In the United States Court of Federal Claims

ABIGAIL SIMS AND DANIEL SIMS, *on behalf of their deceased daughter, A.E.S.*,

Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

No. 15-1526[1]
(Filed: June 25, 2025)

Michael G. McLaren, Black McLaren Jones Ryland & Griffee, P.C., Memphis, TN, for Petitioners.

Voris Edward Johnson, Civil Division, United States Department of Justice, Washington, DC, for Respondent.

OPINION AND ORDER

LERNER, *Judge*.

Petitioners, Abigail and Daniel Sims, filed a claim under the National Vaccine Compensation Act of 1986 ("Vaccine Act") for the 2013 death of their daughter A.E.S. Petition, ECF No. 1; *see also* 42 U.S.C. § 300aa-11. On January 8, 2025, the Special Master awarded compensation to Petitioners. Decision on Damages (hereinafter "Decision") at 9, ECF No. 106; *Sims v. Sec'y of Health & Hum. Servs.*, No. 15-1526V, 2025 WL 394573 (Fed. Cl. Spec. Mstr. Jan. 8, 2025).

A.E.S. received four vaccinations on December 16, 2013. Ruling on Entitlement (hereinafter "Ruling") at 1, ECF No. 97; *Sims v. Sec'y of Health & Hum. Servs.,* No. 15-1526V, 2024 WL 1367151 (Fed. Cl. Spec. Mstr. Mar. 7, 2024). The Special Master determined the vaccinations contributed to her death later that day. *Id.* Respondent, the Secretary of Health and Human Services, seeks review of the Special Master's Decision and challenges the findings in her Ruling. *See* Resp't's Mot. for Review (hereinafter "Resp't Mot.") at 1, ECF No. 108; Resp't's Mem. Supp. Mot. for Rev. (hereinafter "Resp't Mem.") at 1, ECF No. 109; *see also* 42

[1] This Opinion was originally filed under seal on June 10, 2025. The Court provided the parties the opportunity to review the Opinion for any proprietary, confidential, or other protected information and submit proposed redactions no later than June 24, 2025. The parties did not propose any redactions.

U.S.C. § 300aa-12(e)(1) (stating parties may request the U.S. Court of Federal Claims to review a special master's decision).

A petitioner has two avenues to receive compensation for alleged vaccine injuries. *Munn v. Sec'y of Dep't of Health & Hum. Servs.*, 970 F.2d 863, 865 (Fed. Cir. 1992). First, a petitioner may show by a preponderance of the evidence that she suffered an injury listed on the Vaccine Injury Table within the specified timeframe. *Capizzano v. Sec'y of Health & Hum. Servs.,* 440 F.3d 1317, 1319 (Fed. Cir. 2006) (citing *Munn*, 970 F.2d at 865). That the vaccine caused the Table injury is presumed. *Id*. at 1320. Alternatively, a petitioner can allege an off-Table injury when her injury is not listed on the Table or if she did not suffer the injury within the prescribed timeframe. *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1351 (Fed. Cir. 2008). For off-Table injuries, a petitioner must show by a preponderance of the evidence that the vaccine caused the injury. *See* 42 U.S.C. § 300aa–11(c)(1)(C)(ii)(1); *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (laying out a three-prong analysis for proving causation-in-fact for off-Table injuries).

If the petitioner meets her burden under either avenue, the Vaccine Act authorizes compensation provided "there is not a preponderance of the evidence that the . . . injury . . . or death described in the petition is due to factors unrelated to the administration of the vaccine." 42 U.S.C. § 300aa–13(a)(1)(B). "[I]n both Table and off-Table cases the government bears the burden of establishing alternative causation by a preponderance of the evidence." *Walther v. Sec'y of Health & Hum. Servs.,* 485 F.3d 1146, 1151 (Fed. Cir. 2007).

The Special Master determined Petitioners met their burden to show A.E.S. suffered a Table injury. Ruling at 38–43 (citing 42 C.F.R. § 100.3(b)(2) (July 23, 2015) (most recently amended in 2022). Specifically, the Special Master found A.E.S. demonstrated the Table's requisite clinical signs of an encephalopathy (an injury to the brain) and, as a result, died less than nine hours after receiving the vaccines. *Id.* at 43. Alternatively, the Special Master concluded Petitioners satisfied their burden under the *Althen* test to prove that an off-Table vaccine injury caused encephalopathy, as well as cerebral edema and death. *Id.* at 43–51. She also determined Respondent failed to establish an alternative cause, and there was "no evidence that A.E.S. died of a factor unrelated to the administration of the vaccines." *Id*. at 42, 51–52. Petitioners were awarded $300,000 in damages. Decision at 9.

Respondent contends the Special Master made arbitrary and capricious factual findings and acted contrary to law. Resp't Mot. at 1; Resp't Mem. at 1–2. The Secretary argues the Special Master improperly relied on A.E.S.'s death alone to find a Table injury and made factual findings based solely on Petitioners' uncorroborated testimony despite discrepancies with the medical record. Resp't Mem. at 12–17. Alternatively, Respondent asserts the Special Master erred in applying prongs one and two of the *Althen* test in her off-Table injury analysis. *Id*. at 17–20. Finally, Respondent claims the Special Master improperly disregarded evidence that A.E.S.'s death resulted from other factors, including evidence A.E.S. suffered a sudden

unexplained infant death ("SUID").[2] *Id*. at 8–12. Petitioners maintain the Special Master made neither legal errors nor arbitrary factual findings. Pet'rs' Resp. to Mot. for Rev. (hereinafter "Pet'rs Resp.") at 1, ECF No. 111.

Having considered the record, the Special Master's Ruling, and the parties' legal arguments, the Court **DENIES** Respondent's Motion for Review and **SUSTAINS** the Special Master's Decision. *See* 42 U.S.C. § 300aa-12(e)(2)(A). Respondent has not demonstrated the Special Master made either an error of law or arbitrary factual findings in her Table injury analysis. Rather, Respondent's arguments amount to mere disagreement with the Special Master's factual findings and weighing of the evidence. That is not a basis for this Court to set aside the Special Master's thorough and well-reasoned Ruling. *See Hines ex rel Sevier v. Sec'y of Health & Hum. Servs.*, 940 F.2d 1518, 1527 (Fed. Cir. 1991). In addition, the Special Master properly concluded Respondent failed to establish an alternative cause. Since the Special Master needed only to find a Table injury to award damages, the Court does not reach the parties' arguments about whether her off-Table injury finding was erroneous.

I. Background

Petitioners sought compensation under the Vaccine Act on December 15, 2015. Ruling at 1. The Special Master held an Entitlement Hearing from December 17–18, 2020. *See* Transcript (hereinafter "Tr."), ECF Nos. 81 (Tr. pages 1–212) & 82 (Tr. pages 213–333). Factual determinations were based on affidavits, testimony, A.E.S.'s medical history both before and after her vaccinations, the autopsy report, a medical examiner's investigative report, and each party's medical experts' opinions. Ruling at 4–35. The Special Master also summarized the legal standards for fact-finding, the evaluation of expert testimony, and the consideration of medical literature. *Id*. at 37–38. She stated she "reviewed and considered all of the medical records and literature submitted in this matter." *Id*. at 38. The Court summarizes below the relevant facts from the Special Master's Ruling.

A. Medical History and Autopsy

A.E.S.'s medical history showed no cause for health concerns prior to her vaccinations. *Id*. at 11. At approximately eleven weeks old, she received the Pediatrix (DTaP/IPV/HepB), Hib, PCV13 (Prevnar 13), and RotaTeq vaccinations during a routine check-up on December 16, 2013 at around 11:00 AM. *Id.* at 11–12 (citing Pet'rs' Ex. 2 (Children's Clinic of Oxford, P.A. Medical Records) at 7, ECF No. 9-2). The Special Master notes the check-up documented "A.E.S. was a well, breastfed child with no concerns in the first two months of life." *Id*. at 11 (citing Pet'rs' Ex. 2 at 8–10).

[2] The Special Master explained the distinction between SUID and sudden infant death syndrome ("SIDS"); "[t]he two are not synonymous." Ruling at 3. SIDS is a specific "diagnosis of exclusion used when other possibilities have been ruled out." *Id*. SUID, on the other hand, is an umbrella term that encompasses instances when infants "die suddenly and unexpectedly for a variety of reasons" and is not itself a diagnosis. *Id*.

Later that day, at approximately 6:34 PM, Mr. Sims arrived at the hospital with A.E.S in acute distress. *Id*. Mr. Sims reported that eight minutes before arriving, A.E.S. stopped breathing. *Id.* Mr. Sims stated he fed A.E.S. with a bottle, burped her, and put her into her bassinet at 5:30 PM before finding her struggling to breathe, pale, and with blue lips at 6:15 PM. *Id*. at 11–12 (citing Pet'rs' Ex. 7 (Lafayette County Coroner's Report) at 1, 7, ECF No. 9-7). The hospital documented that she had no pulse and had suffered respiratory arrest, cardiac arrest, sepsis, anaphylaxis, and cyanosis, as well as a "gross pulmonary edema from trachea." *Id.* at 11 (citing Pet'rs' Ex. 5 (Baptist Memorial Hospital of North Mississippi Medical Records (A.E.S.)) at 6, 11, ECF No. 9-5). Yet, under "History of Present Illness," the hospital indicated: "normal day – shots – ate normally." *Id*. (citing Pet'rs' Ex. 5 at 10). A.E.S. was pronounced dead at 7:15 PM, after all resuscitation efforts failed. *Id*. at 12 (citing Pet'rs' Ex. 5 at 11, 57–58).

The autopsy report, prepared by Dr. Erin Barnhart, stated the cause and manner of death were "best classified as undetermined." *Id.* at 12 (citing Pet'rs' Ex. 3 (Mississippi State Medical Examiner's Office Autopsy Report) at 4, ECF No. 9-3). She documented a normal breastfed baby. *Id*. The Special Master summarized the autopsy as noting "visceral congestion," "intradermal or submucous hemorrhage" in three areas, and "pulmonary edema," defined as the "presence of abnormally large amounts of fluid in the intracellular tissue spaces" in the lungs. *Id*. at 12 n.8, n.9 (citations omitted). Dr. Barnhart noted the autopsy's findings were "consistent with Sudden Unexplained Infant Death (SUID)." *Id*. at 12 (citing Pet'rs' Ex. 3 at 4). The autopsy also included photographs. *See* Pet'rs' Ex. 18, ECF No. 25. The Special Master concluded the autopsy findings were "generally unremarkable, except for a brain weight of 595 grams." Ruling at 12. "The expected range for brain weight was 461-555 grams." *Id.* at 12 n.10 (citing Pet'rs' Ex. 3 at 3).

B. Affidavits and Testimony of Daniel and Abigail Sims

Mr. Sims submitted two affidavits, the first on March 29, 2016 and the second on November 12, 2020. Ruling at 4; *see also* Pet'rs' Ex. 8 (Affidavit of Daniel Sims), ECF No. 12-1; Pet'rs' Ex. 136 (Second Affidavit of Daniel Sims), ECF No. 65-2. In his first affidavit, he recalled feeding and burping A.E.S. and placing her in her bassinet at about 5:00 PM. Ruling at 4 (citing Pet'rs' Ex. 8 at 2). He found A.E.S. not breathing and with a bluish tint to her upper lip at around 5:45 PM, after which he drove her to the hospital. *Id.* In his second affidavit, Mr. Sims stated A.E.S. was "spaced out" and not cuddling or snuggling as usual while he fed her the first time. *Id*. at 5 (citing Pet'rs' Ex. 136 at 2). Later, he stated A.E.S. was fussing, so he fed her again, and she fed a bit slower than usual. *Id.* He then placed her in her bassinet and checked on her periodically. *Id*. When he checked on her the last time, A.E.S. had turned onto her side with her head tilted back, had slightly blue lips, and looked pale. *Id*. at 4–5 (citing Pet'rs' Ex. 136 at 1). As he picked her up, he heard her exhale. *Id*. at 5. He recalled she was limp, although he thought he felt her move twice as he took her to the car. *Id*.

During his testimony, Mr. Sims stated that before her vaccinations A.E.S. was alert and wide awake, and she was always looking around with a "presence on her face." *Id*. (citing Tr. at 50). After her vaccinations, he was surprised A.E.S. was very quiet on the ride home. *Id*. at 6. He testified that once home she was "super spaced out," was not "locking on to any person," and

was "not all there." *Id.* (citing Tr. at 59–60). He recalled she looked very tired and so he put her into her bassinet facing up. *Id*. (citing Tr. at 57). The family did not have a baby monitor, but he checked on her every five to twenty minutes. *Id*. (citing Tr. at 59–60). The last time he checked on her, she "looked like she was almost trying to turn onto her side slightly," was "facing upward in the bassinet with her mouth open," and her lips were blue. *Id*. at 6 (citing Tr. at 58, 61–62). He then took A.E.S. to the hospital. *Id*. After his daughter's death, Mr. Sims provided details of what happened at home to Mr. Robert Kennedy, the County Medical Examiner Investigator ("CMEI"). *Id*. (citing Tr. at 66–67). Mr. Sims told Mr. Kennedy the position in which he found A.E.S. and that her face was "extremely pale." *Id.* (citing Tr. at 73).

Mrs. Sims also submitted two affidavits, the first on March 29, 2016 and the second on November 12, 2020. *Id*. at 7; *see also* Pet'rs' Ex. 9 (Affidavit of Abigail Sims), ECF No. 12-2; Pet'rs' Ex. 135 (Second Affidavit of Abigail Sims), ECF No. 65-1. In her first affidavit, she stated A.E.S. was a healthy baby prior to her vaccinations. Ruling at 7 (citing Pet'rs' Ex. 9 at 1–2). Mrs. Sims recalled that while at work after the vaccinations, Mr. Sims called between 5:45 PM and 6:00 PM en route to the hospital after finding A.E.S. not breathing. *Id*. In her second affidavit, Mrs. Sims stated that once at home after the vaccinations, A.E.S. was not making eye contact, had a distant look, and did not cuddle. *Id*. (citing Pet'rs' Ex. 135 at 2).

During her testimony, Mrs. Sims stated A.E.S. breastfed approximately three times in the morning before her vaccinations. *Id*. at 8 (citing Tr. at 14). After the vaccinations, A.E.S. was sleepy, fussy, and looked tired. *Id*. A.E.S. was not "looking at [her]" but "kind of looking past [her]" and "had a quiet look in her eye." *Id.* (citing Tr. at 21–22). Mrs. Sims also stated that while A.E.S. tried to nurse several times, she was uncertain if she was actually feeding much. *Id*. (citing Tr. at 21–22). She recalled it seemed like A.E.S. had a headache and she spit up but did not vomit. *Id*. (citing Tr. at 40–41).

Mrs. Sims testified that when A.E.S. arrived at the hospital, she was slightly grayish with blue lips but still warm to the touch. *Id*. at 9. Mrs. Sims did not recall if A.E.S. had a pulse but noted she was not breathing. *Id*. Mrs. Sims also said she answered all of Mr. Kennedy's questions. *Id*. She stated she took precautions to avoid SIDS, including always placing A.E.S. on her back in her bassinet. *Id*.

C. Medical Examiner Robert Kennedy's Investigative Report and Testimony

Mr. Kennedy, the CMEI, produced an investigative report based on the emergency room medical record and the autopsy. *Id*.; *see also* Pet'rs' Ex. 7. He reported that after A.E.S.'s vaccinations, there were no reactions noted throughout the rest of the day until she was found unresponsive. Ruling at 9 (citing Pet'rs' Ex. 7 at 1). On December 16, 2013, the day of A.E.S.'s death, he completed a Sudden Unexplained Infant Death Investigation form, which included several witness interview answers and diagrams of how A.E.S. was positioned before and after being found unresponsive. *Id*. (citing Pet'rs' Ex. 7 at 7–14). He documented "blueness top lip, baby was pale" and that A.E.S. was found "on back, slightly left lateral arms over the side; head/neck back/slightly left." *Id*. (citing Pet'rs' Ex. 7 at 9, 12–13). At the hearing, Mr. Kennedy

testified he completed the form based on information provided by Petitioners, and they were very forthcoming when he questioned them, with no inconsistencies. *Id.* at 11 (citing Tr. 91, 96–99).

D. Medical Experts

Petitioners offered Dr. Robert Shuman and Dr. M. Eric Gershwin as medical experts. *Id.* at 13–23. Respondent presented the medical experts Dr. Christine McCusker and Dr. Brent Harris. *Id.* at 23–35. The Special Master noted all "four experts involved in this case are well known to the Court, equally impressive in their respective specialties, and all recognized as experts in their respective fields." *Id*. at 12. She explained since Petitioners were only pursuing claims of "an on-Table encephalopathy" or, in the alternative, "an off-Table encephalopathy, pulmonary edema, visceral congestion, and death," her decision solely focused on expert opinions relevant to those claims. *Id*. at 12–13. The Special Master noted SIDS was ruled out as a cause of A.E.S.'s death, as both Petitioners' expert, Dr. Shuman, and Respondent's expert, Dr. Harris, agreed the evidence did not support a SIDS diagnosis. *Id*. at 12, 13, 32. The Special Master stated she considered all medical literature submitted in the case, even though her decision did not discuss it all in detail. *Id*. at 38.

1. Petitioners' Expert, Dr. Robert Shuman

In support of Petitioners, Dr. Shuman submitted two reports and testified at the hearing. *Id.* at 13–20; *see also* Pet'rs' Ex. 16 (Expert Report of Dr. Shuman), ECF No. 23-7; Pet'rs' Ex. 92 (Supplemental Report of Dr. Shuman), ECF No. 46-3. His first report found the progressive worsening of A.E.S.'s cardiopulmonary system during the resuscitation efforts was inconsistent with SIDS, she had no risk factors for SIDS, and the autopsy findings were inconsistent with SIDS. Ruling at 13–15. Instead, he stated A.E.S.'s brain weight of 595 grams was consistent with cerebral edema. *Id*. at 15 (citing Pet'rs' Ex. 16 at 31). And he pointed out cerebral edema, pulmonary edema, and congestive heart failure are not features of SIDS. *Id*. Dr. Shuman concluded either the DTaP vaccine, Prevnar 13 vaccine, or the combination of both caused encephalopathy and cerebral edema, which caused cardiopulmonary failure resulting in A.E.S.'s death. *Id*. at 16.

In his supplemental report, Dr. Shuman noted A.E.S.'s heavy brain weight, as documented in the autopsy, was a "robust sign of cerebral edema." *Id*. (citing Pet'rs' Ex. 92 at 1–2). He explained how the vaccines A.E.S. received can affect the brain, including by eliciting cytokines (proteins that help regulate the immune system), which can cause swelling or edema. *Id*. at 16–17 (citing Pet'rs' Ex. 92 at 5). He concluded the vaccines generated cytokines, which circulated to A.E.S.'s brain and caused a malignant cerebral edema that was lethal within six to eight hours. *Id*. at 17 (Pet'rs' Ex. 92 at 4).

At the hearing, Dr. Shuman defined encephalopathy as a disturbance of the brain, or an abnormal or depressed expression of brain function that causes "a negative deviation of behavior from that expected of that person." *Id*. (citing Tr. 127–28). He testified the autopsy findings showed objective signs of cerebral edema, including a full and flattened brain "obviously under pressure," with the brain weight at least two standard deviations above the mean. *Id*. (citing Tr.

at 133–40, 142). There was an absence of inflammation or other obvious cause of death. *Id*. He stated the pathologist's brain examination was limited and may have missed some details. *Id*. at 18 (citing Tr. at 137–40). He noted A.E.S.'s thighs showed swelling at the injection sites on the autopsy photographs, which could occur when cytokines circulate. *Id*. (citing Tr. at 161; Pet'rs' Ex. 18 at 2). He did not think the organ congestion and the frothing of the lungs were the result of resuscitation efforts. *Id*. at 19.

Dr. Shuman testified a diagnosis of encephalopathy requires an analysis of infant behavior, with a focus on visual gaze, fixation, and feeding behavior. *Id*. (citing Tr. at 131). Based on Petitioners' observations, he determined A.E.S. displayed an altered mental state, was irritable, could not self-soothe, did not feed properly, and did not have a normal gaze or normal social responses. *Id*. (citing Tr. at 140–41). He expressed confusion that A.E.S. reportedly drank a bottle because the autopsy showed only "a trace of mucoid food in the stomach." *Id*. (citing Tr. at 136–37). He relied on the parents' testimony for his diagnosis since nothing in the medical records described the clinical signs necessary to diagnose encephalopathy. *Id.* (citing Tr. at 171). Dr. Shuman concluded A.E.S. was encephalopathic with a decreased level of consciousness, inconsistent responses to external stimuli, and clinical signs of absent eye contact. *Id*. at 19–20 (citing Tr. at 163).

2. Petitioners' Expert, Dr. M. Eric Gershwin

In support of Petitioners, Dr. Gershwin provided two reports and testified at the hearing. *Id*. at 20–23; *see also* Pet'rs' Ex. 63 (Expert Report of Dr. Gershwin), ECF No. 43-1; Pet'rs' Ex. 97 (Supplemental Report of Dr. Gershwin), ECF No. 52-1. In his first report, Dr. Gershwin concluded A.E.S. suffered from cerebral edema. Ruling at 20 (citing Pet'rs' Ex. 63 at 1). He opined that multiple vaccines together caused cytokine production, which led to cerebral edema and an enlarged brain and resulted in her death. *Id*. (citing Pet'rs' Ex. 63 at 1–2). However, in his supplemental report Dr. Gershwin noted no evidence of an excessive cytokine response following A.E.S.'s vaccination. *Id.* at 21 (citing Pet'rs' Ex. 97 at 1). Still, he believed A.E.S. was more fragile than a normal infant and the vaccinations were the "only logical explanation" for the injury A.E.S. suffered. *Id*. (citing Pet'rs' Ex. 97 at 2).

At the hearing, Dr. Gershwin testified "there had to be something that was defective on a genetic basis with a receptor in [A.E.S.'s] brain that essentially made her a susceptible host" to the cytokines. *Id*. (citing Tr. at 181) (alternation in original). He noted that none of the medical literature with which he was familiar indicated that the cytokines released in response to vaccinations have crossed the blood brain barrier, but he opined this was due to the rarity of the event. *Id*. at 22. Dr. Gershwin stated cytokines released after vaccinations are not only a "drop in the bucket," as vaccines are designed to "fool the body" into thinking it has the infection. *Id*. (citing Tr. at 315). He noted A.E.S.'s brain showed significant swelling and that another explanation offered—"prolonged "QT Syndrome"—would not explain the cerebral edema and size of A.E.S.'s brain on autopsy. *Id*. at 23 (citing Tr. at 314). He concluded the vaccinations were a substantial factor in her encephalopathy and death. *Id*. (citing Tr. at 197).

3. Respondent's Expert, Dr. Christine McCusker

In support of Respondent, Dr. McCusker submitted three reports and testified at the hearing. *Id.* at 23–30; *see also* Resp't's Ex. A (Expert Report of Dr. McCusker), ECF No. 35-1; Resp't's Ex. E (Supplemental Report of Dr. McCusker), ECF No. 50-1; Resp't's Ex. F (Third Report of Dr. McCusker), ECF No. 86-1. In her first report, Dr. McCusker disagreed A.E.S. suffered an encephalopathy and cerebral edema from her vaccinations. Ruling at 24 (citing Resp't's Ex. A at 5–6). She opined A.E.S. did not display signs of significant cytokine activity and the cytokine response from vaccination is less than the cytokine response from a natural infection. *Id*. (citing Resp't's Ex. A at 6). She also disagreed the Prevnar 13 vaccine has demonstrated any association with encephalopathy after licensure. *Id.* (citing Resp't's Ex. A at 5).

Dr. McCusker discussed that A.E.S.'s younger sibling suffered from "Long QT Syndrome" after birth and suggested A.E.S. may have suffered from the same condition. *Id*. She noted "Long QT Syndrome" has been implicated in SUID cases. *Id*. However, she acknowledged no genetic testing was performed that could have confirmed A.E.S. had the condition. *Id*. (citing Resp't's Ex. A at 3, 7). Dr. McCusker observed the medical examiner ruled this a SUID case, and studies show no evidence of a causal relationship between vaccination and SIDS. *Id*. (citing Resp't's Ex. A at 7). She concluded there was no evidence of cytokine activation or evidence the vaccinations caused A.E.S.'s death. *Id*. (citing Resp't's Ex. A at 7).

In her supplemental report, Dr. McCusker admitted vaccinations activate immune responses in part through cytokines but there is no evidence the cytokine levels are sufficient to cause brain edema. *Id*. at 25 (citing Resp't's Ex. E at 3). She concluded A.E.S. showed no clinical signs of immune activation, acute cerebral edema, or increased intracranial pressure in the ninety minutes prior to Mr. Sims finding her unresponsive. *Id*. at 26 (citing Resp't's Ex. E at 7). Rather, "Long QT Syndrome" was a plausible explanation for A.E.S.'s symptoms. *Id*.

At the hearing, Dr. McCusker argued studies show no concern about infants receiving multiple vaccinations at once, and a combination of vaccines does not significantly increase or change the likelihood of adverse events and inflammation. *Id*. 26–27 (citing Tr. at 262–64). She also disagreed with Dr. Gershwin that A.E.S. had a genetic anomaly, which made her unable to process cytokines properly. *Id*. at 28. Dr. McCusker asserted that if A.E.S. did, the condition would likely have been lethal while she was still in the womb. *Id*. at 28 (citing Tr. at 288–89).

Dr. McCusker did not find the descriptions of A.E.S.'s behavior consistent with an encephalopathic baby, which would "send a parent running" to the ER. *Id*. at 29 (citing Tr. at 298). She stated children experiencing an encephalopathy are in pain, will not and cannot eat, are nauseous, and suffer from severe headaches and vomiting, "not soft behavioral changes as described." *Id*. (citing Tr. at 299). Although she thought "Long QT Syndrome" was an "important possibility to consider in the differential diagnosis," she did not see A.E.S.'s sibling's medical records and there was no genetic testing. *Id.* at 30 (citing Tr. at 310–11). After the

hearing, Dr. McCusker submitted a supplemental report documenting the safety of combining multiple vaccines. *Id*.; *see also* Resp't's Ex. F.

4. Respondent's Expert, Dr. Brent Harris

In support of Respondent, Dr. Harris submitted a report and testified at the hearing. *Id*. at 30–35; *see also* Resp't's Ex. C (Expert Report of Dr. Harris), ECF No. 35-3. In his report, Dr. Harris noted there were no pathological abnormalities in A.E.S.'s brain, but her brain weighed 595 grams, instead of the expected 461–555 grams. Ruling at 30–31. He opined the autopsy findings were "likely correct" and that "the brain appears grossly swollen bilaterally on superior surfaces." *Id*. at 31 (citing Resp't's Ex. C at 4). Dr. Harris determined the autopsy was insufficient for a SIDS diagnosis, in part due to inadequate sampling. *Id.* (citing Resp't's Ex. C at 4). He did note "mild edema and congestion" in all sampled brain tissue. *Id*. (citing Resp't's Ex. C at 4).

Dr. Harris acknowledged medical literature documents rare instances of anaphylaxis after vaccines, which can result in edema, but he said forensic anaphylaxis literature does not document brain edema. *Id*. at 31–32 (citing Resp't's Ex. C at 5). He also found no evidence A.E.S. suffered hemorrhages or neurodegenerative changes and no signs of cell death on her brain tissue. *Id*. at 32 (citing Resp't's Ex. C at 6). He concluded the cause of death was "unknown." *Id.* (citing Resp't's Ex. C at 6).

Dr. Harris had been a consultant on SIDS cases for eight years and testified he would not expect to see cerebral edema in an autopsy of a SIDS case. *Id*. at 32–33 (citing Tr. at 229–30). He noted A.E.S.'s autopsy findings did not specifically include cerebral edema, but tissue is not fresh during an autopsy. *Id.* at 33 (citing Tr. at 230). Based on the heaviness of A.E.S.'s brain and other observations, he was "fairly comfortable to say that this is more likely edema" in A.E.S.'s case. *Id*. (citing Tr. at 231). Dr. Harris determined A.E.S.'s heavy brain was a pathological abnormality without a known cause. *Id.* (citing Tr. at 250–51).

Dr. Harris explained "encephalopathy" is a non-specific clinical term for dysfunction of the brain and a pathology report would never contain a diagnosis of encephalopathy. *Id*. (citing Tr. at 231–32). Regarding whether A.E.S. suffered brain herniation, Dr. Harris testified he could not "rule it [in or] out." *Id*. at 34 (citing Tr. at 237, 256). He opined the medical examiner appropriately concluded the cause of death was undetermined. *Id*. (citing Tr. at 254). He reiterated this is not a SIDS case because "you cannot make a diagnosis of SIDS without a full sampling of the tissues." *Id*. (citing Tr. at 243, 252). Overall, Dr. Harris did not believe vaccines were the cause of A.E.S.'s death, and he was "not aware of any literature to suggest that vaccination . . . could lead to a death like this." *Id*. at 35 (citing Tr. at 242). However, he did not "have an explanation for another diagnosis in this case." *Id*. (citing Tr. at 242–43).

II. Standard of Review

In reviewing a special master's decision, the Court of Federal Claims may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2).

The standards in section 300aa-12(e)(2)(B) "vary in application as well as degree of deference" as each "standard applies to a different aspect of the judgment." *Munn*, 970 F.2d at 870 n.10. The Court evaluates fact findings "under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard." *Id.* Thus, the Court of Federal Claims "reviews the special master's decision essentially for legal error or factual arbitrariness." *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1574 (Fed. Cir. 1993).

This Court reviews *de novo* whether a special master did not act in accordance with the law. *Althen*, 418 F.3d at 1279. "'Not in accordance with the law' refers to the application of the wrong legal standard." *Rodriguez v. Sec'y of Health & Human Servs*., 632 F.3d 1381, 1384 (Fed. Cir. 2011) (citing *Markovich v. Sec'y of Health & Human Servs*., 477 F.3d 1353, 1356 (Fed. Cir. 2007)). The Court owes "no deference to the . . . special master on questions of law." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010).

The standard of review for factual findings is "the most deferential possible." *Munn*, 970 F.2d at 870. When reviewing a special master's findings of fact, the Court does "not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing *Broekelschen*, 618 F.3d at 1349). The Vaccine Act "makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters[']fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process." *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (citing *Munn*, 970 F.2d at 870); *see also Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 718 (2009) ("[T]he law is settled that neither the Court of Federal Claims nor the Federal Circuit can substitute its judgment for that of the special master merely because it might have reached a different conclusion.").

"[S]pecial masters have broad discretion to weigh evidence and make factual determinations." *Dougherty v. Sec'y of Health & Hum. Servs.*, 141 Fed. Cl. 223, 229 (2018). A special master does not need to "discuss every item of evidence in the record" when making a factual finding "so long as the decision makes clear that the special master fully considered a party's position and arguments on point." *Snyder v. Sec'y of Health & Hum. Servs.*, 36 Fed. Cl.

461, 466 (1996), *aff'd*, 117 F.3d 545 (Fed. Cir. 1997) (citation omitted); *see also Hazlehurst v. Sec'y of Health & Hum. Servs.*, 604 F.3d 1343, 1352 (Fed. Cir. 2010) (noting a reviewing court should presume the fact finder has considered all the material in the record, regardless of whether she mentions it all). Furthermore, a "special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen*, 618 F.3d at 1347 (citing *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000)). And a special master's credibility findings "are virtually unchallengeable on appeal." *Lampe*, 219 F.3d at 1362.

III. Discussion

The Special Master found, in turn, that Petitioners met their burden to show (1) A.E.S. suffered the Vaccine Injury Table's requirements for an encephalopathy and (2) in the alternative, the vaccines caused an off-Table injury and death. Ruling at 38–51. She also concluded Respondent failed to show an alternative cause. *Id.* at 51–52.

Respondent argues the Special Master erred in her Table injury analysis because she improperly relied on A.E.S.'s death alone to find the Table injury and made factual findings based solely on Petitioners' uncorroborated statements, despite discrepancies with the medical record. Resp't Mem. at 12–17. Respondent also claims the Special Master erred in her off-Table injury analysis because she misapplied prongs one and two of the *Althen* test. *Id*. at 17–20. Finally, Respondent contends the Special Master did not properly consider Respondent's evidence of likely alternative causes for A.E.S.'s death, including SUID and SIDS. *Id.* at 8–12.

The Court holds the Special Master did not err in her Table injury finding or in determining Respondent failed to show an alternative cause by a preponderance of the evidence. To receive compensation under the Vaccine Act, Petitioners are required to show a Table injury or an off-Table injury; either is sufficient. *See Althen*, 418 F.3d at 1276. Since the Special Master properly found a Table injury, her analysis could have ended there. Therefore, this Court upholds the Special Master's decision based solely on her Table injury finding. The Court does not reach the parties' arguments about the Special Master's off-Table injury finding.

A. The Special Master's Table Injury Finding Was Proper.

The Court reviews the Special Master's conclusions of law about the Table injury requirements *de novo* without deference. *Broekelschen*, 618 F.3d at 1345. Since Petitioners filed their claim on December 15, 2015, their petition must be evaluated under the regulation in effect from July 23, 2015 to March 20, 2017. *See* 42 U.S.C. § 300aa-14(c)(4) ("Any modification . . . of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation."); 42 C.F.R. § 100.3(a) (July 23, 2015) (Vaccine Injury Table). The applicable Vaccine Injury Table defines an encephalopathy that occurred within 72 hours of the administration of a DTaP vaccine as a Table injury. 42 C.F.R. § 100.3(a) (July 23, 2015).

The Qualifications and Aids to Interpretation ("QAIs") further state a petitioner can show the Table injury "only if such recipient manifests, within the applicable period . . . an acute

encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months." *Id.* § 100.3(b)(2). "An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." *Id.* § 100.3(b)(2)(i). Given her death within nine hours of vaccination, A.E.S. did not suffer a chronic encephalopathy lasting more than six months. However, a petitioner can also recover if "[a]ny acute complication or sequela (including death)" of an encephalopathy "arose within the [72-hour] time period prescribed." *Id.* § 100.3(a).

For a child less than 18 months of age, the QAIs state an acute encephalopathy "is indicated by a significantly decreased level of consciousness lasting for at least 24 hours." *Id.* § 100.3(b)(2)(i)(A).

> A 'significantly decreased level of consciousness' is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater . . . (1) Decreased or absent response to environment . . . ; (2) Decreased or absent eye contact . . . ; or (3) Inconsistent or absent responses to external stimuli . . .

Id. § 100.3(b)(2)(i)(D). Meanwhile, "[s]leepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle" do not "alone, or in combination, . . . demonstrate an acute encephalopathy." *Id.* § 100.3(b)(2)(i)(E). Further, "[i]ncreased intracranial pressure may be a clinical feature of acute encephalopathy in any age group." *Id.* § 100.3(b)(2)(i)(C). Petitioners must demonstrate the Table injury requirements by a preponderance of the evidence. *Capizzano,* 440 F.3d at 1320.

1. The Special Master Did Not Err in Finding Petitioners Met the Table's Requirements for an Encephalopathy Even Though A.E.S. Died Less Than 24 Hours After Vaccination.

The relevant QAIs state the clinical signs of a significantly decreased level of consciousness need to be present for at least 24 hours. 42 C.F.R. § 100.3(b)(2)(i)(D) (July 23, 2015). In the Memorandum in support of the Motion for Review, Respondent argued the Special Master made a legal error in applying this requirement. Resp't Mem. at 13. Since A.E.S. died less than 24 hours after being vaccinated, Respondent claimed Petitioners "cannot prove an acute encephalopathy lasting more than 24 hours," as required by the QAIs. *Id.* at 13. However, in response to this Court's Order for Supplemental Briefing, Respondent reversed course. Resp't's Resp. to Order for Suppl. Briefing (hereinafter "Resp't Suppl.") at 5, ECF No. 113. In the response, Respondent concedes "the Special Master was authorized to—and ultimately did—find that A.E.S.'s death was a compensable sequela of an acute encephalopathy even though A.E.S. died less than 24 hours after vaccination." *Id.*

The Special Master observed Respondent's original reading of the QAIs "suggests the impossible . . . . The clinical features of an encephalopathy clearly cannot exist for 24 hours when death occurs before that time." Ruling at 40. Thus, the Special Master analyzed whether A.E.S. suffered the requisite clinical signs of an encephalopathy prior to her death and whether the encephalopathy resulted in her death. *Id.* at 41–43. Whether the Special Master committed an error of law in this regard is now uncontested by either party. But since this Court reviews

questions of law without deference, the Court must determine whether the Special Master legally erred to sustain her Table injury finding. *Broekelschen*, 618 F.3d at 1345. The Court finds she did not.

The Vaccine Injury Table states a petitioner can recover for a "sequela (including death)" of an encephalopathy that arose within the requisite 72-hour time period. 42 C.F.R. § 100.3(a) (July 23, 2015). The Table does not explicitly require a death from encephalopathy to occur more than 24 hours after the administration of the DTaP vaccine. "The Court must assess 'a [regulatory] scheme in its entirety' and 'give full effect to all words contained within [a] statute or regulation, thereby rendering superfluous as little of the statutory or regulatory language as possible.'" *HealthRev, LLC v. United States,* 172 Fed. Cl. 73, 83 (2024) (quoting *Hanser v. McDonough,* 56 F.4th 967, 970 (Fed. Cir. 2022) (alteration in original). Here, the Court must parse the Table's language allowing for recovery for "any . . . death" resulting from an encephalopathy "within the [72-hour] time period prescribed" along with the QAIs' requirement that the clinical signs of an encephalopathy are present for at least 24 hours. 42 C.F.R. §§ 100.3(a), 100.3(b)(2)(i)(D) (July 23, 2015).

The U.S. Court of Appeals for the Federal Circuit has held the Table's language about a "sequela (including death)" within the specified time period requires a petitioner to show (1) the Table injury "occurred within the time period specified in the Table" and (2) the "death occurred as a sequela" (i.e. result) of the injury. *Hellebrand v. Sec'y of Health & Hum. Servs.,* 999 F.2d 1565, 1569 (Fed. Cir. 1993). To assess the first prong, the Court must consider whether the Special Master could legally find Petitioners showed a Table injury within the 72-hour time period even though the Special Master did not find A.E.S. suffered the clinical signs of encephalopathy for at least 24 hours. *See* 42 C.F.R. § 100.3(b)(2)(i)(D) (July 23, 2015). In doing so, the Court must reconcile *Hellebrand* with the Federal Circuit's decisions in *Jay v. Sec'y of Health & Hum. Servs*., 998 F.2d 979, 983 (Fed. Cir. 1993), and *Hodges.* 9 F.3d at 959.

In *Jay,* the Federal Circuit reversed a special master's summary judgment ruling that a child who died eighteen hours after vaccination—and whose autopsy listed SIDS—did not suffer an encephalopathy. 998 F.2d at 981–84. The court ruled the special master erred "in failing to grant summary judgment that [the child] did suffer an encephalopathy." *Id.* at 983. "[T]he death occurred within the 3 day table injury time frame for an encephalopathy" and the special master had improperly discredited a medical expert who testified "that an encephalopathy occurred based on [the child's] entire history including the fact of death." *Id*. at 983–84. The expert found the relevant symptoms of encephalopathy, including "unconsolable crying for six or more hours, . . . and then the subsequent death all occur[ed] within a twenty-four-hour period of time." *Id.* at 983 n.5. And the court held there is "nothing in the Vaccine Act which precludes death from being used as evidence of a table injury, here encephalopathy." *Id*. at 983. Indeed, "there is no more profound and permanent change in level of consciousness than death." *Id*. at 983 n.6.

The Vaccine Injury Table relevant in *Jay* did not require that for an encephalopathy the requisite clinical signs of a significantly decreased level of consciousness had to be present for at least 24 hours. *See* 42 U.S.C. 300aa-14(a)-(b) (1986) (original Vaccine Injury Table). But it did include the same language allowing for recovery for any "sequela (including death)" of an

encephalopathy within the specified 72-hour period that is in the 2015 regulation. *See id.;* 42 C.F.R. § 100.3(a) (July 23, 2015).

In *Hodges,* the Federal Circuit considered whether petitioners could recover for a Table injury where a child died "within 3.5 hours" of vaccine administration. 9 F.3d at 959. The court held petitioners had demonstrated the child suffered symptoms that were among the "statutory indica" of the Table injury because the child was "pale, unresponsive, and in cardiovascular and respiratory arrest." *Id.* at 959–60. However, the court found these were also "symptoms of her death" and did "not independently establish" the Table injury. *Id*. at 960. Thus, petitioners failed to show the Table injury requirements within the specified time period. *Id.* Similarly, in *Hellebrand* the court found "the presence of cardiovascular or respiratory arrest alone" did not satisfy a petitioner's burden to show a Table injury. 999 F.2d at 1569.

Neither *Hodges* nor *Hellebrand* conclusively address whether the Table's minimum duration period for a non-death related symptom disqualifies a victim who exhibits that symptom but dies before the duration period ends. Respondent contends the court held in *Hodges* that "death alone is not compensable if a [T]able injury has not been established, regardless of the interval between vaccination and death." Resp't Suppl. at 4 (citing *Hodges,* 9 F.3d at 960). But this language appears in the court's summary of the respondent's argument, not in the holding. *Hodges,* 9 F.3d at 960. And even so, it does not address whether a petitioner can establish a Table injury in a shorter time frame than otherwise required in the event of an intervening death. Nor did either *Hodges* or *Hellebrand* explicitly disavow *Jay. See* Resp't Mem. at 13 n.4 (acknowledging *Jay* is "equally binding"). And in *Jay,* the Federal Circuit determined "over six hours of intermittent screaming" followed by death was sufficient to meet the Table's requirements for an encephalopathy. 998 F.2d at 983.

The Court of Federal Claims was confronted with the inverse posture to this matter in *Waterman v. Sec'y of Health & Hum. Servs.,* 123 Fed. Cl. 564, 566 (2015). In that case, the relevant QAIs included the same 24-hour requirement for the clinical signs of encephalopathy, and a special master found the petitioners had not met the Table's requirements where a child died less than 24 hours after vaccination. *Id.* But the Court did not affirm the special master on the grounds that a petitioner can *never* establish the Table's requirements for an encephalopathy where the injured party dies in less than 24 hours. *Id.* at 573–74 (finding the petitioners failed to prove their child's death "was a sequela of" encephalopathy). Rather, the Court found the special master properly evaluated the medical records and expert opinions and reasonably concluded the petitioners had "not pointed to any evidence that suggest[ed] [the child's] loss of consciousness was a result of an encephalopathy." *Id.* at 574. The Court held death is not precluded "from being used as evidence of a [T]able injury," but "symptoms of death do not independently establish the existence of a Table injury." *Id*. at 575 (citing *Jay,* 998 F.2d at 983; *Hodges,* 9 F.3d at 960) (alteration in original).

Respondent correctly notes it would be "at odds with the plain language of the [Vaccine] Act" to allow "recovery for any death that occurs within seventy-two hours of receipt of a DTaP vaccine." Resp't Mem. at 13 (citing *Waterman,* 123 Fed. Cl. at 575 (quoting *Hellebrand*, 999

F.2d at 1571)) (alteration in original). But the Vaccine Act also does not deny recovery for any death resulting from an encephalopathy that occurs within 24 hours of a DTaP vaccine.

Thus, the reasonable interpretation of binding precedent and the 2015 regulation is that a petitioner can recover for an encephalopathy that results in death less than 24 hours after vaccination. But to do so, a petitioner must show the deceased suffered clinical signs of an encephalopathy, as defined in the QAIs, prior to death that are *not* also symptoms of death. In this case, the Special Master found Petitioners met this burden. Ruling at 43.

2. The Special Master Reasonably Found Petitioners Met Their Burden To Show A.E.S. Suffered the Table Requirements for an Encephalopathy.

Respondent contends the Special Master erred by failing to affirmatively find clinical symptoms of acute encephalopathy as required by the Table and determining A.E.S.'s "death itself was sufficient to establish a Table encephalopathy." Resp't Mem. at 17; *see also* Resp't Supp. at 5 ("The pivotal question here is whether a preponderance of the evidence supported the Special Master's finding that A.E.S. did, in fact, experience an acute encephalopathy prior to her death."). The Court finds the Special Master did not commit either an error of law in applying the Table requirements for an encephalopathy or make arbitrary factual findings in determining Petitioners met their burden.

In assessing both whether Petitioners met their burden to show A.E.S. suffered the Table's requirements for an encephalopathy and whether the encephalopathy resulted in her death, the Special Master relied on expert medical opinions. Ruling at 41–43. Given the competing expert testimony, the Special Master's Table injury decision was appropriately based on her determination of "the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen,* 618 F.3d at 1347. "[A]rguments as to the weighing of evidence . . . particularly where witness credibility is involved, do not demonstrate reversible error." *Hines ex rel Sevier*, 940 F.2d at 1527. These credibility determinations are "virtually unreviewable" on appeal. *Bradley*, 991 F.2d at 1575 (citing *Hambsch v. Dept. of the Treasury,* 796 F.2d 430, 436 (Fed. Cir. 1986)). This Court must defer to the Special Master's factual determinations and cannot "reweigh the factual evidence." *Porter*, 663 F.3d at 1249.

a. The Special Master Did Not Err in Determining A.E.S. Suffered an Encephalopathy Within 72 Hours of Vaccination.

The Special Master properly based her Table injury finding on both a requisite clinical symptom—decreased or absent eye contact—together with A.E.S.'s subsequent death within nine hours of her vaccinations. *See* Ruling at 42–43. Thus, *Hellebrand*'s first prong was satisfied since the Table injury "occurred within the [72-hour] time period specified in the Table." 999 F.2d at 1570. The Special Master made the following specific findings based on Petitioners' testimony and affidavits, as well as a corroborating medical opinion:

> [T]he behaviors that are [] within the repertoire of an 11-week-old that were demonstrated by A.E.S.—irritability, inability to self-soothe, not cuddling, not

> tracking or making eye contact, and sleeping more—were indicative of an altered state and decreased level of consciousness in the afternoon following her vaccinations sufficient to satisfy the Table requirements for an encephalopathy . . . that resulted in her death.

Ruling at 43. She found credible Dr. Shuman's testimony "that these behaviors are demonstrative of A.E.S. being encephalopathic based on the behavioral repertoire of an 11-week-old." *Id*. at 42 (citing Tr. at 140–41).

The factual finding that A.E.S. was "not tracking or making eye contact" corresponded with a clinical sign of significantly decreased level of consciousness in the QAIs. *See* 42 C.F.R. § 100.3(b)(2)(i)(D)(2) (July 23, 2015) (stating the requisite decreased level of consciousness can be shown by "[d]ecreased or absent eye contact"). And under the regulation, Petitioners need only to demonstrate one of the clinical signs. *Id.* § 100.3(b)(2)(i)(D) (requiring the "presence of *at least one* of the . . . clinical signs") (emphasis added).[3] Importantly, the key clinical sign—decreased or absent eye contact—is not a symptom of A.E.S.'s death since it required A.E.S. to be awake. In other words, the decreased eye contact "was not merely a consequence of the dying process." Pet'rs' Resp. to Order for Suppl. Briefing at 3, ECF No. 114.

Respondent contends the Special Master did not affirmatively find evidence that A.E.S. exhibited the requisite clinical signs of a Table encephalopathy. Resp't Mem. at 17. Rather, Respondent argues the Special Master granted Petitioners "a factual presumption about what the evidence *might* have been *if it were available* as grounds for granting them a legal presumption of causation" afforded by the Table. *Id*. (citing Ruling at 42) (referring to the Special Master's statement that she did "not have the luxury of knowing what [A.E.S.]'s behaviors would have been had she survived"). The Special Master acknowledged Respondent's experts' arguments that "systemic reaction severe enough to cause characteristic and perceptible encephalopathic behaviors would have required at least six to eight hours." Ruling at 42 (citing Tr. at 235). And she stated additional clinical signs may have occurred "when A.E.S. was unobserved during her last 45 minutes of responsive life." *Id*. Thus, Respondent claims the Special Master legally erred by "effectively—and erroneously—determin[ing] that the death by itself was sufficient to establish a Table encephalopathy." Resp't Mem. at 17.

But the Special Master did not base her final determination on any suppositions or factual presumptions. She made specific findings about A.E.S.'s behavior based on the parents' testimony and affidavits, which were corroborated by medical opinion. Ruling at 41–43. Most importantly, the Special Master determined A.E.S. was "not tracking or making eye contact" in the afternoon following her vaccination and that a medical expert diagnosed A.E.S. with an encephalopathy based on the reported behavior. *Id*. at 43.

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[3] The Special Master also found A.E.S. displayed some behaviors that the QAIs state are alone insufficient to demonstrate an acute encephalopathy. These behaviors do not contradict an encephalopathy. 42 C.F.R. § 100.3(b)(2)(i)(E) (July 23, 2015) ("The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness . . . : Sleepiness, irritability (fussiness).").

b. The Special Master Reasonably Credited the Parents' Affidavits and Testimony.

Respondent argues the Special Master erred because she "relied primarily upon petitioners' second affidavits (which were prepared almost seven years after [A.E.S.]'s death[)] . . . and their testimony at hearing, which were significantly different from the histories they gave to both the treating physicians at the hospital and the medical examiner." Resp't Mem. at 15. Respondent contends the Special Master should have given "considerable weight" to the contemporaneous medical records that do not contain information about A.E.S.'s behavior at home beyond noting A.E.S. had a "normal" day. *Id.* at 14–15. Further, Petitioners reported "[n]o reactions" to the medical examiner. Resp't Suppl. at 6 (alteration in original). *See also* Ruling at 9. But the Special Master did not err.

Contemporaneous medical records are generally considered trustworthy evidence. *See Cucuras v. Sec'y of Dep't of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). And "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Campbell ex rel. Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) (citing *United States v. U.S. Gypsum Co*., 333 U.S. 364, 395–96 (1948)). But there is "no basis for presuming that medical records are accurate and complete even as to all physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). This Court has noted:

> [T]here are, at times, reasons why medical records do not accurately reflect all the symptoms a given patient was experiencing at a particular time—in the case of a young child, a given observation may have been overlooked by the caregiver, particularly under traumatic circumstances, or that symptom may have been relayed, but misreported or not recorded by the medical professional.

Campbell, 69 Fed. Cl. at 779. And the Federal Circuit recently reaffirmed it is not "per se arbitrary and capricious" to credit "credible and corroborated testimony" over "conflicting or absent contemporaneous records." *Hinton v. Sec'y of Health & Hum. Servs.*, No. 2023-2161, 2025 WL 763153 at *6 (Fed. Cir. Mar. 11, 2025) (internal quotation marks and quotation omitted).

The Special Master acknowledged "there are some discrepancies in the record" regarding the Petitioners' statements, including that the "autopsy did not mention food content in the stomach" while both parents recalled feeding A.E.S. Ruling at 41. However, she also noted Mrs. Sims "was uncertain if A.E.S. was actually eating." *Id*. (citing Tr. at 21–22). While A.E.S.'s medical records do not corroborate the behaviors her parents later described, they also do not affirmatively contradict or rule them out. *See id.* at 9–11.

In *Kirby*, the Federal Circuit held a reasonable fact finder may conclude testimony does not conflict with medical records where those "medical records are silent about the existence of . . . symptoms, [and] they are also silent about the nonexistence of such symptoms." *Kirby,* 997 F.3d at 1383. Respondent argues *Kirby* is inapposite here because the medical records note a

"normal day" and "[n]o reactions," which conflicts with Petitioners' testimony. Resp't Suppl. at 6 (alteration in original). But the *Kirby* court specifically found that medical records silent on vaccine injury did not contradict later testimony, even when the records included general statements from a patient that she was "feeling fine" and had "no complaints." *Kirby,* 997 F.3d at 1383–84.

Here, the Special Master noted Dr. Shuman's testimony that "the signs of an encephalopathy in an infant at A.E.S.'s age are limited and difficult to assess." Ruling at 43 (citing Tr. at 129, 140–41, 163). This could explain why the parents reported a normal day and no reaction to the hospital personnel, "particularly under traumatic circumstances" on the day of their child's death. *See Campbell*, 69 Fed. Cl. at 779. Thus, it was reasonable for the Special Master to conclude the medical records do not undermine Petitioners' later testimony.

The Special Master, within her purview as the fact finder, appropriately credited the parents' second affidavits and testimony, along with Dr. Shuman's opinion, in finding a Table injury. Ruling at 43. Respondent claims the Special Master should have discounted Petitioners' testimony on the basis that their memories may have become "less reliable over time." Resp't Suppl. at 7. But Respondent's arguments amount to mere disagreement with how the Special Master weighed evidence and assessed the credibility of the testimony. The Special Master was in the best position to make credibility determinations, and this Court will not second guess those determinations. *See Hines ex rel Sevier*, 940 F.2d at 1520.

c. The Special Master Did Not Rely on Unsubstantiated Claims.

Respondent argues the Special Master's fact finding was arbitrary and capricious and contrary to law because she relied on Petitioners' claims alone, which is prohibited by the Vaccine Act. Resp't Mem. at 15 (citing 42 U.S.C. § 300aa-13(a)(1)). But the Special Master did not rely "entirely on petitioners' unsubstantiated testimony to conclude [A.E.S.] suffered an acute encephalopathy." *Id*. The Vaccine Act states a special master may not find a petitioner is entitled to compensation "based on the claims of a petitioner alone, unsubstantiated by medical records *or medical opinion*." 42 U.S.C. § 300aa-13(a)(1) (emphasis added). The statute's "words are unambiguous." *Meeks v. West,* 216 F.3d 1363, 1366 (Fed. Cir. 2000). It permits a petitioner's claims to be substantiated by medical opinion and does not require evidence from the medical records. *See Althen,* 418 F.3d at 1280 (finding section 300aa–13(a)(1) permits the use of "medical opinion as proof").

Here, the Special Master considered A.E.S.'s parents' affidavits and testimony together with the competing diagnoses offered by each side's experts. Ruling at 41–43. She ultimately credited Dr. Shuman's medical opinion to find Petitioners satisfied the Table's requirements for an encephalopathy. And the Special Master considered Dr. Shuman's reliability, noting he has a "special competence in child neurology" and has spent his "life studying the development of children." *Id*. at 13; *see also Hirmiz v. Sec'y of Health & Hum. Servs.,* 119 Fed. Cl. 209, 217 (2014) ("While a special master may base his or her decision on medical opinion alone, . . . he or she is entitled to require some indicia of reliability to support the assertion of the expert witness.") (citations omitted). Dr. Shuman testified that while there "was nothing in the medical

records that described the clinical signs necessary to make a diagnosis," he was able to "conclude that A.E.S. was encephalopathic" based "on the parents' observations." Ruling at 19. Moreover, as discussed above, the medical records do not contradict Petitioners' descriptions of A.E.S.'s behavior.

While it would have been improper for the Special Master to rest her conclusions on Petitioners' statements alone, Respondent points to no authority suggesting it was improper for Dr. Shuman to base his medical opinion on the parents' reported observations. *See* Resp't Mem. at 15. The Federal Rules of Evidence permit an expert to base an opinion on facts or data that he did not personally observe "[i]f experts in the particular field would reasonably rely on those kinds of facts or data." Fed. R. Evid. 703. Respondent's experts did not suggest it was impermissible to base a diagnosis of encephalopathy on the parents' descriptions of A.E.S.'s behavior. Ruling at 29. They disagreed that the reported behavior was severe enough to diagnose A.E.S. with an encephalopathy, but they did not question the method of diagnosis. *Id.* at 42. Nor did they suggest the lack of an encephalopathy diagnosis in the autopsy contradicted Petitioners' experts. In fact, Respondent's expert Dr. Harris testified that "a pathology report," such as an autopsy, "would never contain a diagnosis of encephalopathy." *Id.* at 33 (citing Tr. at 231–32). Thus, Dr. Shuman did not "base[] his opinion on facts not substantiated by the record." *Burns v. Sec'y of Health & Hum. Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993). Nor did he make any factual assumptions. *See Dobrydnev v. Sec'y of Health & Hum. Servs.,* 566 F. App'x 976, 982–983 (Fed. Cir. 2014). Dr. Shuman provided a valid medical opinion substantiating Petitioners' claims.

The Special Master, within her discretion, found Dr. Shuman's opinion more convincing than the Respondent's experts' conflicting opinions. *See Broekelschen,* 618 F.3d at 1347 (citing *Lampe,* 219 F.3d at 1361). Her conclusion properly relied on Dr. Shuman's medical opinion that A.E.S.'s behavior in the afternoon following her vaccination was "demonstrative of A.E.S. being encephalopathic." Ruling at 42–43. Thus, the Special Master's determinations were not "unsubstantiated by . . . medical opinion." 42 U.S.C. § 300aa-13(a)(1).

d. The Special Master Reasonably Determined A.E.S.'s Death Occurred as a Sequela of the Encephalopathy.

The Special Master's findings also properly satisfy *Hellebrand*'s second prong because A.E.S.'s "death occurred as a sequela" of an encephalopathy. 999 F.2d at 1569. Since causation is presumed in Table injury cases, Petitioners did not need to show the vaccines caused the encephalopathy and resulting death. *Capizzano,* 440 F.3d at 1320. They needed only to demonstrate the encephalopathy resulted in A.E.S.'s death. *Hellebrand,* 999 F.2d at 1569. The Special Master credited Dr. Shuman's opinion that "A.E.S. developed an encephalopathy with cerebral edema which caused axial herniation that led to her death." Ruling at 42 (citing Pet'rs' Ex. 16 at 36–37). And she noted Dr. Harris' testimony that he did not "have an explanation for another diagnosis in this case." *Id.* (citing Tr. at 242–43). The Special Master also ruled out other causes of death, finding there "was no trauma and no evidence of neurological disease other than edema." *Id*. at 43. Instead, she determined "the only abnormalities on autopsy were a heavy brain and edema." *Id.*

After weighing all the record evidence and the competing expert testimony, the Special Master concluded "A.E.S. suffered from a Table encephalopathic event with cerebral edema following the receipt of multiple vaccinations that resulted in her death." *Id.* She based her conclusions on the medical records and "the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen,* 618 F.3d at 1347 (citing *Lampe,* 219 F.3d at 1362). Thus, she properly found A.E.S.'s death "occurred as a sequela" of the encephalopathy. *Hellebrand,* 999 F.2d at 1569.

3. The Special Master Did Not Need to Conclusively Determine Whether A.E.S. Suffered Increased Intracranial Pressure.

To support the position that there is insufficient evidence A.E.S. was encephalopathic, Respondent argues the Special Master never conclusively found A.E.S. experienced increased intracranial pressure. *See* Resp't Mem. at 16. The Special Master reviewed the autopsy and noted both Petitioners' expert, Dr. Shuman, and Respondent's expert, Dr. Harris, "agreed that A.E.S.'s brain was abnormally heavy with edema on autopsy." Ruling at 42 (first citing Pet'rs' Ex. 16 at 36–37; and then citing Resp't's Ex. C at 5–6). And she stated "[b]oth experts agreed that once the skull was removed on autopsy, the brain would move back into place, relieving the pressure caused by swelling within the closed compartment of the brain." *Id*. (first citing Pet'rs' Ex. 16 at 31; and then citing Tr. at 236–37). Based on this evidence, the Special Master concluded "the existence of intracranial pressure cannot be ruled out." *Id*. Respondent is correct this is not an affirmative finding. *See* Resp't Mem. at 16.

However, the Special Master did not need to make a conclusive determination to satisfy the Table's requirements for an encephalopathy. The QAIs state "[i]ncreased intracranial pressure *may be* a clinical feature of acute encephalopathy in any age group." 42 C.F.R. § 100.3(b)(2)(i)(C) (July 23, 2015) (emphasis added). This language confirms increased intracranial pressure is not necessary to find the Table injury. As discussed above, the Special Master properly found A.E.S. suffered the requisite decreased level of consciousness within the 72-hour time period. She therefore did not err in finding a Table encephalopathy occurred despite not making a conclusive finding of increased intracranial pressure.

B. The Special Master Did Not Err in Finding Respondent Failed To Establish an Alternative Cause.

Since Petitioners have met their burden to show a Table injury, they are entitled to compensation so long as "there is not a preponderance of the evidence that the . . . injury . . . or death described in the petition is due to factors unrelated to the administration of the vaccine." 42 U.S.C. § 300aa–13(a)(1)(B); *see also Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1149 (Fed. Cir. 1992) ("[T]he Vaccine Act requires, in addition to a Table Injury or causation in fact, the absence of alternative causes."). Respondent bears the burden of showing an alternative cause. *See Walther,* 485 F.3d at 1151. The Vaccine Act excludes as unrelated factors any "idiopathic, unexplained, unknown, hypothetical or undocumentable cause, factor, injury, illness or condition." 42 U.S § 300aa–13(a)(2)(A).

The Special Master found Respondent failed to "show an alternative cause." Ruling at 52. Respondent did not establish by a preponderance of the evidence that the encephalopathy "was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma." 42 C.F.R. § 100.3(b)(2)(iii) (July 23, 2015). The Special Master further noted "there is no evidence that A.E.S. died of a factor unrelated to the administration of the vaccines." Ruling at 42; *see also id.* at 51–52 (holding Petitioners demonstrated "there was no evidence of infection on gross or microscopic examination or cultures post-mortem[,] . . . no indication of predisposing chronic stress," and the "case does not fit the classic profile of SIDS").

Respondent contends the Special Master "intentionally ignore[ed] epidemiological evidence related to SIDS/SUID that was critical" to the alternative cause defense. Resp't Mem. at 8. Respondent further argues her finding that "[t]his is not a SIDS/SUID case" was "flatly contradicted by the evidence" and "effectively deprived" Respondent of the opportunity to present a meaningful defense on that ground. *Id.* at 9. These arguments are unconvincing.

The Special Master considered pathologist Dr. Barnhart's conclusion that the cause of death was "best classified as undetermined" and her statement that the autopsy findings were "consistent with Sudden Unexplained Infant Death (SUID)." Ruling at 12, 41; *see also Nordwall ex rel. Tori v. Sec'y of Health & Hum. Servs.*, 83 Fed. Cl. 477, 488 (2008) ("An autopsy report by a medical examiner is without question a contemporaneous medical record . . . and should be given the same probative weight as other medical records."). But these conclusions are not at odds with the finding that A.E.S. suffered an encephalopathy.

As discussed above, SUID, unlike SIDS, is not a specific diagnosis and includes instances where an infant "die[s] suddenly and unexpectedly for a variety of reasons." Ruling at 3. The Special Master noted Dr. Harris' conclusion that "a pathology report would never contain a diagnosis of encephalopathy." *Id.* at 33 (citing Tr. at 231–32). She also considered that the "autopsy revealed a heavy brain at 595g compared to an expected 491–555g, and cerebral edema," which experts from both sides agreed was unusual. *Id.* at 41–42. Thus, the Special Master reasonably weighed the autopsy findings and concluded they were consistent with encephalopathy despite the pathologist's statement about SUID. And as the fact finder, the Special Master was empowered to find Petitioners had met their burden to show a Table injury and that A.E.S.'s injury was therefore not due to an unknown cause. *Capizzano*, 440 F.3d at 1319.

The Special Master further explained a "distinction exists between sudden unexplained infant death ('SUID') and sudden infant death syndrome ('SIDS')." Ruling at 3. SIDS is a specific "diagnosis of exclusion used when other possibilities have been ruled out," including through "a thorough autopsy, death scene investigation, and review of the clinical history." *Id.* The Special Master considered whether there was evidence of SIDS and concluded it was not the cause of death. *Id.* at 38, 51–52. *See Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010) (holding a special master properly considered evidence of SIDS where an expert discounted "SIDS as a possible cause"). She determined the symptoms A.E.S. displayed while at home, A.E.S.'s body positioning, and the presence of cerebral edema, pulmonary

edema, and congestive heart failure on the autopsy are all contrary to the classic profile of SIDS. Ruling at 51–52. Indeed, Respondent's expert Dr. Harris conceded a SIDS diagnosis was not possible in this case, as there was "an incomplete sampling of brain tissue and no clear environmental trigger [was] present." *Id.* at 38 (first citing Resp't's Ex. C at 5; and then citing Tr. at 243, 253–54).

The Special Master did not discuss some of Respondent's exhibits regarding SIDS, but she did not need to "discuss every item of evidence in the record." *Munoz v. Sec'y of Health & Hum. Servs.*, 174 Fed. Cl. 276, 284 (2024) (citation omitted). It is generally presumed a special master "considered the relevant record evidence even though he does not explicitly reference such evidence in his decision." *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) (citing *Hazlehurst*, 604 F.3d at 1352). This presumption does not apply when a special master indicates otherwise. *Id.* But here, the Special Master specifically stated that "although [her] decision discusses some but not all the literature in detail, [she] reviewed and considered all of the medical records and literature submitted." Ruling at 38.

The Special Master also properly considered Dr. McCusker's discussion of epidemiological studies showing a lack of association between SIDS and vaccines, including Dr. McCusker's statement that these studies include some "sudden unexplained infant death[s] . . . [that] don't qualify as SIDS." *Id.* at 28–30 (quotation omitted). Thus, the Special Master did not ignore epidemiological studies or evidence related to SUID and SIDS or deprive Respondent of the ability to raise a meaningful defense. As the appropriate fact finder, she weighed the evidence and found that these potential causes of injury were less convincing than the competing evidence A.E.S. suffered an encephalopathy.

The Special Master also reasonably determined Dr. McCusker's suggestion that "Long QT Syndrome" is "one plausible explanation for [A.E.S.'s] clinical picture and death . . . [was] unsupported, speculative and/or conclusory in nature." *Id.* at 52; *see also Deribeaux v. Sec'y of Health & Hum. Servs.,* 717 F.3d 1363, 1368 (Fed. Cir. 2013) (holding that to show an alternative cause the Secretary "had to present sufficient evidence to prove that the alternative factor was the sole substantial factor in bringing about the injury") (citing *de Bazan*, 539 F.3d at 1354). In rejecting this theory, the Special Master noted Dr. McCusker's acknowledgment that no genetic testing was done on A.E.S. Ruling at 52. As such, Dr. McCusker's theory was unsupported. *Id.* In sum, the Special Master did not err in finding that, because Respondent "failed to establish an alternative cause that is more than speculative, [P]etitioners are entitled to compensation." *Id.*

IV. Conclusion

Respondent has not demonstrated the Special Master made an error of law or arbitrary factual findings in determining Petitioners met their burden to show a Table injury. Rather, the Special Master applied the correct legal standard and reviewed all the evidence in this case, including competing medical expert opinions. Her decision is appropriately supported by the record, which she determined showed an infant who received the DTaP vaccine and developed clinical signs consistent with an encephalopathy that led to her death approximately eight hours later.

Moreover, the Special Master properly determined Respondent failed to show an alternative cause. The Special Master fully considered the different medical theories offered by each side's experts and concluded Petitioners' experts were more credible. Accordingly, the Court **DENIES** Respondent's Motion for Review, ECF No. 108, and **SUSTAINS** the Special Master's Decision. ECF No. 106. The Clerk of the Court shall enter judgment for Petitioners accordingly.

IT IS SO ORDERED.

s/ Carolyn N. Lerner
CAROLYN N. LERNER
Judge