In the United States Court of Federal Claims

No. 11-685V

(E-Filed: March 22, 2021)[1]

TRYSTAN SANCHEZ, by and through his parents, GERMAIN and JENNIFER SANCHEZ, Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Vaccine; National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34; Scope of Remand; Review of Special Master's Decision.

Lisa A. Roquemore, Rancho Santa Margarita, CA, for petitioners.

Jennifer L. Reynaud, Trial Attorney, with whom were Jeffrey Bossert Clark, Acting Assistant Attorney General, C. Salvatore d'Alessio, Acting Director, Catherine E. Reeves, Deputy Director, Heather L. Pearlman, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

OPINION

CAMPBELL-SMITH, Judge.

Petitioners filed the petition in this case on October 17, 2011. See ECF No. 1. The special master issued his initial entitlement decision on October 9, 2018. See ECF No. 205. Thereafter, petitioners filed a motion for review with this court, see ECF No.

[1] This opinion was filed on February 12, 2021, in accordance with Rule 18(b) of the Vaccine Rules, Appendix B to the Rules of the United States Court of Federal Claims. See ECF No. 278. Pursuant to ¶ 4 of the ordering language, the parties were to propose redactions of the information contained therein on or before February 26, 2021. No proposed redactions were submitted to the court.

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207, which was denied, and the special master's decision was sustained, on February 11, 2019, see ECF No. 217.

Petitioners then filed an appeal with the United States Court of Appeals for the Federal Circuit on April 10, 2019. See ECF No. 220. On April 7, 2020, the Federal Circuit vacated this court's opinion sustaining the special master's entitlement decision and remanded the case for further proceedings. See Sanchez v. Sec'y of Health & Hum. Servs., 809 F. App'x 843 (2020).

The special master issued a second entitlement decision on August 26, 2020, in which he again denied the relief requested by petitioners.[2] See ECF No. 253. Petitioners' motion for review of the special master's August 26, 2020 decision is the motion now before the court. See ECF No. 260. Respondent filed its response on October 19, 2020, see ECF No. 265, and petitioners filed a reply on October 30, 2020, see ECF No. 269. The motion is now fully briefed and ripe for ruling. The court has considered all of the arguments presented by the parties and addresses the issues that are pertinent to the court's ruling in this opinion. For the following reasons, petitioner's motion for review is **DENIED**, and the special master's August 26, 2020 entitlement decision is **SUSTAINED**.

I. Background

Trystan Sanchez was born in August 2008. See ECF No. 253 at 2. The special master describes this case as follows:

> When [Trystan] was conceived, he inherited from his father a mutation in a gene known as an SDHA gene. Coincidentally, he inherited from his mother a different mutation in the SDHA gene. However, these mutations were not detected for many years. In the litigation, the parties dispute the consequences of these mutations.

Id. More specifically, petitioners argue that "several vaccines, including the [diphtheria-tetanus-acellular pertussis (DTaP)], caused [Trystan's] neurodegeneration that was ultimately diagnosed as a mitochondrial disorder, Leigh's Syndrome." ECF No. 260 at 9. Respondents disagree with that assessment.

A. Overview of Trystan's Relevant Medical History

[2] Throughout this opinion, when the court cites to the special master's August 26, 2020 decision, for clarity of the narrative, it will not always include the sources to which the special master cited unless specifically relevant.

The central disagreement in this case involves Trystan's condition following his six-month well-visit. In his post-remand decision, the special master recites the following summary facts:

> At the age of six-months, on February 5, 2009, Trystan was seen by a pediatrician who found Trystan to be developing normally. In this appointment, Trystan received a series of vaccinations including a dose of the dip[h]theria-tetanus-acellular pertussis (DTaP) vaccination.
>
> On the day and evening following the vaccination, Trystan cried inconsolably. He also had a hot red mark on his thigh, and developed a fever that ebbed and flowed for a few days.
>
> On February 16, 2009, Trystan was suffering from a common cold. In the course of this illness, he was congested, had a fever, and jerked around in his father's arms. Trystan also contorted his arms.
>
> Trystan had more colds for which his parents brought him to a pediatrician at the end of April 2009 and in May 2009. During this time, Trystan began to lose some developmental skills.
>
> Trystan's parents brought him for medical attention in August 2009. During this appointment, a physician's assistant noticed his lack of development and referred him to additional medical services. This referral eventually led to an appointment with a neurologist, who also documented problems with Trystan.

ECF No. 253 at 2-3. Several years later, Trystan was diagnosed with Leigh's syndrome, which is "a severe neurological disorder that often presents in the first year of life and is characterized by progressive loss of mental and movement abilities and typically results in death within a couple years." Id. (citations omitted).

According to the special master, the medical records indicate that after receiving the vaccinations on February 5, 2009, Trystan was evaluated next by a medical professional on February 17, 2009, when petitioners took him to an urgent care facility. See id. at 4. Trystan was evaluated by physician's assistant Jonathon P. Luna who diagnosed him with a "common cold" and "[v]iral syndrome." Id. (citations omitted). Petitioners told Mr. Luna that Trystan "had been coughing and congested with fever," but the records do not show that petitioners "told Mr. Luna anything about Trystan exhibiting unusual arm movements or other signs of a neurological condition." Id.

The testimony offered by Trystan's father, Germain Sanchez, includes details not recorded by Mr. Luna. He states that on February 16, 2009:

> Trystan was very hot with a fever of 103.2 and kept crying inconsolably . . . . When I held Trystan in my arms and tried to calm him down, I noticed a change[] in Trystan. He felt very stiff and uncomfortable. Originally, I thought he was throwing some kind of fit and trying to show how miserable he felt by stiffening his body. . . . I had never seen a child do that before. Trystan began to hold his arm behind his back with a lot of tension and jerk his head back. When I tried to comfort him and gently put his arm back to the normal position, Trystan would go right back to holding it behind his back again. This lasted for only a few minutes. . . . (We later learned that this was likely a seizure, but we had no idea at the time that it was occurring.) We continued to rock Trystan to sleep and this strange behavior slowly subsided.

Id. (citing Germain Sanchez affidavit dated October 5, 2011).

Trystan was next seen by a medical provider on April 29, 2009, when he was diagnosed with an ear infection and bronchitis by Dr. Nabil R. Seleem. See id. at 67. Dr. Seleem reported "[n]o unusual arm movements or developmental issues," and "noted '[n]o neurological symptoms.'" Id. (citations omitted). And on May 13, 2009, Trystan was seen by Dr. Philip Brown, who "observed that Trystan's infection appeared to be resolving," and made "[n]o reports of the loss of eye contact or an inability to roll over." Id. (citations omitted).

On August 17, 2009, Trystan was seen by physician's assistant Micaela Marin-Tucker for his one-year well-visit. See id. at 70. Ms. Marin-Tucker noted in Trystan's record that his mother had "noticed a change in [his] development about 2-3 months ago." Id. (citations omitted). "Upon a review of systems, Ms. Marin-Tucker found that Trystan did not walk, stand, crawl, and hold his head up while sitting, or make any attempt to move his lower extremities." Id. at 71 (citations omitted). She further noted that "his extremities seemed soft yet rigid at times." Id. (citations omitted). Following this examination, Ms. Marin-Tucker referred Trystan to a neurologist, physical therapist, and an occupational therapist. See id. At the same appointment, "Trystan received his third hepatitis B vaccine, as well as his second doses of the pneumococcal conjugate, DTaP, and Hib vaccines." Id. (citations omitted).

Ms. Marin-Tucker examined Trystan again during a follow-up visit on October 7, 2009. See id. at 72. She "noted no seizures, weakness, or tics. She made no notation of tremors or twitching." Id. But she "found Trystan to be unable to grasp, sit, crawl, or make much eye contact." Id.

On November 12, 2009, Dr. David J. Michelson, a neurologist, evaluated Trystan and found that he was experiencing "muscle spasms, global developmental delay,

weakness [and] walking problems," among other things. Id. at 74. He also noted that "[w]hile Trystan had previously held his right arm stiffly behind him episodically, he had not done this lately." Id. Dr. Michelson ordered an MRI, which was performed in December 2009 and showed "problems in Trystan's basal ganglia," consistent with Leigh's syndrome.[3] Id. at 74-75.

B. Petition for Compensation and Coincident Developments

In their petition, petitioners allege that the vaccinations Trystan received on February 5, 2009, "were the actual cause of Trystan's symptoms including fever and subsequent seizure activity/disorder leading to his development issues." ECF No. 1 at 12. In support of the petition, petitioners submitted medical records, testimony from family members, and expert testimony, including testimony from Dr. Lawrence Steinman, a pediatric neurologist. See ECF No. 253 at 3-4.

Petitioner's expert, Dr. Steinman, relied on Mr. Sanchez's report of Trystan's unusual arm movements on February 16, 2009, in his evaluation. See id. at 4. In his first report, Dr. Steinman first stated that "'[e]leven days [after receiving the vaccinations] in the context of a febrile illness, [Trystan] may have had a seizure, manifest[ed] by stiffening and holding his arm behind his back with a lot of tension and jerked his head back.'" See id. at 5 (citing Dr. Steinman's September 28, 2011 report) (emphasis in original and internal quotation marks omitted). Later in the report, Dr. Steinman's assessment of Trystan's arm movements appears more definitive; he notes that Trystan "'was given multiple vaccines, he suffered from fever and he suffered from seizures.'" Id. (citing Dr. Steinman's September 28, 2011 report). Despite this apparent inconsistency, the special master characterizes the remainder of Dr. Steinman's report as "premised upon Trystan having a seizure." Id.

In Dr. Steinman's opinion, the vaccines "triggered" Trystan's seizures, and but for the vaccinations, Trystan "would not have suffered such devastating neurological consequences." Id. (quoting Dr. Steinman's September 28, 2011 report) (quotation marks omitted). According to respondent, however, Trystan did not suffer neurological consequences close enough in time to receiving the vaccines to be entitled to compensation. See id. Of particular relevance to the outcome of this case, "the parties and their experts disputed whether Trystan displayed unusual arm movements starting in February 2009." Id. at 6.

[3] Trystan continued to receive medical care after the December 2009 MRI, but because the central issue in this case relates to the events in 2009, the court will omit the detailed recitation of those facts here and instead will include any relevant aspects of that care in the analysis section of this opinion.

On April 10, 2013, the special master issued a document titled Ruling Finding Facts, ECF No. 45, which was intended to serve as the basis for expert reports and ultimately an entitlement decision. See id. at 6-8. In the ruling, the special master concluded, among other things, that "Trystan did not begin to exhibit arm contortions" at the time of the February 17, 2009 urgent care visit. ECF No. 45 at 13. He also found that between the February 17, 2009 urgent care visit and the next pediatrician visit on April 29, 2009, Trystan "did not lose control of his head and trunk, nor did he stop making eye contact or stop wanting to play anymore. He did not exhibit arm contortions." Id.

During the following years of this litigation, however, the facts and expert opinions related to Trystan's condition continued to develop. In 2014, Trystan underwent genetic testing which revealed "a heterozygous mutation in the SDHA gene." ECF No. 253 at 10. Thereafter, Trystan was diagnosed with Leigh's syndrome. See id. at 12 n.7. Petitioners presented several expert reports, including one from Dr. Dmitriy Niyazov, an expert in mitochondrial disorders, in which the doctors opined that Trystan's Leigh's syndrome initially manifested as the inconsolable crying and fever he experienced after the February 5, 2009 vaccinations. See id. at 12-13. Dr. Niyazov also took the view that absent the vaccinations, Trystan's genetic mutations may not have developed into Leigh's syndrome at all. See id. at 13. Dr. Steinman issued another report, dated December 10, 2015, in which, according to the special master, he "roughly presented the same view." Id.

In response to Dr. Niyazov's and Dr. Steinman's reports, respondent produced a report from Dr. Gerald Raymond, an expert in genetics and neurology.[4] See id. at 5-6, 14. In this report, Dr. Raymond concluded that Trystan is "'a child with Leigh syndrome secondary to mutations in the gene SDHA. This is the sole cause of his neurologic condition and the onset was not caused by immunizations received and his disease course is consistent with the condition and was not aggravated by the receipt of vaccination.'" Id. at 14 (quoting Dr. Raymond's March 16, 2016 report). After the parties exchanged additional expert reports to address this disagreement, the special master set the case for a hearing, and ultimately found that petitioners were not entitled to compensation. See id. at 14-15; ECF No. 205.

After this court sustained that entitlement decision, see ECF No. 217, the Federal Circuit vacated that decision, and remanded the case to the special master for further proceedings, noting that the special master's decision "left certain critical issues

[4] Respondent has also presented expert testimony from Dr. Stephen J. McGeady, Dr. Edward Cetaruk, and Dr. Dean Jones. See ECF No. 253 at 27-30. Their opinions will be discussed more fully where relevant.

unresolved,"[5] see Sanchez, 809 F. App'x at 844. On remand, the special master permitted the parties to file additional expert reports and held an additional hearing. See ECF No. 253 at 20-21. After considering the Federal Circuit's April 7, 2020 decision and the record in this case, the special master issued his August 26, 2020 decision, of which petitioners now seek review. See id. at 21; ECF No. 260.

II. Legal Standards

This court has jurisdiction to review the decision of a special master in a Vaccine Act case. See 42 U.S.C. § 300aa-12(e)(2). "Under the Vaccine Act, the Court of Federal Claims reviews the decision of the special master to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]'" de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1350 (Fed. Cir. 2008) (quoting 42 U.S.C. § 300aa-12(e)(2)(B) and citing Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1277 (Fed. Cir. 2005)).

This court uses three distinct standards of review in Vaccine Act cases, depending upon which aspect of a special master's judgment is under scrutiny.

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed . . . 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.

Munn v. Sec'y of Dep't of Health & Hum. Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

As the Federal Circuit has held, when reviewing a special master's decision, this 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). "Rather, as long as a special master's finding of fact is 'based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.'" Id. (quoting Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010)). Under this standard "reversible error is 'extremely difficult to demonstrate' if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.'" Lampe v. Sec'y of

[5] The United States Court of Appeals for the Federal Circuit's decision and the scope of the remand is the subject of some dispute between the parties and is addressed more fully below.

Health & Hum. Servs., 219 F.3d 1357, 1360 (quoting Hines v. Sec'y of Health & Hum. Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

Petitioners bear the burden of proving, by a preponderance of the evidence, that "the vaccination brought about [their] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278. "Because causation is relative to the injury, . . . petitioner[s] must provide a reputable medical or scientific explanation that pertains specifically to the petitioner[s'] case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010) (quoting Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)). If petitioners "satisf[y] this burden, [they are] 'entitled to recover unless [respondent] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.'" Althen, 418 F.3d at 1278 (quoting Knudsen, 35 F.3d at 547).

III. Analysis

A. The Federal Circuit's Opinion Remanding the Case

The Federal Circuit summarized petitioner's three primary grounds for appeal as follows:

> First, the petitioners contend that the rulings of the special master and the Claims Court are contrary to the 2015 decision of this court in Paluck v. Secretary of Health & Human Services, 786 F.3d 1373 (Fed. Cir. 2015). Second, they argue that the central component of the special master's ruling—that Trystan's Leigh's syndrome was not triggered by his February 5, 2009, vaccinations—is contrary to the evidence. Third, they argue that the special master failed to address their "challenge-rechallenge" argument, i.e., their contention that the combination of the first vaccination in February 2009, and the second vaccination, in August 2009, triggered or aggravated Trystan's condition.

Sanchez, 809 F. App'x at 850. The Circuit noted its "extremely limited" authority to review the special master's factual findings, see id., and then addressed each issue in turn.

1. Paluck

Petitioners in Paluck sought compensation for injuries sustained by their minor son, who had an underlying mitochondrial disorder, after he received a series of

vaccinations at his one-year well-visit. Paluck, 786 F.3d at 1377-78. In that case, the child developed a fever, irritability, and fatigue within forty-eight hours of receiving the vaccinations, and his doctors documented neurological decline within twenty-three days. See id. at 1381-82. The special master concluded that the child's decline was not sufficiently "linear" to establish entitlement to compensation, but both this court and the Federal Circuit disagreed. Id. at 1382-83. The Federal Circuit held that the special master's decision was arbitrary and capricious because he had failed to consider "'the record as a whole,'" in reaching this conclusion. Id. at 1382 (quoting 42 U.S.C. § 300aa-13(a)(1)).

The Federal Circuit also found that the special master had erred in setting a strict timeframe within which symptoms must be apparent, made inferences unsupported by the record, and arbitrarily disregarded record evidence. See id. at 1383-85. Accordingly, the Circuit affirmed this court's decision granting petitioner's motion for review and vacating the special master's decision to deny compensation. See id. at 1386.

In reviewing the present case, the Federal Circuit first noted the similarities between this case and its decision in Paluck: "Like this case, Paluck involved a child with a mitochondrial disorder. And, as in this case, the evidence in Paluck showed that vaccines can activate the immune system, which in an individual with mitochondrial disease can result in oxidative stress that can, in turn, cause progressive neurological deterioration over time." Sanchez, 809 F. App'x at 851. The Circuit, however, concluded that there were sufficient differences between this case and Paluck, that Paluck alone did not address all of the issues at bar. Id. Specifically, the Circuit noted that: "In this case, unlike in Paluck, the special master did not adopt a strict time limit or a requirement of 'linearity' for the manifestation of signs of Trystan's neurological regression. . . . Nor did the special master draw the improper inferences noted by this court in Paluck or disregard medical evidence or the observations of the treating physicians." Id.

2. Causation Analysis

The Federal Circuit next addressed petitioners' arguments related to the special master's causation analysis. Id. at 852. Specifically, petitioners argued that Trystan's fever and inconsolable crying following his February 5, 2009 vaccinations, along with his arm contortions eleven days later, on February 16, 2009, are evidence that Trystan "had suffered an adverse neurological event." Id. In his original entitlement decision, the special master rejected this argument, concluding that Trystan's symptoms on February 16, 2009 were typical cold symptoms. See id. The Circuit explained petitioners' argument on appeal as follows:

> The petitioners do not challenge the finding that Trystan was suffering from a cold, but they contend that the evidence shows that he was also suffering

> from a neurological injury at that time. In particular, the petitioners dispute the special master's finding that Trystan's symptoms—his arm contortions in particular—were symptoms of a cold. That finding, they contend, is wholly lacking in record support.

Id.

In this regard, the Circuit identified a discrepancy between the facts included in the special master's Ruling Finding Facts and the published entitlement decision:

> In his 2013 Ruling Finding Facts, the special master found that although Trystan "kept kicking his feet and jerking around" in his father's arms on that evening, he "did not begin to exhibit arm contortions" at that time, and he "did not exhibit arm contortions" between that time and the time Ms. Sanchez took him to the doctor in late April 2009. In the 2018 Published Decision Denying Compensation, however, the special master found that on that evening, Trystan's "arms contorted and he was jerking around."

Id. Given the centrality of this fact to petitioner's theory of causation, the Circuit found that the contradiction between the two documents was "significant." Id.

In the 2013 Ruling Finding Facts, the special master noted that: "The parties are ordered to provide this ruling to any expert they retain. If the expert's opinion is not consistent with these findings of fact, the opinion is likely to not be persuasive." ECF No. 45 at 16. The Federal Circuit noted that defendant's experts relied on the 2013 Rulings Finding Fact, and "did not have before them the special master's later finding that Trystan's arm contortions began as early as February 16." Sanchez, 809 F. App'x at 852. In addition, the Circuit noted, if the special master changed his view of the date on which Trystan's arm contortions began based on his father's testimony, that could lend credence to Dr. Steinman's opinion. See id. at 852-53. For these reasons, the Circuit found it "necessary to remand for further consideration of the causation issue in light of the special master's findings in 2018 regarding Trystan's arm contortions." Id. at 853.

The Federal Circuit also concluded that, in his causation analysis, the special master did not carefully delineate between the second and third Althen factors, and directed the special master to do so on remand. See id. The Circuit explained that:

> it is important for the special master to make explicit findings as to two separate issues: (1) whether there was a logical sequence of cause and effect linking Trystan's vaccinations and his injuries as well as a proximate temporal relationship between the vaccinations and the onset of the injuries; and (2) whether Trystan's infections between February and May of 2009 caused the manifestation of his Leigh's syndrome, independent of his vaccinations.

Id. If, however, "the special master finds that the petitioners have not met their burden as to the first issue, it is unnecessary for the special master to address the second issue." Id.

3. Challenge-Rechallenge

Next, the Federal Circuit held that the special master failed to fully consider petitioners' challenge-rechallenge theory, which is a "theory of causation . . . that the combined effect of the February and August vaccinations caused or aggravated Trystan's condition." Id. at 854. The special master focused on the findings in the 2013 Ruling Finding Facts, but did not account for petitioners' expert testimony offered after that ruling was made, which focused on the challenge-rechallenge theory. See id.

The Circuit also found that the medical records from August 17, 2009, the date on which Trystan received his second round of vaccinations, and October 7, 2009, the date on which he was seen for a follow-up visit, may indicate some "loss of skills during [that] period." Id. It was, therefore, an error for the special master to not explicitly address the challenge-rechallenge theory. Id.

4. Whether Trystan's Leigh's Syndrome Would Have Been the Same Regardless of the Vaccinations

Finally, the Federal Circuit held that "it may be necessary for the special master to address . . . whether [respondent] showed, because of Trystan's mutations, the timing and severity of his Leigh's syndrome would have been the same, regardless of the effect of the vaccinations." Id. The Circuit noted that the science on this point "has been developing rapidly," and suggested that "the special master on remand may wish to give the parties an opportunity to supplement the record with any relevant medical research or reports postdating the hearing held by the special master two and one-half years ago." Id.

B. The Special Master's Decision on Remand

Following the Federal Circuit's opinion remanding the case, the special master accepted supplemental expert and status reports from the parties, and held a hearing on July 9, 2020, during which the parties' experts testified. See ECF No. 245 (transcript of hearing).

On August 26, 2020, the special master issued a lengthy new entitlement decision taking into account the Federal Circuit's opinion. See ECF No. 253. After recounting the factual and procedural background of this case, and discussing the qualifications of the parties' experts, the special master addressed the petitioners' burden under the test set forth by the Federal Circuit in Althen. See id. at 1-31. As noted above, petitioners bear the burden of proving, by a preponderance of the evidence, that "the vaccination brought

about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury."[6] Althen, 418 F.3d at 1278.

1. First Althen Factor

The special master found, as he had in his first entitlement decision, that petitioners met their burden to prove a "medical theory causally connecting the vaccination and the injury." Id. (citations omitted); ECF No. 253 at 31-34; see also ECF No. 205. He also noted that on appeal, despite the fact that respondent argued in a footnote that the special master had committed a harmless error with regard to the first Althen factor, the parties did not address the matter fully before the Federal Circuit. See ECF No. 253 at 32. And, the special master understood the Federal Circuit to "endorse the theory that vaccines can cause fever and fever can cause neurodegeneration based upon its opinion in Paluck." Id.

Furthermore, the special master reasoned, the law of the case doctrine "precludes relitigation of issues explicitly or implicitly decided on appeal." Id. at 33-34 (citing Travelers Ins. Co. v. United States, 72 Fed. Cl. 316, 325 (2006) ("The doctrine [of the law of the case], of course does not constrain a trial court's consideration of an issue that has not been considered on appeal. . . . But the doctrine extends to issues that were implicitly addressed."); and Am. Satellite Co. v. United States, 34 Fed. Cl. 468, 480 (1995) (quotation omitted)). Here, because respondent raised the issue of a harmless error with regard to the first Althen factor on appeal, and the Federal Circuit did not direct the special master to reconsider his findings, the special master declined to do so. See id. at 34.

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[6] After a lengthy discussion of causation under Althen, the special master addressed an alternative theory under which he also found that petitioners were not entitled to compensation. See ECF No. 253 at 80-97. Respondent argued, and the special master agreed, that Trystan's genetic mutations "constitute the sole substantial cause of [his] Leigh's syndrome." Id. at 81. The special master considered this question in response to the Federal Circuit's comment in its decision remanding this case for further proceedings that "it may be necessary for the special master to address . . . whether the Secretary showed, because of Trystan's mutations, the timing and severity of his Leigh's syndrome would have been the same, regardless of the effect of the vaccinations." Sanchez v. Sec'y of Health & Hum. Servs., 809 F. App'x 843, 854 (Fed. Cir. 2020); see also ECF No. 253 at 20 (special master noting the Federal Circuit's invitation to consider this issue further). Because the court agrees with the special master that petitioners have not met their burden to prove causation under Althen, the special master's decision on this alternative theory is unnecessary to sustain his entitlement decision. Accordingly, the court declines to review the strength of the scientific data bearing on the likely manifestation of Trystan's Leigh's syndrome absent administration of the vaccines.

"Accordingly, the finding in the October 9, 2018 decision remains undisturbed. The theory that the DTaP vaccine can cause neurodegeneration, potentially through the intermediate step of a fever, is sound and reliable under prong 1." Id.

2. Second Althen Factor

The second factor, and most complicated part of the Althen analysis in this case, required the special master to evaluate whether petitioners had shown, by a preponderance of the evidence, "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. In this section, the special master addressed the timing of the onset of Trystan's neurodegeneration, and drew conclusions as to what that timing indicates about the causal relationship between the vaccinations and Trystan's injury. See ECF No. 253 at 38-80.

According to petitioners, "Trystan's response to the vaccine changed his life." Id. at 41. Petitioner's expert Dr. Steinman testified at the post-remand hearing that after the vaccinations, "Trystan started a 'downward cascade,'" and experienced a continuous process of neurodegeneration and loss of skill from that point. Id. And Dr. Niyazov offered his opinion that Trystan's "'developmental regression was slowly developing ever since the crying and fever took place as a result of the vaccination.'" Id. (quoting Dr. Niyazov's expert report, ECF No. 127-1 at 8).

After reviewing a series of previously-decided vaccine cases that petitioners argue militate in favor of compensation, see id. at 42-46, the special master reviewed Trystan's medical history between February 5, 2009—the date on which he received the vaccine—and December 2009, see id. at 46-75, and gave particular attention to the notes made by Trystan's treating physicians, see id. at 75-80.

a. Trystan's Neurodegeneration

i. February 5, 2009

According to the special master, Trystan's pediatrician, Dr. Philip Brown, found Trystan's "growth and development to be normal" at his six-month well-visit. Id. at 46. Dr. Brown specifically found that Trystan was meeting the following developmental milestones: "turning to sound, self-feeding, self-comforting, responding to his name, sitting with support, grasping and mouthing objects, smiling, laughing, squealing, showing interest in toys, showing differential recognition of parents, babbling reciprocally, rolling over from back to front, and standing when placed." Id. at 46-47. He also noted that Trystan had "no head lag when pulled to sit." Id. at 47. At the visit, Trystan received the DTaP, hepatitis B, Haemophilus influenzae type B, inactivated polio, and pneumococcal conjugate vaccines. See id.

After the wellness visit, Trystan cried inconsolably, developed a fever that ebbed and flowed for several days, and developed a lump on his left thigh. See id. The special master found that, of these three facts, the inconsolable crying was the "most important," because it "can be a manifestation of an encephalopathy or injury to the nervous system." Id. In support of this conclusion, the special master cited to testimony from both petitioners' and respondent's experts—Dr. Steinman, Dr. Niyazov, and Dr. Raymond, as well as a previously decided vaccine case, Estep v. Secretary of Health & Human Services, No. 90-1062V, 1992 WL 357811, at *3 (Fed. Cl. Spec. Mstr. Nov. 3, 1992), mot. for rev. denied, 28 Fed. Cl. 664 (1993). See id. The special master also concluded, however, that inconsolable crying is not necessarily a sign of injury, it could also be an expression of discomfort or pain. See id. at 47-48. Respondent's experts Dr. McGeady and Dr. Raymond testified that Trystan's crying was the latter. See id. at 48.

The special master further concluded that "the presence of a fever is non-specific" due to broad agreement that vaccines can cause an elevated temperature as part of a normal response. Id. None of the experts expressed any unusual concern about the lump on Trystan's thigh. See id. at 48-49.

In the special master's view, petitioners and their experts "appear to place undue weight on Trystan's health on February 5-7, 2009. They seem to reason that because inconsolable crying can be a manifestation of an encephalopathy or injury to the nervous system, Trystan must have suffered a neurological injury." Id. at 49. Considering the evidence as a whole, however, "Trystan's health could be entirely compatible with an expected response to the vaccination given in the morning of February 5, 2009." Id.

ii. February 16-17, 2009

Trystan again developed a fever, along with congestion, on February 15, 2009. See id. at 54. Around midnight on February 16, 2009, Trystan's fever increased, and he began to cry very loudly. See id. Mr. Sanchez attempted to calm Trystan, but he "startle[d] awake like he could not breathe through his stuffy nose." Id. at 54-55. Mr. Sanchez testified that when he was trying to calm Trystan, "'he kept kicking his feet and jerking around'" in his arms, "'almost as if he didn't want to be held.'" Id. at 55. Petitioners did not take Trystan to the urgent care that night because after they gave him some fever reducing medication, Trystan fell asleep. See id.

The next morning, February 17, 2009, Trystan was examined by a physician's assistant Mr. Luna, and was diagnosed with a "'[c]ommon cold,'" and "'[v]iral syndrome,'" and his fever was noted. Id. Mr. Luna's notes, however, "do not indicate that Ms. Sanchez told Mr. Luna anything about Trystan exhibiting unusual arm movements or other signs of a neurological condition." Id.

The parties' experts presented opposing theories about Trystan's symptoms, which included "high-pitched cry[ing], fever, congestion, startling awake, jerking around, and arm contortions." Id. Dr. Steinman first opined that Trystan had experienced a seizure, and later identified the reaction as dystonia. See id. Both Dr. Steinman and Dr. Niyazov believe Trystan's reaction was evidence of "an episode of neurodegeneration." Id. The special master noted that "[i]n contrast, in the December 2017 hearing, Dr. Raymond maintained that these conditions (except for the arm contortions) reflected a common cold." Id.

Considering the foregoing, the special master concluded that the evidence shows that Trystan was suffering from a common cold or upper respiratory infection, from which he recovered. See id. at 55-56. The special master found Dr. Steinman's and Dr. Niyazov's "skepticism over such a basic point" reduced their credibility. Id. at 56. He also found that the evidence indicated that Trystan's February 15, 2009 fever was different from his February 5, 2009 fever—and that there was no demonstrated connection between the second fever and the vaccinations. See id.

The special master then noted that "[b]eyond the fever and congestion that are part of a common cold, Trystan also cried, startled awake, jerked around in his father's arms, and, most importantly for this remand decision, contorted his arms. These behaviors are the foundations for Dr. Steinman's opinion that Trystan suffered a seizure or dystonia." Id. Dr. Steinman's credibility, however, was compromised by the fact that his opinion evolved over time. See id.

Dr. Steinman first suggested, based on Mr. Sanchez's account of Trystan's behavior on the night of February 16, 2009, that Trystan had suffered a seizure. See id. During the December 2017 hearing, Dr. Steinman acknowledged that a seizure could only be diagnosed conclusively by an electroencephalogram (EEG), and that in the absence of an EEG "we're not very good at guessing." See id. at 56-57. In light of this weakness in his theory, Dr. Steinman then opined that "Trystan's arm contortions were dystonic posturing." Id. at 57. Notably, the special master stated that Dr. Steinman's new opinion on dystonia was also based on Mr. Sanchez's account of Trystan's behavior on the night of February 16, 2009. See id. At the time that the special master issued his post-remand decision, Dr. Steinman was of the opinion that Trystan suffered from both dystonia and seizures. See id. at 58.

The special master found Dr. Steinman's opinion unpersuasive for four reasons. First, as Dr. Steinman himself acknowledged, seizure activity cannot be confidently diagnosed absent an EEG, a test that was not performed on Trystan in mid-February 2009. See id. Second, when Trystan did develop seizures, they "involved deviation of

his head and eye, an altered consciousness, and a postictal period."[7] Id. Based on the difference in presentation and passage of time before confirmed seizures, the special master concluded that petitioners had not demonstrated a pattern of seizures beginning in February 2009. See id. Third, respondent's expert disagreed with Dr. Steinman that Trystan had suffered seizures. See id. And fourth, while the records from Trystan's treating physician, Dr. Haas, include a note about arm contortions, that note was made on August 7, 2012, and was apparently a record of the narrative from Ms. Sanchez about Trystan's condition following the vaccinations. See id. Dr. Haas "did not assess the arm contortions as indicative of a seizure or neurological issues." Id. For these reasons, the special master found that petitioners had not "established with preponderant evidence that Trystan suffered a seizure on February 16, 2009." Id. at 59.

Having rejected petitioners' theory that Trystan suffered a seizure on February 16, 2009, the special master then turned to the issue of whether Trystan had suffered dystonia, which he defined as "'dyskinetic movements due to disordered tonicity of muscle.'" Id. He further explained that the term dyskinetic comes from the root word dyskinesia, which means "'distortion or impairment of voluntary movement, as in tic, spasm, or myoclonus.'" Id. Dystonia originates in the basal ganglia, and "can be a manifestation of many neurologic disorders,'" including Leigh's syndrome. Id. Based on expert testimony and medical journal arguments, the special master concluded that "[t]he cumulative probability of having an onset of Leigh's syndrome with dystonia at six months is approximately five percent." Id.

Dr. Steinman and Dr. Raymond disagreed as to whether a six-month old was likely to manifest dystonia by moving his arm behind his back, and Mr. Sanchez testified Trystan had done on the night of February 16, 2009. See id. at 4, 60. According to Dr. Raymond, six-month-old children would not have myelination progression sufficient to allow such movement. See id. at 60. Dr. Steinman emphasized the progressive nature of myelination, and believed dystonia was possible at six months of age. See id. The special master noted that "[a]s an abstract question whether six-month-old infants are sufficiently myelinated to experience dystonia by moving their arms backward is difficult to answer on this case's evidentiary record." Id. He concluded, however, that Dr. Raymond's fellowship in developmental neuropathology qualified him better to answer the question than Dr. Steinman's fellowship in chemical immunology. See id. at 60-61. "This difference in advanced specialization would break any tie in Dr. Raymond's favor." Id. at 61.

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[7] In the citations accompanying this sentence, the special master includes a reference to "Exhibit 138 at 99 (Dr. Wong's Dec. 7, 2010 report)." This citation appears to include a typographical error, as it is a reference to Dr. Nicole M. Antonio's July 12, 2016 report, which appears at ECF No. 166-2, which is Exhibit 138 at 99-103. Dr. Valarie Wong's December 7, 2010 report appears at ECF No. 116-2 at 9-11, which is Exhibit 138 at 9-11.

With regard to Trystan's case specifically, Dr. Raymond opined that if he had experienced dystonia on February 16, 2009, it would have been "persistent and obvious," while Dr. Steinman asserted that dystonia could be "intermittent." Id. Dr. Steinman, however, "could not specify how frequently even 'intermittent' dystonia appears." Id. The special master found the contention that "Trystan could have dystonia in February but not again for many months" unpersuasive. Id. Based on the foregoing, the special master concluded that petitioners "have not shown by preponderant evidence that Trystan's February 16, 2009 arm contortions were a manifestation of a seizure or an episode of dystonia," and that the "arm contortions do not constitute a neurologic abnormality caused by his vaccination." Id. at 62.

iii. End of February to Beginning of April 2009

After the February 17, 2009 visit with Mr. Luna, Trystan did not see a medical provider again until April 29, 2009. See id. In the 2013 Ruling Finding Facts, the special master found, and repeated in his post-remand entitlement decision, as follows:

> 12. Sometime [after February 17, 2009], Trystan's extended family gathered to watch a boxing match. During this gathering, Trystan was sick, crying, fussy, and congested. He was not contorting his arms nor was he limp or rigid.
>
> 13. Between [Ms. Sanchez]'s birthday and the next time she took him to the doctor nearly two months later in late April, Trystan suffered from cough and congestion episodically. During this time, he did not lose control of his head and trunk, nor did he stop making eye contact or stop wanting to play anymore. He did not exhibit arm contortions.

Id. at 63 (quoting ECF No. 45 at 13) (citations omitted). He also characterized these facts as "not contested." Id. Neither of petitioners' experts could identify facts to the contrary, but noted that it was possible for parents to miss signs of delayed development in such a young child. See id. at 63-64.

Petitioners' experts also argued that Trystan experienced a fade response, a phenomenon written about by Dr. Bob Naviaux in an article called Commentary on, Fever Plus Mitochondrial Disease Could Be Risk Factors for Autistic Regression by Shoffner et al. See id. at 64. Dr. Niyazov, who relied on the article, could not say whether the article was peer-reviewed, but relayed his personal confidence in Dr. Naviaux. See id. The special master also noted that the article addressed children with autism, not Leigh's syndrome. See id. In the article, Dr. Naviaux describes children with mitochondrial disease who suffer a fade response when they regress. See id. When a child experiences a fade response, which can occur between two and ten days after a

fever, "'their consciousness fades,'" and the "'child can become difficult to fully awaken, or will stop walking, stop talking, stiffen or lose muscle tone, or have a seizure, or a stroke-like episode.'" Id.

The special master found, however, that there was "not preponderant evidence that Trystan experienced a fade." Id. at 65. According to the special master, "[t]here is no evidence that in the months after his February 5, 2009 vaccination, Trystan began to lose consciousness or was difficult to awaken. In contrast, the [2013] Ruling Finding Facts found that Trystan continued to play." Id. And the episode of arm contortions experienced by Trystan on February 16, 2009 was "short-lived, singular, and did not signify a neurologic injury due to vaccination." Id. On this basis, the special master found that the Naviaux article was "inapt," id., and found Trystan's case to be materially different from the caselaw offered as analogous by petitioners, see id. at 65-66.

iv. April to May 2009

Based on the medical records presented in this case, the special master found that Trystan had "relatively good health" from the end of February 2009 to mid-April 2009. Id. at 67. On April 29, 2009, however, Trystan was diagnosed with an ear infection and bronchitis by Dr. Seleem, who noted that Trystan had been suffering from a cough and congestion for about two weeks. See id. At that time, Dr. Saleem noted "'[n]o neurological symptoms.'" Id. Trystan was next seen by Dr. Brown on May 13, 2009, at which time his ear infection was clearing. See id. The doctor's notes include no concern about loss of eye contact or ability to roll over. See id.

In presenting their theories, petitioners' experts "largely ignored the visits with Dr. Seleem and Dr. Brown." Id. at 68. A fact that, the special master reasoned, is "inconsistent with [Dr. Steinman's] later testimony that 'infections . . . can devastate or kill' children with mitochondrial diseases." Id. After the special master questioned Dr. Steinman on this point, Dr. Steinman opined that Trystan's late-April, early-May illness did not contribute to his neurological decline because he did not have a fever. See id. at 68-69. Dr. Niyazov, for his part, indicated that such illness could contribute to Trystan's decline, but maintained his theory that Trystan's decline began on February 5, 2009. See id. at 69. The special master did not credit this theory: "The flaw . . . is that . . . [petitioners] have not presented persuasive evidence that Trystan's decline started on February 5, 2009." Id.

v. August 2009

On August 8, 2009, Trystan cried inconsolably. See id. at 70. At some points of the day, his body was limp; at others, he contorted his arms. See id. On August 17, 2009, Trystan was seen by physician's assistant Ms. Marin-Tucker for his one-year well-visit. See id. at 69, 70. At that visit, Ms. Sanchez reported to Ms. Marin-Tucker, that she

"'noticed a change in [Trystan's] development about 2-3 months ago but since she had taken [Trystan to the pediatric clinic] with Dr. Brown she thought that everything was ok.'" Id. at 70 (citations omitted). Ms. Sanchez contradicted these notes when she testified more than two years later that she had actually reported that Trystan's developmental changes began five to six months prior to the visit with Ms. Marin-Tucker.[8] See id. at 70 n.39.

During the visit, Ms. Marin-Tucker found that "Trystan did not walk, stand, crawl, and hold his head up while sitting, or make any attempt to move his lower extremities. She also noted in her examination that his extremities seemed soft, yet rigid at times." Id. at 71. Ms. Marin-Tucker referred Trystan to a neurologist, physical therapist, and occupational therapist, and administered his second doses of the pneumococcal conjugate, DTaP, and Hib vaccines, with directions to return the following week for the measles, mumps, rubella, varicella, and hepatitis A vaccines. See id.

According to the special master, Trystan's presentation at the August 17, 2009 well-visit was consistent both with Dr. Raymond's explanation that "problems originating in the basal ganglia would present . . . first with hypotonia and later with dystonia," and with Dr. Naviaux's fade response theory. Id.

vi. October to December 2009

Petitioners took Trystan for a follow-up visit with Ms. Marin-Tucker on October 7, 2009. See id. at 72. "Ms. Marin-Tucker noted no seizures, weakness, or tics," and "made no notation of tremors or twitching." Id. at 72. She did find, however, that Trystan was "unable to grasp, sit, crawl, or make much eye contact." Id.

Dr. Steinman interpreted this report as evidence that Trystan's neurological condition had further deteriorated—a conclusion the special master found to be reasonable. See id. Due to this decline, the special master evaluated whether Trystan had experienced a challenge-rechallenge reaction. See id. "A rechallenge event occurs when a patient who had an adverse reaction to a vaccine suffers worsened symptoms after an additional injection of the vaccine." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1322 (Fed. Cir. 2006). In addition, according to Dr. Raymond, "'[t]he challenge should meet the criteria of same latency and same effects, and must exclude well-accepted alternative explanations.'" ECF No. 253 at 72.

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[8] The special master noted that Ms. Marin-Tucker's report that Ms. Sanchez had noticed changes in Trystan's development two to three months before his August 17, 2009 well-visit—between May 17, 2009 and June 17, 2009—suggests a logical connection between his late-April, early-May illness and his decline. See id. at 69-70. This timeline fits more neatly with the theories advanced by the medical literature that decline would occur within about two weeks of the inciting event. See id. at 70.

Petitioners contested Dr. Raymond's additional criteria, but the special master ultimately decided that the nuance was immaterial because petitioners "have not established the challenge aspect" of the challenge-rechallenge theory because they "have not presented preponderant evidence that Trystan suffered any neurologic problem within at least one month of the February 5, 2009 vaccine." Id. at 73. He concluded that, "by simple definition, without a 'challenge,' there can be no 'rechallenge.'" Id. Moreover, the reactions Trystan displayed after each set of vaccinations were not sufficiently similar. See id.

The special master stated his conclusion with regard to the second Althen factor, as follows:

> In sum, this section . . . has considered both how [petitioners'] experts predicted an adverse reaction to the vaccination would appear and how Trystan actually appeared. Because of the dichotomy between the predicted and the actual, the sequence of events is not logical. Thus, [petitioners] have not met their burden regarding prong 2.

Id. at 75.

vii. Treating Doctors

As part of his analysis of the second Althen factor, and in accord with the Federal Circuit's directive, the special master took particular note of the information available from Trystan's treating physicians. See id. (citing Capizzano, 440 F.3d at 1326). He concluded, however, that petitioners "overstate the significance of these reports." Id. He summarized the basis for his conclusions for each of four treating physicians.

First, in 2010 and 2011, Dr. Jennifer Friedman raised the possibility that Trystan may have acute disseminated encephalomyelitis (ADEM), which could be related to a vaccination. See id. The special master discounted this opinion because Trystan suffers from Leigh's syndrome, not ADEM. See id.

Second, Dr. Akhil Sharma's notes included, on October 2, 2013—and again on June 26, 2015—a conclusion that Trystan had a "'probable vaccine induced injury.'" Id. at 76. This conclusion, however, was based not on Dr. Sharma's evaluation, but on Ms. Sanchez's recitation of Trystan's history. See id. For this reason, the special master concluded that "Dr. Sharma's reports carry little persuasive value." Id.

Third, Dr. Haas, who first saw Trystan on August 7, 2012, recorded Trystan's medical history as recited by petitioners, much like Dr. Sharma. See id. In those notes, he stated: "Trystan is a 4 year old boy who had acute onset regression and dystonia at 6 months of age, following vaccination, which repeated with the next set of vaccines at 12 months." Id. at 77. The special master first notes that Dr. Haas' observation that Trystan

experienced symptoms "following vaccination" is a "recitation of a chronological sequence of events [and] is not the same as an opinion regarding causation." Id. at 78. Moreover, these statements pre-date Trystan's Leigh's syndrome diagnosis. See id. After the diagnosis was made, Dr. Haas wrote a letter in which he stated: "Trystan Evan Sanchez has a mitochondrial disease caused by Complex II deficiency of the respiratory chain. This is a genetic disease causing in Trystan dystonia, developmental delay, encephalopathy, neuromuscular disease[, and an] abnormal MRI." Id. In the letter, Dr. Haas did not link Trystan's condition to the vaccinations. See id. Finally, the special master considered Dr. Haas' statement that due to his Leigh's syndrome, "'it is medically acceptable for [Trystan] to avoid immunizations.'" Id. The special master concluded that "a recommendation to avoid vaccinations is not necessarily the same as a statement that a vaccine caused an injury." Id.

And fourth, Dr. Derek Wong saw Trystan on January 28, 2016. In recording Trystan's history, Dr. Wong quoted from Dr. Haas' notes and documented Ms. Sanchez's recollection of Trystan's developmental delays. See id. at 79. Dr. Wong acknowledged Trystan's Leigh's syndrome diagnosis, and noted that his "manifestations include developmental regression, following vaccines and/or viral syndrome." Id. at 80. In the special master's view, "Dr. Wong's record provides little assistance to [petitioners]" because "[a]t best . . . Dr. Wong recognizes a temporal sequence in which Trystan's developmental regression 'follow[ed] vaccines and/or viral syndrome.'" Id.

To summarize his findings based on the treating physician's reports, the special master stated:

> In summary, the records from four doctors who treated Trystan do not help [petitioners] meet their burden of showing that the DTaP vaccination contributed to Trystan's Leigh's syndrome. Dr. Friedman presented her opinion before Trystan's Leigh's syndrome was diagnosed after genetic studies. Dr. Sharma and Dr. Haas obtained histories that are not entirely accurate. Even so, Dr. Sharma, Dr. Haas, and Dr. Wong appear to present temporal sequences. Accordingly, while these reports have been considered, they do not constitute persuasive evidence for [petitioners].

Id.

3. Third Althen Factor

In his analysis of the third Althen factor, the special master explained that the inquiry has two parts. See id. at 34. "[T]he proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." Id. (quoting de Bazan, 539 F.3d at 1352). In other

words, "[a] petitioner must show the 'timeframe for which it is medically acceptable to infer causation' and that the onset of the disease occurred in this period." Id. (quoting Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op. 503 F. App'x 952 (Fed. Cir. 2013)). The parties dispute both parts of the third Althen factor.

With regard to the appropriate timeframe for inferring causation, the special master reviewed a series of medical journal articles in his first entitlement decision, which he concluded were not comprehensive, but "suggested that neurodegeneration would occur within approximately two weeks." Id. at 35. The special master also noted, however, that on the basis of the Federal Circuit's decision in Paluck, 786 F.3d at 1383, he would not set a "hard and fast deadline." Id. Because the Federal Circuit did not "correct this approach" on appeal, the special master did not revise the approach on remand. Id. at 38.

The second part of the third factor required the special master to determine "whether [petitioners] presented persuasive evidence that Trystan began to suffer lasting neurologic problems within approximately two weeks of the vaccination." Id. He concluded that, based on his analysis of the second Althen factor, that petitioners had failed to carry this burden. See id.

Specifically, the special master found that within two weeks of his February 5, 2009 vaccinations, Trystan "experience[d] two episodes"—the "fever, inconsolable crying and a mark on his leg" the night after receiving the vaccinations, and "fever, congestion, restlessness, jerking around, and arm contortions" eleven days later. Id. at 66. The special master concluded, however, that the two episodes lacked context to suggest they were "behaviors that suggested any neurologic problems from February 17, 2009, to at least May 1, 2009." Id. Accordingly, the special master held that Trystan's neurologic problems began "well beyond the approximate two-week onset of symptoms anticipated by [petitioners'] medical theory," and as such, petitioners had failed to carry their burden with regard to the third Althen factor.[9] Id. at 66-67.

C. Motion for Review

Petitioners' motion for review now before the court proceeds in four parts. First, petitioners allege that the special master went beyond the Federal Circuit's mandate on remand by considering additional evidence and expert testimony with regard to Trystan's

[9] The special master noted in his decision that "[t]o be clear, in determining that [petitioners] have not met their burden regarding prong 3, [he did] not consider[] the effect of the colds for which Trystan was treated on April 29, 2009 and May 13, 2009." ECF No. 253 at 67 n.37.

arm contortions, and relied on an "unfounded newly created fact" as a result. ECF No. 260 at 27, 24-42. Second, petitioners argue that the special master arbitrarily and capriciously failed to consider the record as a whole in determining whether petitioners carried their burden to prove causation, including with regard to their challenge-rechallenge theory. See id. at 42-51. Third, petitioners argue that the special master arbitrarily and capriciously failed to consider the record as a whole in concluding that the infections Trystan suffered between February and May 2009 caused his Leigh's syndrome to manifest independent of the vaccines. See id. at 51-54. And finally, petitioners argue that the special master's decision that Trystan's Leigh's syndrome was the sole and substantial cause of his neurological condition was arbitrary and capricious because he relied on only one reference. See id. at 54-74.

The court will only review the first two of petitioners' four arguments. As the court has previously explained, in reviewing the initial entitlement decision in this case, the Federal Circuit concluded that, in his causation analysis, the special master did not carefully delineate between the second and third Althen factors, and directed the special master to do so on remand. See Sanchez, 809 F. App'x at 853. The Circuit explained that:

> it is important for the special master to make explicit findings as to two separate issues: (1) whether there was a logical sequence of cause and effect linking Trystan's vaccinations and his injuries as well as a proximate temporal relationship between the vaccinations and the onset of the injuries; and (2) whether Trystan's infections between February and May of 2009 caused the manifestation of his Leigh's syndrome, independent of his vaccinations.

Id. If, however, "the special master finds that the petitioners have not met their burden as to the first issue, it is unnecessary for the special master to address the second issue." Id. In the post-remand entitlement decision, the special master found that petitioners did not meet their burden on the first issue, and the court sustains that decision in this opinion. Accordingly, as the Federal Circuit explicitly stated, addressing the second issue is unnecessary.

The court will likewise refrain from review of the special master's determination that Trystan's genetic mutations "constitute the sole substantial cause of [his] Leigh's syndrome." ECF No. 253 at 81. The special master considered this question in response to the Federal Circuit's comment in its decision remanding this case for further proceedings that "it may be necessary for the special master to address . . . whether the Secretary showed, because of Trystan's mutations, the timing and severity of his Leigh's syndrome would have been the same, regardless of the effect of the vaccinations." Sanchez, 809 F. App'x at 855; see also ECF No. 253 at 20 (special master noting the Federal Circuit's invitation to consider this issue further). Because the court sustains the

special master's conclusion that petitioners have not met their burden to prove causation under Althen, the special master's decision on this alternative theory is unnecessary to sustain his entitlement decision. Accordingly, the court declines to review the strength of the scientific data bearing on the likely manifestation of Trystan's Leigh's syndrome absent administration of the vaccines.

1. Evidence and Testimony Regarding Trystan's Arm Contortions

a. Scope of the Mandate

As an initial matter, petitioners argue that the special master "went beyond the scope of the [m]andate by ordering additional expert reports and testimony on the issue of whether the arm contortions in February of 2009 were consistent with a cold." ECF No. 260 at 24. According to petitioners, the Federal Circuit wanted the special master "to address causation given his finding of the arm contortions on February 16, 2009 and given that the finding that it was consistent with a cold was unsupported." Id. (emphasis in original). Petitioners, therefore, ask the court to exclude "any new facts obtained from the expert reports filed post remand and/or at the Remand hearing on July 10, 2020." Id.

"The mandate rule provides that 'issues actually decided [on appeal]—those within the scope of the judgment appealed from, minus those explicitly reserved or remanded by the court—are foreclosed from further consideration'" Amado v. Microsoft Corp., 517 F.3d 1353, 1360 (Fed. Cir. 2008) (quoting Engel Indus., Inc. v. Lockformer Co., 166 F.3d 1379, 1383 (Fed. Cir. 1999)). "Unless remanded by [the appellate] court, all issues within the scope of the appealed judgment are deemed incorporated within the mandate and thus are precluded from further adjudication." Engel, 166 F.3d at 1383.

Petitioners fundamentally misunderstand the Federal Circuit's decision on this point. The relevant section of the opinion reads as follows:

> In support of their argument on causation, the petitioners point to testimony from their experts that Trystan's fever and inconsolable crying were evidence of the onset of neurodegeneration, and that Trystan's arm contortions on February 16, 2009, only 11 days after his vaccinations, were also indicative that he had suffered an adverse neurological event.
>
> The special master rejected that argument, in large part because he concluded that Trystan was diagnosed with a cold on February 17, and that his symptoms the night before were of the type typically displayed by infants suffering from a cold. The petitioners do not challenge the finding that Trystan was suffering from a cold, but they contend that the evidence shows that he was also suffering from a neurological injury at that time. In particular, the petitioners dispute the special master's finding that Trystan's

> symptoms—his arm contortions in particular—were symptoms of a cold. That finding, they contend, is wholly lacking in record support.
>
> Analyzing this issue is complicated by the manner in which the special master made factual findings relating to the events of February 16, 2009. In his 2013 Ruling Finding Facts, the special master found that although Trystan "kept kicking his feet and jerking around" in his father's arms on that evening, he "did not begin to exhibit arm contortions" at that time, and he "did not exhibit arm contortions" between that time and the time Ms. Sanchez took him to the doctor in late April 2009. In the 2018 Published Decision Denying Compensation, however, the special master found that on that evening, Trystan's "arms contorted and he was jerking around."
>
> That discrepancy is significant. The government's expert witnesses, testifying based on the special master's 2013 findings, said that the symptoms exhibited by Trystan on the night of February 16, 2009—inconsolable, high-pitched crying and "jerking around" in his father's arms—were consistent with a cold and were not indicative of a seizure. However, the government's witnesses did not have before them the special master's later finding that Trystan's arm contortions began as early as February 16. Moreover, if the special master's 2018 finding was based on the testimony of Trystan's father, it seems plausible that Mr. Sanchez's testimony—that Trystan repeatedly held his arm behind his back and kept returning it to that position—could be regarded as evidence of a seizure or dystonia, as the petitioners' expert Dr. Steinman testified. And a seizure or dystonia at that time, Dr. Steinman testified, "could be evidence of brain damage."
>
> Importantly, because of the change in the findings made with respect to the arm contortions, the special master's finding that Trystan's behavior on the night of February 16 was consistent with a cold is not supported by expert testimony that specifically addressed the arm contortions. Because this issue is of central importance to the causation analysis, it is necessary to remand for further consideration of the causation issue in light of the special master's findings in 2018 regarding Trystan's arm contortions.

Sanchez, 809 F. App'x at 852-53. Contrary to petitioner's assertion, the Federal Circuit did not find that the special master's conclusion that Trystan's arm contortions on February 16, 2009, were consistent with a cold to be definitively unsupported by the evidence. The court agrees with respondent's assertion that "the Federal Circuit made plain that the question remained open as to whether the arm contortions were evidence of a seizure, dystonia, or a cold, because respondents' experts had not been permitted, prior

to the special master's 2018 Decision, to offer testimony on this fact pattern." ECF No. 265 at 20-21 n.15.

Because the Circuit explicitly remanded this case for further consideration of causation as a result of the out-of-date information on which some experts based their opinions, the special master did not exceed the scope of the mandate by allowing the experts to supplement their opinions. See Amado, 517 F.3d at 1360. In the court's view, the special master's decision to consider further expert reports and testimony on the causation issue in light of the finding that Trystan contorted his arms on February 16, 2009, is a logical correction of the error identified by the Federal Circuit.

b. Frequency of Trystan's Arm Contortions

Petitioners next argue that the special master erred when he "failed to consider the record as a whole," and relied upon "a critical unfounded newly created fact" in reaching his decision. ECF No. 260 at 27. According to petitioners, the special master's conclusion that Trystan's arm contortions on February 16, 2009 "were a one-time event . . . . is without any evidentiary basis," and they insist that "the evidence is overwhelmingly at odds with this newly created finding." Id. at 28.

Petitioners assert that the "newly created fact permeates the entire Remand Decision," id. at 27, but the root of the objection appears to be the special master's conclusion that "Trystan did not display any neurologic problems for weeks after the February 16, 2009 incident," ECF No. 253 at 43. According to petitioners, the evidence shows that "Trystan suffered the arm contortions for at least a month and several times a day." ECF No. 260 at 34. They also suggest that had the special master properly considered the evidence, he would have concluded that it demonstrated "a progression of symptoms," indicating neurological injury. Id. at 34.

As an initial matter, the special master's post-remand decision does not say that Trystan's arm contortions were a "one-time event." That phrase, as used by petitioners, is misleading. The special master, in fact, found that "Trystan contorted his arm on February 16, 2009, [but] this isolated event was not a manifestation of a neurologic problem. For the relevant time after the February 5, 2009 vaccine, Trystan was developing normally." ECF No. 253 at 98 (emphasis added). In discussing Trystan's arm contortions as an isolated event, the special master was designating the event as isolated only within the relevant timeframe. Elsewhere in the opinion, the special master noted that Trystan did develop neurological problems, but found that those problems manifested "no sooner than May 1, 2009." Id. at 97; see also ECF No. 45 at 14 (noting in the 2013 Ruling Finding Facts that Trystan contorted his arms on August 8, 2009). Accordingly, to the extent that petitioners expand the inquiry beyond the relevant

timeframe—which they do not seriously contest in their motion for review[10]—the argument is immaterial to the special master's conclusions with regard to whether petitioners have carried their burden under Althen. See ECF No. 260 at 28 (noting, but not objecting to, the special master's conclusion that "he would again primarily look for evidence of neurologic decline within two weeks of the vaccination," but "if Trystan's neurologic decline were to occur slightly outside of two weeks, then [petitioners] could meet their burden regarding Althen prong three"); see also ECF No. 253 at 36 (noting that petitioners argued in post-remand briefing that "neurodegeneration would often occur within two weeks, possibly three weeks after the inciting event") (citing ECF No. 247 at 53-64).

A vast majority of petitioners' lengthy argument on this point invites the court to reweigh the evidence considered by the special master. See ECF No. 260 at 33-42. Such an exercise is not permitted by the scope of this court's review. 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, 663 F.3d at 1249. On review, "reversible error is 'extremely difficult to demonstrate' if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.'" Lampe, 219 F.3d at 1360 (quoting Hines, 940 F.2d at 1528). Accordingly, the court will restrict its analysis to whether petitioners have identified either any relevant evidence of record not considered by the special master or any implausible inferences drawn by the special master, and whether petitioners have demonstrated that the special master failed, in this case, to articulate a rational basis for his decision.

In support of their argument that the special master erred in finding that "Trystan did not display any neurologic problems for weeks after the February 16, 2009 incident," ECF No. 253 at 43, petitioners point to two categories of evidence—medical records and family testimony, see ECF No. 260 at 29-33.

Petitioners identify the following medical records as relevant to establishing the frequency of Trystan's arm contortions: (1) August 17, 2009 well-visit notes; (2) Dr.

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[10] The only reference to petitioners' disagreement with the special master's definition of the relevant time frame is in a footnote, in which petitioners state "[p]etitioners do not agree as previously outlined in their Federal Circuit appeal that onset symptoms must occur within two weeks of the vaccination. However, for purposes of this Motion for Review, the arm contortions did occur within approximately two weeks." ECF No. 260 at 50-51 n.21. This assertion is an insufficient basis for a substantive review of the relevant time frame, as determined by the special master. Petitioners must advance their relevant arguments at each stage of the proceedings, and the court cannot be charged with an obligation to review prior filings to discern which arguments petitioners are reasserting.

Michelson's November 12, 2009 notes; (3) December 24, 2009 pediatrician notes; (4) Dr. Katrina Dipple's May 10, 2010 notes; (5) Dr. Friedman's August 2, 2010 notes; and (6) Dr. Haas's August 7, 2012 notes. As outlined above, the special master explicitly considered and discussed four of these six reports. See e.g., ECF No. 253 at 8, 69-72 (discussing Ms. Marin-Tucker's August 17, 2009 notes); id. at 8-9, 74-75 (discussing Dr. Michelson's November 12, 2009 notes); id. at 8-9, 14, 74 (discussing Dr. Friedman's August 2, 2010 notes); id. at 10, 13, 58-59, 76-78 (discussing Dr. Haas's August 7, 2009 notes). Accordingly, any argument that the special master failed to consider this evidence is unfounded.

Moreover, it was not implausible for the special master to conclude that these notes failed to establish preponderant evidence that Trystan's arm contortions on February 16, 2009, were not an indication of neurological injury. Of these records, only two include notes that specifically indicate that Trystan's arm contortions happened repeatedly. Dr. Friedman's August 2, 2010 notes state that Trystan's episodes of arm contortions "would happen again intermittently, maybe 10 times a day, lasting a minute or two at a time," and "continued [with] high frequency for about a . . . month." ECF No. 6-5 at 24. And Dr. Haas' August 7, 2010 notes state that "11 days after [his six-month] vaccination, he had an episode of 'contortion' in the upper limbs," for "minutes at a time," and "continued [with] high frequency for about a . . . month." See ECF No. 48-1 at 1. In his entitlement decision, however, the special master specifically considered the notes made by Trystan's treating physicians, including both Dr. Friedman and Dr. Haas, but found them unpersuasive evidence for petitioners.

Dr. Friedman's notes were the source of some debate between the parties as early as 2014, and the special master specifically instructed the parties that their experts were not to rely on "Dr. Friedman's record for the basis of events in Trystan's life between February 2009 through November 2009." ECF No. 253 at 9 (citing ECF No. 63 at 2 (January 31, 2014 order)). The special master found Dr. Friedman's notes unreliable for the purpose of establishing Trystan's history prior to her August 2, 2010 examination because they were not a contemporaneous record of his condition, and instead were petitioners' "account of remote events in Trystan's life." Id. Indeed, just before the passage cited by petitioners, Dr. Friedman notes that Trystan "was accompanied to the visit today by his parents who provided the his[to]ry." ECF No. 6-5 at 24. The special master repeated his concern with the passage of time in the post-remand decision, and discounted the value of Dr. Haas' notes—which were made two years after Dr. Friedman's—for the same reason. See ECF No. 253 at 58, 74.

The final two medical records identified by petitioners as evidence contrary to the special master's findings are of no assistance to their case. Petitioners are correct that the December 24, 2009 pediatrician's note states as follows: "extremity contracted upper and lower extremities, spastic quadriplegia of all extremities." ECF No. 6-2 at 26. It also states: "Neurologic exam: normal for age." Id. And Dr. Dipple's May 10, 2010 notes

included the following assessment under "review of systems": "Neurologic: global developmental delay, abnormal movements, hypertonicity." Id. at 45. Even assuming that either doctor's note intended to record arm contortions, they appear to relate solely to Trystan's condition on the date of the exam and do not speak to his condition in the weeks following his February 5, 2009 vaccinations, nor do they speak to a pattern within the relevant time period.

Petitioners also object to what they claim was the special master's failure to fairly consider testimony from petitioners' family members about Trystan's condition with regard to the frequency of his arm contortions. See ECF No. 260 at 31-33. They include the following: (1) testimony about Trystan's condition at a family gathering in March 2009; (2) Ms. Sanchez's testimony with regard to Trystan's condition as reported at his April 2009 doctor's visit; (3) Mr. Sanchez's testimony about Trystan's condition at the time of his May 13, 2009 doctor's visit; (4) testimony about Trystan's condition the day of Ms. Sanchez's baby shower on August 8, 2009; and (5) Mr. Sanchez's testimony that Trystan continued to contort his arms prior to his April 2009 doctor's visit. See id.

As previously noted, petitioners acknowledge, but do not dispute, the special master's conclusion that "he would again primarily look for evidence of neurologic decline within two weeks of the vaccination," but "if Trystan's neurologic decline were to occur slightly outside of two weeks, then [petitioners] could meet their burden regarding Althen prong three." See ECF No. 260 at 28. After Trystan's visit with Mr. Luna on February 17, 2009, he was next seen by a medical provider on April 29, 2009, when he was diagnosed with an ear infection and bronchitis by Dr. Seleem. See ECF No. 253 at 67. Dr. Seleem reported "[n]o unusual arm movements or developmental issues," and "noted '[n]o neurological symptoms.'" Id. (citations omitted).

The court has reviewed the family testimony identified by petitioners, and has found several instances in which that testimony indicates that Trystan contorted his arms in the days following his February 17, 2009 appointment with Mr. Luna. See ECF No. 33 at 34-36 (Lupe Sanchez's testimony); 156 (Emma Fernandez's testimony); 189-90 (Germain Sanchez's testimony). This testimony was taken on May 15, 2012, prior to the special master's 2013 Ruling Finding Facts. See id. at 2.

In the special master's 2013 Ruling Finding Facts, he stated:

> 12. Sometime [after February 17, 2009], Trystan's extended family gathered to watch a boxing match. During this gathering, Trystan was sick, crying, fussy, and congested. He was not contorting his arms nor was he limp or rigid.
>
> 13. Between Jennifer's birthday and the next time she took him to the doctor nearly two months later in late April, Trystan suffered from cough and

> congestion episodically. During this time, he did not lose control of his head and trunk, nor did he stop making eye contact or stop wanting to play anymore. He did not exhibit arm contortions.

ECF No. 45 at 13 (citations omitted). The special master specifically relies on these findings in his post-remand decision, and characterizes "[t]hese facts [as] not contested." ECF No. 253 at 63. As such, the question before the court is whether the special master erred in relying on these findings of fact in rendering his post-remand decision without more explicitly explaining the basis on which he had previously reached these conclusions. The court finds that such reliance was not in error.

These factual findings were clearly part of the record well in advance of the Federal Circuit's review, having been issued on April 10, 2013. See ECF No. 45. The court further notes that Trystan's condition between February 17, 2009 and April 29, 2009 was the subject of much debate between the parties. The special master explains, in his post-remand decision, that the available medical records were at odds with the recollection of certain family members. See ECF No. 253 at 4-5. In an effort to resolve the factual dispute, the special master held a hearing on May 15, 2012, at which he heard testimony from five family members. See id. at 6-7. He then directed the parties to work through their factual disputes, and based in part on the parties' efforts, the special master issued his 2013 Ruling Finding Facts. See id. at 7. It, therefore, appears to the court that the special master not only invited the testimony from petitioners' family members, but went through a deliberate process of reaching factual findings considering the evidence before him.

Furthermore, in its decision remanding this case to the special master, the Federal Circuit specifically noted the conflict between the family's testimony and the medical records relating to Trystan's condition after the February 17, 2009 examination:

> Trystan suffered from coughing and congestion episodically for the next couple of months. Ms. Sanchez testified that during that period, Trystan continued to have arm contortions, sometimes several times a day. In addition, she testified that Trystan "started to lose control of his head," that his "trunk . . . was not as strong," that he "didn't have any eye contact," and that he "didn't want to play" anymore. Again, however, the special master did not credit Ms. Sanchez's testimony because it was not corroborated by medical reports.

Sanchez, 809 F. App'x at 846. Despite having discussed this factual dispute, the Circuit neither criticized the special master's conclusion, nor remanded the case for further consideration on this point. The Circuit's conclusion with regard to arm contortions related only to the need to clarify the causation analysis in light of the discrepancy in the record with regard to whether Trystan contorted his arms on the night of February 16,

2009. See id. at 852-53. Accordingly, because whether the special master failed to appropriately consider the family's testimony in making his 2013 factual findings was "within the scope of the judgment appealed from," but was not "explicitly reserved or remanded" by the Circuit, it is "foreclosed from further consideration" by this court. Amado, 517 F.3d at 1360.

For the foregoing reasons, the court finds that petitioners have not identified any relevant evidence of record that the special master failed to consider or any implausible inferences drawn by the special master with respect to whether Trystan contorted his arms in the weeks following February 16, 2009. In addition, the court finds that petitioners have not demonstrated that the special master failed to articulate a rational basis for his decision in this regard. The special master's decision on this issue, therefore, is sustained. See Lampe, 219 F.3d at 1360.

2. Petitioners' Failure to Prove Causation

In its remand decision, the Federal Circuit found that the special master improperly combined the analysis of the second and third Althen factors. See Sanchez, 809 F. App'x at 853. The Circuit directed the special master to consider "whether there was a logical sequence of cause and effect linking Trystan's vaccinations and his injuries as well as a proximate temporal relationship between the vaccinations and the onset of the injuries."[11] Id. As is reflected in the court's summary of the special master's post-remand entitlement decision, the special master reviewed the record in painstaking detail with regard to petitioners' proof of causation. In their motion for review, petitioners do not argue that the special master failed to comply with the mandate, but argue that he nevertheless committed reversible error in his analysis of the issues.

a. Second Althen Factor and the Challenge-Rechallenge Theory

The second Althen factor requires the special master to determine whether petitioners have demonstrated, by a preponderance of the evidence, "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. As the court summarized above, the special master considered at great length the issue of whether petitioners had met this burden. See ECF No. 253 at 38-50. He ultimately concluded as follows:

[11] The Federal Circuit also instructed that the special master should consider "whether Trystan's infections between February and May of 2009 caused the manifestation of his Leigh's syndrome, independent of his vaccinations," but only if petitioners meet their burden to show the requite logical sequence of cause and effect and proximate temporal relationship. Sanchez, 809 F. App'x at 853. Because the court sustains the special master's conclusion that petitioners did not make the initial showing, the second analysis is unnecessary.

> In sum, this section . . . has considered both how [petitioners'] experts predicted an adverse reaction to the vaccination would appear and how Trystan actually appeared. Because of the dichotomy between the predicted and the actual, the sequence of events is not logical. Thus, [petitioners] have not met their burden regarding prong 2.

Id. at 75.

In their motion for review, petitioners criticize the special master for finding flaws with Trystan's treating physicians' notations that the vaccine may have caused his injuries. See ECF No. 260 at 43. Petitioners claim that each of the doctors was "thinking about the vaccination as being the cause of Trystan's issues." Id. Even assuming this to be the case, the special master fully considered the records, and articulated a rational basis for discounting the notes that suggested that a vaccination caused Trystan's injuries. The court will not reweigh the evidence or review the special master's credibility determinations. Porter, 663 F.3d at 1249.

To summarize his findings based on the treating physician's reports, the special master stated:

> In summary, the records from four doctors who treated Trystan do not help [petitioners] meet their burden of showing that the DTaP vaccination contributed to Trystan's Leigh's syndrome. Dr. Friedman presented her opinion before Trystan's Leigh's syndrome was diagnosed after genetic studies. Dr. Sharma and Dr. Haas obtained histories that are not entirely accurate. Even so, Dr. Sharma, Dr. Haas, and Dr. Wong appear to present temporal sequences. Accordingly, while these reports have been considered, they do not constitute persuasive evidence for [petitioners].

ECF No. 253 at 80. The court finds this explanation, and the extensive discussion of each doctor's records that preceded it, see id. at 75-80, sufficient to survive this court's review.

Next, petitioners argue that the special master erred in finding that they did not meet their burden with regard to the second Althen factor because the "evidence shows that Trystan['s] response to the DTAP vaccine was consistent with the theories articulated." ECF No. 260 at 44 (emphasis in original). Specifically, petitioners contend that Trystan experienced symptoms that were "[c]onsistent with the vaccine package insert," such as "fever, inconsolable crying and fussiness within the time indicated," and that his condition thereafter was consistent with the medical theories articulated by their experts, Dr. Steinman and Dr. Niyazov. Id. Petitioners then claim that the special master did not consider all of the relevant evidence because he did not discuss the fact that

"Trystan did experience what one would expect based on Dr. Steinman's theories and Dr. Niyazov's theory." Id.

This argument is simply not supported by the record. The special master thoroughly discussed the competing medical theories over the course of dozens of pages in his post-remand decision. See ECF No. 253 at 41-75. The fact that his analysis was perhaps not organized in the way petitioners would have preferred, or did not reach the conclusion they would have favored, does not make it legally deficient.

Petitioners' final challenge to the special master's decision on the second Althen factor relates to their assertion of a challenge-rechallenge theory. See ECF No. 260 at 45-48. In the post-remand decision, the special master noted that "'[a] rechallenge event occurs when a patient who had an adverse reaction to a vaccine suffers worsened symptoms after an additional injection of the vaccine.'" ECF No. 253 at 72 (quoting Capizzano, 440 F.3d at 1322). He also noted Dr. Raymond's testimony that "'[t]he challenge should meet the criteria of same latency and same effects, and must exclude well-accepted alternative explanations.'" Id. And although the special master did not explicitly require that the challenge and rechallenge event be the same, he noted a long list of cases that tend to support Dr. Raymond's opinion, and notes that similarity between the events "would seem to contribute to the strength of the challenge-rechallenge paradigm."[12] Id. at 73.

Ultimately, the special master concluded as follows:

> Dwelling on the nuanced points of challenge-rechallenge seems unnecessary in this case. [Petitioners] have not established the challenge aspect. As explained above, [petitioners] have not presented preponderant evidence that Trystan suffered any neurologic problem within at least one month of the February 5, 2009 vaccine. And, by simple definition, without a "challenge," there can be no "rechallenge."

Id.

In the motion for review, petitioners do not contest that a challenge is necessary before a rechallenge can be established; instead, they insist that they have demonstrated a challenge event, and that the special master committed reversible error in finding

[12] In their motion for review, petitioners claim that the special master "impermissibly rais[es] the burden of proof" by requiring them to show that the rechallenge reaction and timing are "exactly the same" as the challenge reaction. ECF No. 260 at 47. The special master, however, was not so categorical. The court does not understand his statement that similarity in reaction and timing "would seem to contribute to the strength of the challenge-rechallenge paradigm," to raise petitioner's burden beyond a preponderant showing. ECF No. 253 at 73.

otherwise. See ECF No. 260 at 46-48. The primary basis for petitioners' argument on this point is their insistence that Trystan's arm contortions on February 16, 2009 were evidence of a neurologic injury.

Petitioners have identified no evidence of record that the special master failed to consider, nor any implausible inference that he made. See Lampe, 219 F.3d at 1360. Moreover, petitioners effectively ask the court to reweigh the evidence related to whether Trystan suffered a neurologic injury on February 5, 2009, and to judge the credibility of witnesses, two tasks that fall outside the scope of this court's review. Porter, 663 F.3d at 1242. For this reason, the court sustains the special master's conclusion that petitioners have not demonstrated a challenge-rechallenge injury.

b. Third Althen factor

The third Althen factor requires petitioners to prove, by preponderant evidence, "a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278. As the special master noted at the outset of his discussion of the third Althen factor in his post-remand decision:

> "[T]he proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). Thus, the third prong of Althen implicitly has two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and that the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013).

ECF No. 253 at 34.

In his initial entitlement decision, the special master found—based on a review of the available medical literature and caselaw—that the relevant time period for establishing Trystan's injury was approximately two weeks, but declined to set a hard deadline. He summarized this approach in the post-remand decision, as follows:

> While [the cited] cases suggest that sometimes the interval between the vaccination and the onset of symptoms is too long to support a finding of causation-in-fact, Paluck cautions against defining the limits too rigidly. With this guidance, the undersigned attempted to point out that the evidence, imperfect as it might be, seemed to coalesce around a finding that two weeks

> from vaccination to the onset of neurologic decline is an interval that would support a finding of causation. Decision at 25, 2018 WL 5856556, at *15. Yet, at the same time, the undersigned tried to balance what the evidence showed with Paluck's recognition that more studies would be helpful. Cf. Sharpe v. Sec'y of Health & Human Servs., 964 F.3d 1072, 1083 (Fed. Cir. 2020) (criticizing special master for noting that different evidence could lead to a different result).
>
> On appeal, the Federal Circuit did not correct this approach. Because the mandate does not remand for reconsideration of the first part of Althen prong 3, the undersigned will again primarily look for evidence of neurologic decline within two weeks of the vaccination. However, if Trystan's neurologic decline were to occur slightly outside of two weeks, then [petitioners] could meet their burden regarding Althen prong 3.

Id. at 37-38. On this basis, the special master concluded that petitioners failed to show an injury within approximately two weeks because "[w]hen the record is considered as a whole, the symptoms that Trystan displayed on February 5, 2009, as well as on February 15-16, 2009, including his arm contortions, are not manifestations of a neurologic disorder." Id. at 38.

Petitioners make no substantive argument on this point in their motion for review. After summarizing the Federal Circuit's decision, recounting the special master's conclusion as articulated in the post-remand decision, and repeating their disagreement with the special master's finding that Trystan's arm contortions on February 16, 2009, were not evidence of an neurologic injury, see ECF No. 260 at 49-50, petitioners state as follows:

> If the record as a whole was properly considered, then the evidence overwhelmingly shows that the arm contortions, like in Markovich, continued for at least a month and several times a day. The failure to consider and analyze the record as a whole was error and arbitrary and capricious. Petitioners submit that the arm contortions, at minimum, commenced within the time parameters outlined by [the special master]. The full analysis on Temporal Association is within Petitioner's Post Remand Hearing Brief filed July 29, 2020 at pages 39-64. This Remand Decision, accordingly, must be set aside.

Id. at 51.

The court finds this argument unconvincing for several reasons. First, as the court has discussed at length in this opinion, it sustains the special master's conclusion that Trystan's arm contortions on February 16, 2009, were not a manifestation of neurologic

injury. As such, to the extent that petitioners' argument is premised on a foundational disagreement on that point, it cannot succeed. Second, if there is more to petitioners' argument than has been previously addressed, it is insufficient for petitioners to simply assert that the special master failed to consider the record as a whole without identifying the specific errors. And finally, petitioners cannot incorporate by reference their July 29, 2020 post-remand hearing brief into their motion for review. Petitioners must advance their relevant arguments at each stage of the proceedings, and the court cannot be charged with an obligation to review prior filings to discern which arguments petitioners are reasserting. Moreover, the July 29, 2020 brief was filed before the special master issued his post-remand decision. Thus, any arguments made therein would need to be addressed in light of his new decision to have any bearing on this court's review thereof.

For the foregoing reasons, the court finds that petitioners have identified no evidence of record that the special master failed to consider, nor any implausible inference he made with regard to the third Althen factor, and have not shown that his decision lacked a rational basis. See Lampe, 219 F.3d at 1360. Accordingly, the special master's conclusion that petitioners have not carried their burden on the third Althen factor is sustained.

IV. Conclusion

The court reiterates the acknowledgement, by the Federal Circuit and the special master, of petitioners' dedication to their son as demonstrated by their commitment to this long and complicated litigation. The court's decision to sustain the special master's post-remand decision is made after careful consideration of the record, and with respect for petitioners' position.

For the above-stated reasons, however, the court sustains the entitlement decision of the special master. Accordingly,

(1) Petitioners' motion for review, ECF No. 260, is **DENIED**;

(2) The decision of the special master, filed on August 26, 2020, ECF No. 253, is **SUSTAINED**;

(3) The clerk's office is directed to **ENTER** final judgment in accordance with the special master's August 26, 2020 decision; and

(4) The parties shall separately **FILE** any proposed redactions to this opinion, with the text to be redacted blacked out, on or before **February 26, 2021**.

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
PATRICIA E. CAMPBELL-SMITH
Judge