



## I. Facts

A brief recitation of the facts provides necessary context.<sup>2</sup>

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 23<sup>rd</sup> 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 than 102 degrees Fahrenheit, crankiness, stuffy nose, rattling in his chest, occasional chesty coughs, reduced activity, vomiting, and diarrhea. On July 10, 2016, A.R. D-C’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<sup>3</sup> and pancytopenia<sup>4</sup> for which he received a blood transfusion, and

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<sup>2</sup> 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*.

<sup>3</sup> Thrombocytopenia is defined as a “decrease in the number of platelets.” *Dorland’s Illustrated Medical Dictionary* 1069 (32nd ed. 2012) (“*Dorland’s*”) at 1922.

<sup>4</sup> Pancytopenia is defined as a “deficiency of all cellular elements of the blood.” *Dorland’s* at 1368.

febrile neutropenia<sup>5</sup> 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.”<sup>6</sup>

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”).<sup>7</sup> 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”).<sup>8</sup> A.R. D-C underwent treatment, which included chemotherapy<sup>9</sup> and radiation<sup>10</sup> 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.

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<sup>5</sup> 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.

<sup>6</sup> Leukemia is “a progressive, malignant disease of the blood-forming organs, characterized by distorted proliferation and development of leukocytes and their precursors in the blood and bone marrow.” *Dorland’s* at 1026.

<sup>7</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.” *Dorland’s* at 1085.

<sup>8</sup> 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.

<sup>9</sup> Chemotherapy is “the treatment of a disease by chemical agents.” *Dorland’s* at 341.

<sup>10</sup> 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.

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.<sup>11</sup> *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.

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

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]etitioner 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.* 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).<sup>12</sup> The petitioners argue that the Special Master inappropriately interpreted the word “return” because “[t]he relevant language of the Vaccine

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<sup>12</sup> 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.

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 v. Cloer*.” See *Sebelius v. Cloer*, 569 U.S. 369, 376–77 (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 (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.<sup>13</sup> While the respondent does not reject the petitioners’ understanding of the “plain 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 (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 (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

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<sup>13</sup> 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.

its context and interpreted in a vacuum. *See Houlihan v. Sec’y of Health & Human Servs.*, 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 (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. Sec’y of Dep’t of Health & Human Servs.*, 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.” *Houlihan*, 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. *Houlihan*, 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.<sup>14</sup> Unless Congress is explicit in seeking to 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 (2013); *Morrison v. National Bank of Australia, Ltd.*, 561 U.S. 247, 255 (2010); *Microsoft Corp. v. AT&T Corp.*, 580 U.S. 437, 454 (2007); *E.E.O.C. v. Arabian Am. Oil Co.*, 499 U.S. 244, 248 (1991).<sup>15</sup> 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(a)(1). Vaccines sold or re-sold “for 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.<sup>16</sup>

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

<sup>15</sup> *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.

<sup>16</sup> For example, several years before Congress considered the Vaccine Act, the former Shah of Iran sought medical treatment in the United States, triggering strong reactions in Iran, including the seizure of the U.S. Embassy and the taking of hostages.

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**