In the United States Court of Federal Claims

No. 13-960V
E-Filed Under Seal: October 2, 2015
E-Filed for Publication: October 23, 2015[1]

ERIC WATERMAN and TAREE WATERMAN, parents and natural guardians of A.T.W., a minor, deceased,	)	
Petitioners,	)	Vaccine Injury; Motion for Review; Table Injury; DTaP Vaccine; Encephalopathy
v.	)	
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

Lorraine J. Mansfield, Las Vegas, NV, for petitioners.

Gordon Shemin, Trial Attorney, with whom were Benjamin C. Mizer, Principal Deputy Assistant Attorney General, Rupa Bhattacharyya, Director, Vincent J. Matanoski, Deputy Director, and Gabrielle M. Fielding, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for respondent.

OPINION and ORDER

CAMPBELL-SMITH, Chief Judge

Petitioners, Eric and Taree Waterman, seek review of the special master's decision dismissing their claim for compensation under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), codified as amended at 42 U.S.C. § 300aa-1 to -34 (2012). Petitioners allege that as a result of the administration of a Diphtheria, Tetanus, and Pertussis (DTaP) vaccination, their son, A.T.W., suffered a Vaccine Injury Table (Table)

[1] Pursuant to Vaccine Rule 18(b) of the Rules of the United States Court of Federal Claims, this Opinion initially issued under seal to provide the parties the opportunity to object to the public disclosure of information contained within it. Neither party requested any redactions. The Opinion is thus reissued for publication in its entirety.

encephalopathy that led to his death. A.T.W. received the DTaP vaccination on August 20, 2013. Approximately two months old at the time, A.T.W. died later that evening.

On review, the question for the court is whether the special master's decision that petitioners failed to show that their son suffered from encephalopathy prior to his death was arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law. The court finds that the special master's decision was not. Thus, the court **DENIES** petitioners' motion for review and **SUSTAINS** the decision of the special master.

I. Background

A. Procedural History

On December 6, 2013, petitioners filed a petition under the Vaccine Act, in which they alleged, inter alia, that A.T.W. "suffered the 'Table Injury' known as death" within hours of his receipt of the DTaP and five other vaccinations.[2] Pet. 1–3, ECF No. 1 (emphasis omitted). Attached to their petition were ten exhibits, consisting of a birth and death certificate, Exs. 1, 3, medical records, Exs. 2, 4–8, affidavits of both Eric and Taree Waterman, Ex. 9, and a Vaccine Adverse Event Reporting System (VAERS) Report, Ex. 10. On February 12, 2014, petitioners filed exhibits 11 through 13, consisting of an autopsy report, Ex. 11, ECF No. 6; a toxicology report, Ex. 12, ECF No. 6-1; and a Medical Examiner's report, Ex. 13, ECF No. 6-2. On March 13, 2014, petitioners filed exhibit 14, a police report. ECF No. 9. On March 18, 2014, they filed exhibit 15, a report authored by petitioners' expert, pediatrician Dr. Leroy Bernstein (Dr. Bernstein), ECF No. 10, and on March 19, 2014, petitioners filed a statement of completion, ECF No. 11.

On March 25, 2014, the special master held the first of three telephonic status conferences with counsel for the parties.[3] See ECF No. 12. During the status conference, the special master advised petitioners' counsel that "death is not, in and of itself, [a] Table injury," although it may be a complication or sequela of a Table injury. EDR 1:41:52–43:07. The special master then instructed petitioners' counsel to file a supplemental expert report that identified the Table injury(s) that ultimately led to

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[2] For the purpose of awarding compensation under the National Vaccine Injury Compensation Program, the Vaccine Injury Table (Table) "is a table of vaccines, the injuries, . . . and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries . . . and deaths is to occur after vaccine administration." 42 U.S.C. § 300aa-14(a) (2012); see also infra Part II.A.

[3] The telephonic status conferences were recorded by the court's Electronic Digital Recording (EDR) system. The times noted in citations to the status conferences refer to the EDR record.

A.T.W.'s death. EDR 1:45:02–27; see also EDR 1:49:25–43 (addressing scheduling of petitioners' supplemental expert report).

On April 17, 2014, respondent, the Secretary of Health and Human Services, filed a Vaccine Rule 4(c) report opposing the petition for compensation. Resp't's Rpt., ECF No. 13.

On May 29, 2014, petitioners filed exhibit 16, which purported to be Dr. Bernstein's supplemental report. Ex. 16, ECF No. 15. Although exhibit 16 is titled "Dr. L. Bernstein Supplemental Report," it consists only of an article published in Human & Experimental Toxicology, a journal. Id.

On June 10, 2014, the special master held a second telephonic status conference with counsel for the parties, see ECF No. 17, during which counsel for petitioners notified the special master that exhibit 16 was in fact missing Dr. Bernstein's signed report, EDR 4:41:17–40. The special master again advised petitioners that Dr. Bernstein's original expert report (exhibit 15) failed to offer any theory of causation. EDR 4:42:17–32. Following the status conference, petitioners filed Dr. Bernstein's supplemental expert report as exhibit 17. Ex. 17, ECF No. 16.

The following day, on June 11, 2014, the special master issued an order directing respondent to advise whether Dr. Bernstein's supplemental expert report modified respondent's case. ECF No. 17. Further to the court's order, respondent filed a status report on July 22, 2014 stating that "the supplemental report and literature from Dr. Bernstein [did] not change respondent's position regarding th[e] case." Resp't's Status Rpt., ECF No. 18.

On August 14, 2014, the special master held a third and final telephonic status conference with counsel for the parties, see ECF No. 17, during which the special master set deadlines for the parties to brief respondent's motion for ruling on the record and/or a motion for summary judgment, EDR 3:17:14–33; 3:20:44–21:07.

Respondent filed a motion for ruling on the record or, in the alternative, for summary judgment on September 11, 2014, Resp't's Mot., ECF No. 22; petitioners filed a response to respondent's motion on September 29, 2014, Pet'rs' Resp., ECF No. 23; and respondent filed a reply to petitioner's response on October 22, 2014, Resp't's Reply, ECF No. 24.

In its response, petitioners advanced, for the first time, the theory at issue in their motion for review: that A.T.W. suffered from a Table encephalopathy. Pet'rs' Resp. 9. Petitioners alleged that "A.T.W. presented with encephalopathy within the stated time period after vaccination," and that they were "entitled to a presumption that [A.T.W.'s] death was caused by the vaccine." Id. at 11.

On June 30, 2015, the special master issued her sealed decision denying compensation, allowing time for the parties to propose redactions. Decision, ECF No. 25. Neither party proposed redactions, and the special master publicly reissued her decision on July 22, 2015.[4] ECF No. 26. The special master found, inter alia, that "[t]here [was] no evidence in the record that A.T.W. had symptoms of encephalopathy." Decision 7; see infra Part III.B (discussing the special master's findings in more detail). As such, the special master concluded that petitioners had "failed to prove that A.T.W. suffered from encephalopathy, as defined by the Table, or that A.T.W.'s death was a sequela[5] of such encephalopathy."[6] Decision 8 (footnote added).

Petitioners filed a motion for review on July 24, 2015, Pet'rs' Mot., ECF No. 27, to which respondent filed a response on August 24, 2015, Resp't's Resp., ECF No. 29. "Petitioners challenge only the special master's decision that [A.T.W.'s] death was not a Vaccine Table Injury," asserting that A.T.W. "suffered death from encephalopathy well within" the seventy-two hour time frame as required by the Table. Pet'rs' Mot. 7 (internal citations omitted).

Respondent responds that the special master's conclusion is well-supported and thus entitled to deference. See Resp't's Resp. 1–2, 6, 8.

B. Evidence Before the Special Master

The special master's decision sets forth A.T.W.'s medical history and petitioners' expert's opinion. See Decision 2–4. The court focuses on that information that is

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[4] Although unpublished, the special master's decision is available through commercial electronic databases. See, e.g., Waterman v. Sec'y of Health & Human Servs., No. 13-960V, 2015 WL 4481244 (Fed. Cl. June 30, 2015). As both parties cited to the page numbers in the decision filed on the court's CM/ECF system, ECF No. 25, the court follows suit.

[5] "The term 'sequela' means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table." 42 C.F.R. § 100.3(b)(5); cf. id. § 100.3(a) (listing death as a possible sequela of Table encephalopathy).

[6] The special master also denied petitioners' alternative theories for compensation: that A.T.W. suffered from Table anaphylaxis and that A.T.W.'s death was caused-in-fact by the vaccinations he received. Decision 6–9, ECF No. 25. In their motion for review, petitioners do not contest those portions of the special master's decision; they challenge only the finding that A.T.W. did not suffer from a Table encephalopathy. See generally Pet'rs' Mot., ECF No. 27.

relevant to its review, and is informed by the special master's decision and the exhibits filed by petitioners. See Decision 3–4; Exs. 1–17.[7]

1. Medical History

A.T.W. was born at term on June 11, 2013, by scheduled cesarean section. Ex. 1; Ex. 4 at 4. Ms. Waterman's pregnancy was "uncomplicated," and A.T.W. was healthy at birth, weighing seven pounds and eleven ounces. Ex. 4 at 4, 6; see also Ex. 9 at 2, 5. Ms. Waterman later reported to the police that A.T.W. was a "very healthy [baby] with the exception of some previous slight jaundice." Ex. 13 at 4.

On August 20, 2013, at approximately 11:00 a.m., A.T.W. received six vaccinations—DTaP, Hep B, IPV, HiB, Prevnar 13, and RotaTeq—during a two-month well-child check-up.[8] Ex. 6 at 2–4, 18; Ex. 2. A.T.W. was administered 40 mg of Tylenol following the vaccines. Ex. 6 at 2. Records from the check-up indicate that A.T.W. was "healthy" and "appear[ed] to be in no acute distress." Id. at 2–3. A.T.W's pediatrician did detect a possible hurt murmur, id. at 3, and Mrs. Waterman subsequently reported to the police that A.T.W.'s doctor intended to refer him to a cardiologist, Ex. 13 at 4.

As the special master observed, see Decision 4, there are some discrepancies and inconsistencies in the record as to A.T.W.'s behavior, feeding, and sleep schedule the afternoon and evening following vaccine administration. A few hours after A.T.W.'s death, Mrs. Waterman informed the police that "[A.T.W.] appeared to tolerate the [check-up] appointment and the rest of the day with no apparent distress or complications." Ex. 13 at 4, 6. Mrs. Watermen also related that "he was eating, sleeping, and having normal bowel movements." Id. at 4. Mrs. Waterman added that, at 7:00 p.m., "she fed him approximately 4 ounces of formula before he fell asleep." Id. But see id. (stating that A.T.W. "was fed approximately four ounces of [powder formula] mixed with water, per directions during that day and six ounces [of powder formula] mixed with water and Gerber Rice Cereal for his nighttime feeding"). But Mr. and Mrs. Waterman stated in the affidavits filed in support of their vaccine claim that A.T.W. "seemed different from his normal appearance and behavior," and that "[h]e looked as though he was still sleeping by 7:00 p.m." Ex. 9 at 2, 5. Mr. and Mrs. Waterman averred further

[7] When citing to exhibits 1–10, the court refers to the Bates number(s) assigned by Petitioners, which appear in the bottom right corner of each page. When citing to exhibits 11–17, some of which do not have Bates numbers, the court refers to the page number(s) assigned by the court's electronic case management system, which appear in the top right corner of each page.

[8] Hep B, IPV, HiB, Prevnar 13, and RotaTeq protect against hepatitis B, polio, haemophilius influenza b, pneumococcal pneumonia, and rotavirus, respectively. See Ex. 2.

that A.T.W. "only took three (3) ounces of his bottle instead of his usual six (6) ounces," and that A.T.W. "went down to sleep between 8:00 and 8:30 p.m." Id.

According to the police report, Mrs. Waterman related that, at approximately 9:30 p.m., she moved A.T.W. to "a full[-]sized bed with approximately 4 pillows surrounding him with his head turned to the right." Ex. 13 at 4. Mrs. Watermen also related that at around 10:50 p.m., a family friend entered the bedroom and noticed that A.T.W. was lying face-down. Id. After observing "what appeared to be vomit on the bedding and . . . his mouth and nose," the family friend called the family into the bedroom for assistance.[9] Id. In their affidavits, Mr. and Mrs. Waterman averred that, at approximately 11:00 p.m., Mr. Waterman "observed that [A.T.W.'s] skin appeared pale and mottled white and that his body appeared stiff and abnormal. He was wheezing and seemed to have much difficulty breathing. He was laying in vomit, with vomit around his nose." Ex. 9 at 2, 5. Cardiopulmonary Resuscitation was immediately administered, and the family called 911. Id. at 2, 6; Ex. 13 at 4. Paramedics arrived approximately twenty minutes later and transported A.T.W. to St. Rose Dominican Hospital where attempts to resuscitate A.T.W. failed. Ex. 9 at 3, 6; see also Ex. 7 at 1; Ex. 8 at 2; Ex. 13 at 4. A.T.W. was pronounced dead at 11:28 p.m. Ex. 13 at 4; Ex. 3.

A.T.W.'s autopsy report lists the following as his "diagnoses":

1. Scattered Petechiae of the Thymus, Epicardial Surface and Visceral Pleura . . . .
2. Pulmonary Edema, Bilateral, Lungs.
3. Pulmonary Congestion, Bilateral, Lungs.
4. Status Post – Octavalent Vaccination (20 August 2013).

Ex. 11 at 3. Notably, the medical examiner did not identify any abnormalities associated with A.T.W.'s brain: "The leptomeninges and the surfaces of the cerebral hemispheres are unremarkable. The vessels at the base of the brain have a normal configuration. The base of the skull shows no evidence of injury. On serial sectioning the brain reveals no grossly visible changes of natural disease." Id. at 8.

Under the "comment" portion of the autopsy report, the medical examiner wrote:

> The possibility of a true causal connection between the administration of an Octavalent Vaccination (20 August 2013) and the death cannot be eliminated, however, the current medical literature does not support such a

[9] The record is inconsistent as to who first discovered A.T.W. in a state of distress. Compare Ex. 13 at 4 (indicating that a family friend found A.T.W.), and Ex. 14 at 4 (same), with Ex. 7 at 2 (stating that Mr. Waterman found A.T.W.), Ex. 8 at 2 (same), and Ex. 9 at 2, 5 (suggesting same). The identity of the individual who initially discovered A.T.W. in distress is not determinative to the outcome of this case.

> causal connection to a reasonable degree of medical certainty. This case is formally reported to Vaccine Adverse Event Reporting System (aka VAERS) . . . .
>
> Additionally, the fact that [A.T.W.] was found face-down in the context of a firm bed with an absence of obstruction in moving head side-to-side . . . and the known normal ability of [A.T.W.] to move his head side-to-side easily does not support the possibility of suffocation as cause of death.

Id. at 3. The autopsy report concludes that A.T.W.'s manner of death was "natural" and that he died as a result of Sudden Infant Death Syndrome (SIDS).[10] Id.; accord Ex. 8 at 2. A.T.W.'s death certificate lists SIDS as his immediate cause of death. Ex. 3.

2. Petitioners' Expert

Dr. Bernstein has been a practicing pediatrician for over forty-two years. Ex. 15 at 3, 5. His curriculum vitae states that "[h]e has been the physician for thousands of infants, children and adolescents." Id. at 5; see also id. at 3 (stating that he "regularly diagnose[s] and treat[s] infants, children and adolescents"). As of March 2014, Dr. Bernstein was a staff member at Sunrise Hospital and Medical Center in Las Vegas, Nevada, and an Assistant Professor of Pediatrics at both the Touro University School of Medicine and the University of Nevada School of Medicine. Id.

In March 2014, Dr. Bernstein provided petitioners with an expert report in which he opined that:

> A.) Multiple vaccination[s] should not be given on the same day to infants. In my pediatric practice I limit, at most, two vaccines at a time. Many pediatricians do not give vaccines all at once.
> B.) A subset of infants may be more susceptible to reactions to immunizations. I do not administer multiple vaccines at the same time because one infant in perhaps thousands will have a reaction.
> C.) The multiple vaccination[s] administered to infant [A.T.W.] was a possible cause of his death. To my reasonable knowledge, the six vaccines administered the same day could have caused a reaction which caused his death.

[10] Sudden Infant Death Syndrome (SIDS) is defined as "the sudden and unexpected death of an apparently healthy infant, typically occurring between the ages of three weeks and five months, and not explained by careful postmortem studies." Dorland's Illustrated Medical Dictionary 1850 (32d ed. 2012).

Id. at 4. Dr. Bernstein's opinion was based upon his review of the available medical records and the affidavits of Mr. and Mrs. Waterman. Id. at 3.

In May 2014, Dr. Bernstein provided petitioners with a supplemental expert report, which stated in full:

> 1.) The baby possibly would not have died had he not received multiple vaccinations on the same day.
> 2.) The vaccinations could have been a factor.
> 3.) Medicine is an imperfect science.
> 4.) No doctor could state conclusively that the vaccination caused the baby's death.

Ex. 17 at 3. Attached to Dr. Bernstein's supplemental expert report was an article published in Human & Experimental Toxicology. Id. at 4–13 (Neil Miller and Gary Goldman, Infant mortality rates regressed against number of vaccine doses routinely given: Is there a biochemical or synergistic toxicity?, 30(9) Hum. Exp. Toxicol. 1420–28 (2011)). Employing a linear regression analysis, the article concludes that "nations that require more vaccine doses tend to have higher infant mortality rates." Id. at 11 (italicization omitted).

II. Legal Standards

A. Recovery Under the Vaccine Act

The Vaccine Act was enacted to create "a federal no-fault compensation scheme under which awards were to 'be made to vaccine-injured persons quickly, easily, and with certainty and generosity.'" Paluck v. Sec'y of Health & Human Servs., 786 F.3d 1373, 1378 (Fed. Cir. 2015) (quoting H.R. Rep. No. 99–908, at 3 (1986) reprinted in U.S.C.C.A.N. 6344). "A petitioner seeking compensation under the Vaccine Act must establish, by a preponderance of the evidence, that a covered vaccine caused the claimed injury." Id. at 1379; see 42 U.S.C. § 300aa-13(a)(1)(A). A petitioner can recover in one of two ways: either by proving an injury listed on the Table or by proving causation-in-fact (off-Table). See 42 U.S.C. §§ 300aa-11(c)(1)(C), -13(a)(1); Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1374 (Fed. Cir. 2009).

Where, as here, a petitioner alleges a Table injury, the petitioner must prove by a preponderance of the evidence that "he or she received a vaccine listed in the Table, that he or she suffered an injury listed in the Table, and that the injury occurred within the prescribed time period." Nuttall v. Sec'y of Health & Human Servs., 122 Fed. Cl. 821, 829 (2015) (citing Andreu, 569 F.3d at 1374), appeal docketed, No. 15-5153 (Fed. Cir. Sept. 29, 2015). "If petitioner can make such a showing, causation is presumed and petitioner is deemed to have made out a prima facie case of entitlement to compensation

under the Act."[11] Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1102 (Fed. Cir. 1996); see Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1147 (Fed. Cir. 1992) ("The Vaccine Table, in effect, determines by law that the temporal association of certain injuries with the vaccination suffices to show causation."). The petitioner is then entitled to recover unless the respondent can show, by a preponderance of the evidence, that the injury was caused by a factor unrelated to the vaccine. 42 U.S.C. § 300aa–13(a)(1)(B)); Shalala v. Whitecotton, 514 U.S. 268, 270–71 (1995); de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). A special master may not award compensation under the Act "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a).

B. Standard of Review of the Special Master's Decision

In response to a motion for review of a decision issued by a special master, the court has jurisdiction "to undertake a review of the record of the proceedings," and may "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." 42 U.S.C. § 300aa–12(e)(2)(B); Markovich v. Sec'y of Health & Human Servs., 477 F.3d 1353, 1355–56 (Fed. Cir. 2007). "These standards vary in application as well as degree of deference," and "[e]ach standard applies to a different aspect of the judgment." Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992); see also Masias v. Sec'y of Health & Human Servs., 634 F.3d 1283, 1287–88 (Fed. Cir. 2011). Of relevance here, findings of fact are reviewed under the highly deferential arbitrary and capricious standard, and legal questions are reviewed de novo under the "not in accordance with law" standard.[12] See Masias, 634 F.3d at 1287–88; Munn, 970 F.2d at 870 n.10.

With respect to the arbitrary and capricious standard of review, "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." Hines on Behalf of Sevier v. Sec'y of Health & Human Servs., 940 F.2d

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[11] "In an off-Table case, a petitioner who received a vaccine listed in the Table but suffered an injury not listed in the [T]able does not receive a presumption of causation, and instead must prove causation by a preponderance of the evidence." Nuttall v. Sec'y of Health & Human Servs., 122 Fed. Cl. 821, 829 (2015) (citing Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010)), appeal docketed, No. 15-5153 (Fed. Cir. Sept. 29, 2015).

[12] The abuse of discretion standard "rarely come[s] into play except where the special master excludes evidence." Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

1518, 1528 (Fed. Cir. 1991); Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting same). As the Federal Circuit has stated,

> Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute 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 & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993). That is, the court must 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 & Human Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011).

III. Discussion

Petitioners allege that A.T.W. experienced a Table encephalopathy, which resulted in his death, that was attributable to the DTaP vaccine he received earlier in the day. Pet'rs' Mot. 7, 10. The Table identifies encephalopathy as an injury covered by the DTaP vaccine if it arose within seventy-two hours of the vaccination. 42 C.F.R. § 100.3(a). The alleged injury suffered by A.T.W. arose within twelve hours of receiving the DTaP vaccine. See Ex. 13 at 4. It is beyond dispute that petitioners have established that A.T.W. "received a vaccine listed in the Table, . . . and that the [alleged] injury occurred within the prescribed time period." See Nuttal, 122 Fed. Cl. at 829. Thus, the question upon review is whether the Special Master's determinations that A.T.W. did not suffer from a Table Encephalopathy and that his death was not a sequela thereof were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.

A. Encephalopathy

The Table defines encephalopathy as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." 42 U.S.C. § 300aa-14(b)(3)(A). The Table further provides, in relevant part, that a "vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description . . . of an acute encephalopathy." 42 C.F.R. § 100.3(b)(2).

An acute encephalopathy, in turn, is defined as "one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." Id. § 100.3(b)(2)(i). "Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group." Id. § 100.3(b)(2)(i)(C). An acute encephalopathy in

children under the age of eighteen months, "who present without an associated seizure event, . . . is indicated by a significantly decreased level of consciousness lasting for at least 24 hours." Id. § 100.3(b)(2)(i)(A). And a "significantly decreased level of consciousness" is indicated by the presence of one or more of the following signs: "(1) [d]ecreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) [d]ecreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) [i]nconsistent or absent responses to external stimuli (does not recognize familiar people or things)." Id. § 100.3(b)(2)(i)(D).

Notably, "[s]leepiness, irritability (fussiness), high-pitched and unusual screaming, [and] persistent inconsolable crying" are not, standing alone or in combination, signs of an acute encephalopathy. Id. § 100.3(b)(2)(i)(E); see also 42 U.S.C. § 300aa-14(b)(3)(A) (providing that "[s]igns and symptoms such as high pitched and unusual screaming, persistent [i]nconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy").

B. Relevant Findings of the Special Master

Based on the evidence in the record, the special master determined that A.T.W. did not suffer from a Table encephalopathy. First, the special master found that "encephalopathy is a disease of the brain, and the autopsy indicates nothing abnormal about A.T.W.'s brain." Decision 7 (citing Ex. 11); see 42 U.S.C. § 300aa-14(b)(3)(A). Next, the special master observed that "although A.T.W. was found in distress, with vomit around his mouth and nose and having difficulty breathing," this state did not qualify as "unresponsive" within the meaning of the Table. Decision 7–8 (citing, inter alia, 42 C.F.R. § 100.3(b)(2)(i)(A), (D)(1)).[13] The special master noted that the symptoms A.T.W. may have exhibited following vaccine administration, to include feeding changes and sleepiness, are explicitly identified in the Table "as insufficient to indicate encephalopathy." Id. at 8 (citing, inter alia, 42 C.F.R. § 100.3(b)(2)(i)(E)).

Having concluded that "there [were] insufficient medical records supporting Petitioners' claim," id. at 9, the special master next turned to whether petitioners' expert opinion supported the existence of a Table encephalopathy, id. at 8; see id. at 5 (stating that "[i]f the medical records do not disclose a diagnosis of a Table [i]njury, Petitioners must submit a medical expert's opinion interpreting A.T.W.'s symptoms as a Table injury" (citing Schneider ex rel. Schneider v. Sec'y of Health & Human Servs., 2005 WL 318697 at *2 (Fed. Cl. Feb. 1, 2005)); id. at 9 (similar). The special master observed that "Dr. Bernstein[] has never diagnosed A.T.W. with encephalopathy or suggested that he displayed symptoms consistent with encephalopathy." Id. at 8. The special master

[13] The court understands that the special master equated "unresponsive" with "[a] 'significantly decreased level of consciousness' [as] indicated by the presence of . . . [d]ecreased or absent response to environment." 42 C.F.R. § 100.3(b)(2)(D)(1).

concluded that Dr. Bernstein failed to offer an opinion that established the existence of a Table injury. Id. at 9.

Based on the foregoing, the special master found that the petitioners "failed to prove that A.T.W. suffered from encephalopathy, as defined by the Table, or that A.T.W.'s death was a sequela of such encephalopathy." Id. at 8.

C. Petitioners' Objection to the Special Master's Findings

Petitioners object to the Special Master's reading of the requirements of encephalopathy as set forth in the Table. Pet'rs' Mot. 4. Specifically, petitioners argue that the special master erred in concluding that A.T.W.'s "death was not a Vaccine Table Injury." Id. at 7. Petitioners allege that the medical records reflect that the symptoms experienced by A.T.W., and his ultimate death, establish that A.T.W. suffered from a Table encephalopathy. See id. at 4 (claiming that A.T.W. "suffered and died from encephalopathy"); id. at 10 (claiming that "A.T.W.'s condition satisfied the requirements of an encephalopathy set forth in the [Table]" (citing 42 C.F.R. § 100.3(b))). Petitioners appear to raise both a legal and factual challenge to the special master's decision. See, e.g., id. at 6 ("This review argues that the special master made a legal error when she denied Petitioners claim for compensation."); id. at 7–9 (challenging the special master's findings of fact).

Petitioners allege that A.T.W. experienced a significantly decreased level of consciousness, as defined by 42 C.F.R. § 100.3(b)(2)(i)(D). Pet'rs' Mot. 8–9. As support, petitioners point to medical records that suggest that A.T.W. was in cardiac arrest, which rendered him unconscious, and that both his blood pressure and heart rate were zero. Id.; see id. at 9 (claiming that "[b]eing in a coma is the quintess[ential] definition of decreased level of consciousness"). Petitioners also address each of the clinical signs identified in 42 C.F.R. § 100.3(b)(2)(i)(D) as indicative of a significantly decreased level of consciousness:

> 1.) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); – A.T.W. responded to nothing in the environment – not to pounding on his chest for CPR, not to being injected with epinephrine, not to the screech of the ambulance sirens.
> 2.) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); – A.T.W. did not respond to his own father, [let] alone paramedics or emergency room doctors.
> 3.) or Inconsistent or absent responses to external stimuli (does not recognize familiar people or things). – A.T.W. did not respond to people, lights, sounds, noises, nothing.

Id. at 9–10.

Petitioners also challenge the special master's observation that an "[e]ncephalopathy is a disease of the brain, and [that] the autopsy indicates nothing abnormal about A.T.W.'s brain." Id. at 7 (citing Decision 7). Petitioners argue that there was no visible swelling to A.T.W.'s brain because he died rapidly. See id. ("When a person dies rapidly[,] the brain cannot swell if blood has stopped circulating."). Petitioners add that A.T.W. in fact suffered from "neurological damage to [his] brain due to deprivation of oxygen to the brain for several minutes." Id.; see id. ("Brain anoxia leads to death in a few minutes.").

D. The Court's Review of the Special Master's Decision

The special master's determination that A.T.W. did not suffer from a Table encephalopathy, or that his death was a sequela thereof, was well-supported by the record and in accordance with law. A.T.W. was never diagnosed with encephalopathy, there is no indication in his medical records that he suffered any of the symptoms of encephalopathy—to include a decreased level of consciousness, see 42 C.F.R. § 100.3(b)(2)—and his autopsy report indicates nothing abnormal about his brain, Ex. 11 at 8.[14] Moreover, to the extent that A.T.W. exhibited symptoms of sleepiness or fussiness following vaccine administration, see Ex. 9 at 2, 5, these symptoms are not, standing alone or in combination, signs of an encephalopathy, 42 C.F.R. § 100.3(b)(2)(i)(E).

Having failed to find sufficient support in A.T.W.'s medical records for petitioners' claim that A.T.W. suffered from a Table encephalopathy, the special master looked to whether petitioners' expert supported their claim. See 42 U.S.C. § 300aa-13(a) (providing that a special master may not award compensation under the Act "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion"); Dickerson v. Sec'y of Health & Human Servs., 35 Fed. Cl. 593, 599 (1996) (referring to "the firm requirement that medical opinion evidence is . . . necessary . . . to support an on-Table theory" where medical records fail to establish the existence of a Table injury by a preponderance of the evidence); Schneider, 2005 WL 318697, at *2 (stating that numerous cases construing 42 U.S.C. § 300aa-13(a) "hold uniformly that if an injured person's medical records do not disclose a diagnosis that the injured person's symptoms constitute a Table injury, then the petitioner must submit a medical expert's opinion interpreting the injured person's symptoms as a Table injury" (emphasis omitted)).

The special master correctly observed that "Dr. Bernstein[] has never diagnosed A.T.W. with encephalopathy or suggested that he displayed symptoms consistent with

[14] Petitioners' claim that A.T.W. in fact suffered from "neurological damage to [his] brain due to deprivation of oxygen to the brain for several minutes," Pet'rs' Mot. 7, is unsubstantiated, see 42 U.S.C. § 300aa-13(a) (providing that compensation may not be awarded under the Act "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion").

encephalopathy." Decision 8. Rather, Dr. Bernstein opined that A.T.W. "possibly would not have died had he not received multiple vaccinations on the same day." Ex. 17 at 3; see also Ex. 15 at 4 (stating that the multiple vaccinations A.T.W. received were "a possible cause of his death"). As respondent suggests, Resp't's Resp. 6, Dr. Bernstein's contention that a possible connection exists between A.T.W.'s vaccination and his death does not approach the preponderance of the evidence standard necessary to recover under the Vaccine Act, see 42 U.S.C. § 300aa-13(a)(1)(A); see also Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (stating that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence).

Moreover, the court finds that the special master's conclusion that "death, in and of itself, is not a Table injury, though it may be a sequela of a Table injury," Decision 2; see also Mar. 25, 2014, EDR 1:41:52–43:07 (similar), is in accordance with law. As the U.S. Court of Appeals for the Federal Circuit has stated, "death alone is not compensable if a [T]able injury has not been established." Hodges, 9 F.3d at 960. Instead, in order to recover for a death based on an alleged Table injury, a petitioner must establish two things by a preponderance of the evidence: "First, the petitioner must show that one of the four injuries or conditions listed in the Table occurred within the time period specified in the Table for that injury or condition. Second, the petitioner must show that death occurred as a sequela of that injury or condition." Hellebrand v. Sec'y of Health & Human Servs., 999 F.2d 1565, 1569 (Fed. Cir. 1993). Thus, to the extent that petitioners' contend that A.T.W.'s death, alone, was a Table injury, see Pet'rs' Mot. 7, such a contention is contrary to law.

The court now turns to petitioners' attempt to characterize A.T.W.'s presentation immediately prior to his death as symptoms of encephalopathy. See Pet'rs' Mot. 8–10. Petitioners suggest that because A.T.W. was unconscious prior to being pronounced dead, he was experiencing a "significantly decreased level of consciousness" as defined by 42 C.F.R. § 100.3(b)(2)(i)(D). However, the facts of this case and binding case law do not support petitioners' claim.

As petitioners acknowledge, A.T.W. "died rapidly," id. at 7, and was unconscious for approximately forty minutes prior to his death, see Ex. 13 at 4 (stating that A.T.W. was found at 10:50 p.m.); Ex. 13 at 4 (stating that A.T.W. was pronounced dead at 11:28 p.m.). That death is preceded by a loss of consciousness is not unusual, and petitioners have not pointed to any evidence that suggests that A.T.W.'s loss consciousness was a result of an encephalopathy. See Carraggio v. Sec'y of Health & Human Servs., No. 93-0438V, 1997 WL 74694, at *5 (Fed. Cl. Jan. 31, 1997) (observing that "any death is accompanied by . . . loss of consciousness and cardiovascular and respiratory arrest," and noting that the Vaccine Act "is intended to reimburse only those deaths in which it has been shown, by a preponderance, that a listed Table injury occurred and death was a sequela of that injury or condition"), aff'd sub nom. Carraggio v. Sec'y of Health & Human Servs., 38 Fed. Cl. 211 (1997).

Although "nothing in the Vaccine Act . . . precludes death from being used as evidence of a [T]able injury," Jay v. Sec'y of Health & Human Servs., 998 F.2d 979, 983 (Fed. Cir. 1993), it is well-established that symptoms of death do not independently establish the existence of a Table injury, Hodges, 9 F.3d at 960. To conclude otherwise would result in recovery for any death that occurs within seventy-two hours of receipt of a DTaP vaccine—a result that "is at odds with the plain language of the [Vaccine] Act." Hellebrand, 999 F.2d at 1571; see Hodges, 9 F.3d at 960 ("[D]eath alone is not compensable if a [T]able injury has not been established."). Thus, as respondent correctly observes:

> [T]he flaw with petitioners' contention is that in every case involving death (SIDS or otherwise) a vaccine recipient would exhibit a decreased level of consciousness immediately preceding death. This would require the special master to reflexively find a Table encephalopathy in any SIDS case occurring within 72 hours of receipt of a DTaP vaccine.

Resp't's Resp. 7. The record supports a conclusion that the loss of consciousness A.T.W. suffered prior to his death was a consequence of the dying process.

The special master ultimately determined that "[p]etitioners' bare assertions [were] insufficient to meet their burden." Decision 8. In light of the foregoing, the court concludes that "the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for [the] decision." Hines, 940 F.2d at 1528. The court does not find the special master's determination to be arbitrary and capricious. Nor does the court find that the special master's decision was contrary to law. Accordingly, the court upholds the special master's decision.

IV. Conclusion

The special master's denial of petitioners' claim was not arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law. Accordingly, the court **DENIES** petitioners' motion for review and **SUSTAINS** the decision of the special master. The Clerk of the Court shall enter judgment accordingly.

IT IS SO ORDERED.

s/ Patricia Campbell-Smith
PATRICIA CAMPBELL-SMITH
Chief Judge