Cl. 101 (2014), *aff'd*, 602 Fed. App'x 528 (Fed. Cir. 2015). Petitioners argue that "repeat visitor[s]" present a "special risk" of bringing infectious diseases from foreign countries to the United States and making them eligible for this program would encourage them to get vaccinated. Pet. Resp. at 9. However, any visitor who is not vaccinated might potentially spread infectious disease, on either a first or repeat entry into the United States. It is illogical to suggest that Congress recognized this issue but decided to tolerate first-time entries by unvaccinated visitors but encourage vaccination for repeat visitors.[15]

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15. Outside of the Vaccine Act, Congress actually draws a distinction between foreign nationals entering the United States permanently versus temporarily. In 1996, Congress amended the Immigration and Nationality Act to provide that foreign nationals applying for immigrant visas abroad or seeking to adjust to permanent residency status while in the United States are required to provide proof of vaccinations recommended for the general United States population by the Secretary of Health and Human Services. Failure to provide this proof is cause for exclusion from admission into the United States. 8 U.S.C. § 1182(a)(1)(A)(ii) (as amended Sept. 30, 1996); *see also* U.S. Citizenship and Immigration Services,

*Appendix C*

The statutory language at issue in this case is admittedly puzzling and is not explained in the legislative history. In my view, it most reasonably can be read to address persons who reside in the United States, who receive vaccinations while living or working abroad, and then return within six months. Such persons might receive the vaccinations with knowledge of the United States' public health initiatives and laws regarding vaccination. Congress's use of the word "person" rather than "citizen" in this section (and throughout the Vaccine Act generally) evinces an intent to liberally include persons who are expected to be present in the United States apart from a temporary absence and to benefit domestic public health.[16]

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*Vaccination Requirements*, https://www.uscis.gov/news/questions-and-answers/vaccination-requirements (last accessed April 19, 2019); U.S. Department of State, *Vaccinations — Important Notice to Immigrant Visa Applicants Concerning Vaccination Requirements*, https://travel.state.gov/content/travel/en/us-visas/immigrate/vaccinations.html (last accessed April 19, 2019). In contrast, foreign nationals visiting the United States temporarily for business or pleasure are excluded from the definition of "immigrant" and not subject to these vaccination requirements. 8 U.S.C. § 1101(a)(15)(B). Such persons apply instead for non-permanent visas for business (B-1), pleasure (B-2), or a combination of both (B-1/B-2). "Pleasure" is defined as "legitimate activities of a recreational character including tourism, amusement, visits with friends or relatives, rest, *medical treatment*, and activities of a fraternal, social, or service nature." 22 C.F.R. § 41.31(b)(1) (2006) (emphasis added). In this case, A.R.D-C. was issued a B-1/B-2 visa to enter the United States for the first time on January 12, 2017, shortly before entering the United States for more advanced medical treatment. Pet. Ex. 11 at 5.

16. *But see* 42 U.S.C. § 300aa-11(c)(1)(B)(II) (permitting a claim for a vaccine received abroad by a United States "citizen" while serving in the Armed Forces or otherwise employed by the United States, without a return requirement).

In this case, there is no evidence of intent for A.R.D-C. to live in the United States. His paternal grandmother, father, and mother's established primary place of residence was in The Bahamas. While the paternal grandmother owned a residential property in the United States, that was only a destination for periodic "visits." Pet. Exs. 10, 16. Petitioners aver that A.R.D-C., as well, would "likely... have been a frequent visitor to the United States had he not died as a result of his vaccine-related illnesses." Pet. Resp. at 12. While this may be true, A.R.D-C.'s entire first year of life was spent in The Bahamas and there is little doubt that the family was domiciled there.

He received the vaccines at issue as part of his pediatric care in The Bahamas, and not related to any visa application or other vaccination program administered by the United States. While he was only a year old when he received the vaccines at issue and he was his parents' first child, the record does not suggest that they were applying for daycare or school in the United States. Additionally, when A.R.D-C. was issued a temporary visa for the first time, it did not require proof of vaccination.

That visa was to enter the United States in order to obtain more sophisticated medical treatment. Additionally, that entry was never intended to be permanent. The parents expressed a desire to go "home" to The Bahamas. *See* Pet. Ex. 10 ¶ ¶ 18-19 (the mother's recollection that they were not permitted to "trave[l] back home to The Bahamas," until they were "finally given permission to leave the USA... provided [they] come back to Miami Children's Hospital for monthly visits"); Pet. Mot. Mem.

at 3 (stating that A.R.D-C. was only able to "return briefly to The Bahamas" two times before he passed away in the United States). Thus, his entry to the United States for medical treatment, although it was effectively permanent, cannot be construed as a "return."

## III. CONCLUSION

I express my deep personal sympathy and condolences to this family for the tragic loss of their child, regardless of possible causation by the vaccines he received. However, they are not eligible to seek compensation from the Vaccine Program. First, A.R.D-C. cannot be viewed to be a "person" who was present in the United States prior to his vaccinations.

Second, even if A.R.D-C. was viewed to be a person upon being carried *in utero* into the United States, there is not sufficient evidence that he would have "returned" within six months, as that word is construed to mean under the Vaccine Act, apart from the need for more sophisticated medical care that was not available in his home country of The Bahamas. While A.R.D-C. may have temporarily visited the United States, like his parents, there is no evidence that he would have established a permanent presence in this country. Interpreting "return" more broadly to encompass this claim would run too far afield of Congress's intent to create a "national" program. Accordingly, the petition must be **DISMISSED**.

*Appendix C*

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court shall enter judgment in accordance herewith.[17]

**IT IS SO ORDERED**.

**/s/ Thomas L. Gowen**
Thomas L. Gowen
Special Master

17. Entry of judgment is expedited by each party's filing notice renouncing the right to seek review. Vaccine Rule 11(a).

## APPENDIX D — DENIAL OF REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, DATED NOVEMBER 19, 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2020-1137

ROBERT DAVID DUPUCH-CARRON,
ELIZABETH JOANNA CARRON, AS THE LEGAL
REPRESENTATIVES OF THEIR
MINOR SON, A. R. D-C.,

*Petitioners-Appellants,*

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

*Respondent-Appellee.*

Appeal from the United States Court of Federal Claims in No. 1:17-vv-01551-RAH, Judge Richard A. Hertling.

**ON PETITIONS FOR PANEL REHEARING AND REHEARING *EN BANC***

Before Prost, *Chief Judge*, Newman, Lourie, Clevenger,* Dyk, Moore, O'Malley, Reyna, Wallach, Taranto, Chen, Hughes, and Stoll, *Circuit Judges.*

Per Curiam.

* Circuit Judge Clevenger participated only in the decision on the petitions for panel rehearing.

*Appendix D*

**ORDER**

Appellant Elizabeth Joanna Carron filed a petition for rehearing en banc. Appellant Robert David Dupuch-Carron separately filed a combined petition for panel rehearing and rehearing en banc. The petitions were referred to the panel that heard the appeal, and thereafter the petitions for rehearing en banc were referred to the circuit judges who are in regular active service.

Upon consideration thereof,

It Is Ordered That:

The petitions for panel rehearing are denied.

The petitions for rehearing en banc are denied.

The mandate of the court will issue on November 30, 2020.

For the Court

November 19, 2020
Date

/s/Peter R. Marksteiner
Peter R. Marksteiner
Clerk of the Court