



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 the National Vaccine Injury Compensation Program, alleging that A.R.D-C.'s March 26, 2016 vaccines caused his injuries and death.<sup>3</sup> 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.

## I. Summary of Relevant Facts<sup>4</sup>

### 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.

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<sup>3</sup> 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").

<sup>4</sup> 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.

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 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,<sup>5</sup> pancytopenia<sup>6</sup> for which he was given a blood transfusion, and febrile neutropenia for which he was given intravenous Zosyn, an antibiotic.<sup>7</sup> 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-

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<sup>5</sup> Thrombocytopenia is “a decrease in the number of platelets.” *Dorland’s Illustrated Medical Dictionary* (32nd ed. 2012) [hereinafter “*Dorland’s*”] at 1922.

<sup>6</sup> Pancytopenia is “deficiency of all cellular components of the blood.” *Dorland’s* at 1368.

<sup>7</sup> Neutropenia is “an abnormal decrease in the number of neutrophils in the blood.” *Dorland’s* at 1272.

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, 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”).<sup>8</sup> 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, 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,

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<sup>8</sup> 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.

pursuant to 42 U.S.C. § 300aa-11(c)(1)(B)(III), as required to be eligible to receive compensation under the Vaccine Act.

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 WL 1676767 (Fed. Cl. Spec. Mstr. April 9, 2010) (same); *Melton v. Sec’y of Health & Human Servs.*, No. 01-105V, 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<sup>9</sup> (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 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

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<sup>9</sup> As amended by the wide-ranging 21<sup>st</sup> Century Cures Act, P.L. 114-255, December 13, 2016, 130 Stat. 1033. The 21<sup>st</sup> 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.*

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.<sup>10</sup>

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 WL 1676767; *Melton*, 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” “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.

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<sup>10</sup> 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.”

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 (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 WL 691272, \*10 (Fed. Cl. Spec. Mstr. Jan. 20, 2015); *Waddell v. Sec'y of Health & Human Servs.*, No. 10-316V, 2012 WL 5504421, \*8 (Fed. Cl. Spec. Mstr. Sept. 20, 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")<sup>11</sup>; *Sutherland Statutes and Statutory Construction* (7<sup>th</sup> ed.

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<sup>11</sup> 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 Section 11(c)(1)(B)(III). Pet. Mot.

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 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 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*, 569 U.S. at 1894, n. 4; *see also Hellebrand v. Sec’y of Health & Human Servs.*, 999 F.3d 1566, 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 (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 (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 (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

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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. Sec’y of Health & Human Servs.*, 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 WL 504728, at \*7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

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.<sup>12</sup>

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 school.” H.R. Rep. No. 99-908 at \*4-7.<sup>13</sup> The legislative history is generally focused on public health within the United States.

Petitioners characterize this purpose of compensation broadly as “humanitarian.”<sup>14</sup> 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

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<sup>12</sup> 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.

<sup>13</sup> 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).

<sup>14</sup> 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](https://www.oxfordlearnersdictionaries.com/us/definition/english/humanitarian_2) (“concerned with reducing suffering and improving the conditions that people live in”).

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 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, 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.<sup>15</sup>

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<sup>15</sup> 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

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.<sup>16</sup>

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

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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, *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.

<sup>16</sup> 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).

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**.

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.<sup>17</sup>

**IT IS SO ORDERED.**

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

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