



optic neuritis, and developmental delay [collectively “Hailey’s injuries”]. Pet. at ¶ 27. Petitioners allege that Hailey’s injuries were caused-in-fact by her influenza vaccination. *Id.*

### PROCEDURAL HISTORY.

Petitioners filed Hailey’s medical records on October 30, 2006; April 6, 2007; May 8, 2007; October 31, 2007; and both parties continue to periodically update them. On April 25, 2007 petitioners filed an expert report and a curriculum vitae [“CV”] from Dr. Timothy Lotze.<sup>3</sup> They then filed an expert report from Dr. Elizabeth Mumper on May 8, 2007. Petitioners’ Exhibit [“Pet. Ex.”] 11. On July 30, 2007, respondent filed her report pursuant to Vaccine Rule 4(c) that recommended I deny compensation in this case. Respondent also filed the expert report and CV of her medical expert, Dr. W. Paul Glezen. Respondent’s Exhibits A and B.

In a status conference held January 28, 2008, the parties indicated that they had agreed to pursue a litigative risk settlement and were initiating a joint lifecare plan to assist them in their negotiations. The parties have worked diligently since that time to reach a resolution. On June 30, 2010, the parties filed a joint motion for ruling on the record [“Joint Motion”]. The parties are still actively negotiating settlement of damages and anticipate that a ruling on entitlement will facilitate that resolution.

Respondent averred in the Joint Motion that while she “maintains her view that this case is not appropriate for entitlement to compensation under the terms of the Vaccine Act, respondent believes that an entitlement hearing would not be an efficient use of Program resources and does not intend to further contest this case.” Joint Motion at 2. Respondent also noted that she “believes the facts of this case are particularly unique, and will strongly object to any future attempt to interpret respondent’s decision not to defend this matter as an acquiescence to any aspect of vaccine causation regarding any particular injury or fact pattern in any other case.” *Id.* at n.1.

Based on the record as a whole, I find sufficient evidence to grant the Joint Motion and issue a ruling as to the cause of Hailey’s injuries. I find that as a result of an influenza vaccine received on October 31, 2003, Hailey suffered transverse myelitis, ADEM with severe spinal cord involvement, bilateral optic neuritis, and developmental delay, and that these injuries persisted for longer than six months. Petitioners are therefore entitled to compensation.

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<sup>3</sup> Petitioners filed these two exhibits without exhibit numbers.

## THE EVIDENTIARY RECORD.

Hailey was born prematurely on December 4, 2001, with Apgar scores<sup>4</sup> of eight and nine. Pet. Ex. 13, p. 5. She spent two weeks in the neonatal intensive care unit, did well, and was discharged home on December 19, 2001. See *id.* at 8. Hailey's pediatric records reflect typical childhood illnesses as part of normal health and development through October of 2003. See Pet. Ex. 3, pp. 1-6.

On October 31, 2003, Hailey presented to her pediatrician for a sick visit. Her mother was concerned that Hailey was "breathing fast," especially at night, and did not have an appetite. Pet. Ex. 3, p. 7. Hailey had vomited the day before the visit. The pediatrician diagnosed an upper respiratory infection and prescribed medication for possible nocturnal asthma. Hailey received an influenza vaccine at this visit. *Id.*

At subsequent visits on November 14, 2003; November 17, 2003; and November 20, 2003; Hailey exhibited signs of declining mobility and strength. Pet. Ex. 3, pp. 8-9, 13-14. Hailey was admitted to the hospital on November 20, 2003. Pet. Ex. 1, p. 1. An MRI of Hailey's spine supported diagnoses of transverse myelitis, ADEM, and bilateral optic neuropathy. *Id.* These conditions or their sequelae persist, and have caused Hailey to experience significant developmental delay. See, e.g., Pet. Ex. 7.

## DISCUSSION.

In order to prevail under the Program, petitioners must prove either a "Table" injury<sup>5</sup> or that a vaccine listed on the Vaccine Injury Table was the cause-in-fact of an injury. Based on the record as a whole, petitioners have established that the influenza vaccine Hailey received on October 31, 2003 was the cause-in-fact in Hailey's injuries. See § 300aa-11(c)(1)(C)(i).

The Vaccine Act provides that a special master may not make a finding awarding compensation based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion. § 300aa-13(a)(1). Petitioners have proffered both medical records and the expert medical opinions of Dr. Lotze and Dr. Mumper.

To satisfy their burden of proving causation-in-fact, petitioners must "show by preponderant evidence that the vaccination brought about [Hailey's] injury by providing:

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<sup>4</sup> The Apgar score is a numerical assessment of a newborn's condition, usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle tone, reflex irritability, and color, with from zero to two points awarded in each of the five categories. See DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1670 (30th ed. 2003).

<sup>5</sup> A "Table" injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified. Petitioners do not allege a "Table" injury in this case.

(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); see also *Hines v. Sec'y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). They must show "that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." *Grant v. Sec'y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Circumstantial evidence and medical opinions may be sufficient to satisfy the second *Althen* factor. *Capizzano v. Sec'y, HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Without more, "evidence showing an absence of other causes does not meet petitioner[s'] affirmative duty to show actual or legal causation." *Grant*, 956 F.2d at 1149. Mere temporal association is insufficient to prove causation-in-fact. *Moberly v. Sec'y, HHS*, 592 F.3d 1315, 1323 (Fed. Cir. 2010).

When petitioners allege an "off-Table" injury, eligibility for compensation—the *prima facie* case—is established when the petitioners demonstrate, by a preponderance of the evidence, that: (1) Hailey received a vaccine set forth on the Vaccine Injury Table; (2) that she received the vaccine in the United States; (3) that she sustained or had significantly aggravated an illness, disability, injury, or condition caused by the vaccine; and (4) that the condition has persisted for more than six months.<sup>6</sup>

There is no dispute between the parties, and the records reflect, that Hailey received a vaccine set forth on the Vaccine Injury Table administered in the United States. It is also clear that the injuries and sequelae alleged in this case have persisted beyond the six month requirement. Therefore the only issue left to resolve is whether the influenza vaccine administered on October 31, 2003 was the cause-in-fact of Hailey's injuries.

In support of causation, Dr. Lotze opined that by the process of molecular mimicry, Hailey's influenza vaccination prompted an autoimmune response that manifested as inflammation in the brain and spinal cord, resulting in her injuries.<sup>7</sup> I find that Dr. Lotze's report meets the criteria for causation-in-fact set forth in *Althen*. 418 F.3d at 1278. Transverse myelitis and other demyelinating conditions similar to Hailey's have been associated with molecular mimicry within the time frame after vaccination in which Hailey's injuries occurred. See, e.g., *Schmidt v. Sec'y, HHS*, No. 07-20V, 2009 WL 5196169 (Fed. Cl. Spec. Mstr. Dec. 17, 2009); *Wise v. Sec'y, HHS*, No. 05-0694V, 2009 WL 1220986 (Fed. Cl. Spec. Mstr. Apr. 14, 2009). Influenza virus is recognized as a cause of ADEM. *Snyder v. Sec'y, HHS*, No. 01-162V, 2009 WL 332044, at \*105

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<sup>6</sup> Section 300aa-13(a)(1)(A). This section provides that petitioners must demonstrate by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1). Section 300aa-11(c)(1) contains the four factors listed above, along with others not relevant to this case.

<sup>7</sup> Doctor Mumper, a pediatrician, provided a similar explanation for causation in her report. As Dr. Lotze was both a treating physician and a board-certified pediatric neurologist, I find his report sufficient to establish causation in this case.

and n.335 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). Dr. Lotze's report provided a logical sequence of cause and effect between the influenza vaccine and Hailey's injuries. The weight of the evidence favors a causal connection in this case.

### **CONCLUSION.**

Petitioners have established the statutory requirements for entitlement. Based on the record before me, I find that there is preponderant evidence that Hailey's influenza vaccination was a substantial cause of her transverse myelitis, ADEM, bilateral optic neuritis, and developmental delay. I further find that Hailey's injuries have persisted for more than six months.

I hold that petitioners have established entitlement to compensation for Hailey's injuries.

**IT IS SO ORDERED.**

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**Denise K. Vowell**  
Special Master