

NOTE: This disposition is nonprecedential.

**United States Court of Appeals  
for the Federal Circuit**

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**TRYSTAN SANCHEZ, BY AND THROUGH HIS  
PARENTS, GERMAIN SANCHEZ, JENNIFER  
SANCHEZ,**  
*Petitioners-Appellants*

v.

**SECRETARY OF HEALTH AND HUMAN  
SERVICES,**  
*Respondent-Appellee*

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2019-1753

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Appeal from the United States Court of Federal Claims  
in No. 1:11-vv-00685-PEC, Judge Patricia E. Campbell-  
Smith.

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Decided: April 7, 2020

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LISA A. ROQUEMORE, Law Offices of Lisa A. Roquemore,  
Rancho Santa Margarita, CA, argued for petitioners-appellants.

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Before NEWMAN, BRYSON, and REYNA, *Circuit Judges*.

BRYSON, *Circuit Judge*.

This is an appeal from a decision of the Court of Federal Claims (“the Claims Court”) reviewing the decision of a special master denying a petition for compensation under the National Vaccine Injury Compensation Program (“the Vaccine Act”), 42 U.S.C. § 300aa-10 *et seq.* *Sanchez v. Sec’y of Health & Human Servs.*, 142 Fed. Cl. 247 (2019). The parties, the special master, and the Claims Court judge have all put enormous time and thoughtful attention into this complex and difficult case. For that reason, it is with reluctance that we have come to the conclusion that it is necessary to burden the parties and the adjudicators with additional work. Nonetheless, because the record has left certain critical issues unresolved, we are required to vacate the judgment and remand for further proceedings.

I

A

Trystan Sanchez received several vaccines in February 2009 when he was six months old. Shortly after his vaccinations, he developed a fever and displayed what his parents characterized as “inconsolable crying.” Several days later, he again developed a fever and was congested. He was diagnosed at that time with a common cold.

In August 2009 Trystan received a second round of vaccinations. Trystan’s mother reported at that time that she had noticed a change in Trystan’s development. A neurologist who saw Trystan in November 2009 determined that he was exhibiting global developmental delays. Trystan continued to show developmental delays for the next several years.

In 2011, suspecting that the 2009 vaccinations had been responsible for Trystan's developmental difficulties, the Sanchezes filed a petition for compensation under the Vaccine Act. While the petition was pending, Trystan underwent genetic testing. Based on two mutations in Trystan's DNA discovered during that testing, Trystan was diagnosed with Leigh's syndrome. Leigh's syndrome is a rare but severe genetic disorder that typically manifests itself in the first year of life and causes progressive loss of mental and physical abilities, usually resulting in early death.

## B

Prior to Trystan's genetic testing and his Leigh's syndrome diagnosis, the special master who was assigned to the case held a hearing to determine the facts relating to Trystan's condition. Based on the evidence at the hearing and the parties' joint statement of stipulated facts, the special master then entered a detailed *Ruling Finding Facts* in April 2013. In several instances in his factual findings, the special master chose to credit the written medical reports' descriptions of Trystan's symptoms over the testimony of Trystan's parents.

The special master found that Trystan appeared healthy and was developing normally before February 5, 2009, when he received his first round of vaccines. Shortly after his pediatric visit that day, however, Trystan began to cry inconsolably, he ran a temperature of 102.2, and he developed a lump on his left thigh that was hot to the touch. The fever ebbed and flowed over the next several days.

On February 15, Trystan became congested and began running a fever again. The following night, his fever became worse, and he began what his mother described as "loud, high-pitched" crying. His father sought to calm Trystan by holding him, but when Trystan would fall asleep, he would repeatedly startle awake. According to his father, Trystan "kept kicking his feet and jerking

around” in his father’s arms, “almost as if he didn’t want to be held.” His father testified that Trystan was “jerking his body” and “holding his arm behind his back kind of in an uncomfortable position.” Trystan’s father said that when he “went to put [Trystan’s] arm back to the normal position,” he could “feel that he had a lot of tension in that arm. And when I did put it back, his arm went right back holding it back towards the back of his body.” In his 2013 *Ruling Finding Facts*, the special master did not appear to credit Trystan’s father’s testimony regarding Trystan’s arm movements. In that ruling, the special master said that “[a]t this time, Trystan did not begin to exhibit arm contortions.”

The following morning, Trystan’s mother took Trystan to the pediatrician’s office, where he was examined by Jonathan P. Luna, a certified physician’s assistant. Mr. Luna diagnosed Trystan with a “common cold” and “viral syndrome.” Ms. Sanchez testified that she told Mr. Luna about Trystan’s arm contortions, but Mr. Luna did not make a note of her observations in his record of the visit. In light of the absence of a report of the arm contortions in Mr. Luna’s record of the visit, the special master found that Trystan did not begin to exhibit arm contortions at that time.

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.

On April 29, 2009, after Trystan had suffered from a cough and congestion for two weeks, his mother took him

to a pediatrician, Dr. Nabil R. Seleem. She testified that she told Dr. Seleem about Trystan's arm contortions. Dr. Seleem, however, did not note any such comments in his record of the visit, and his notes reflect his observation that Trystan appeared to be neurologically normal. Based on Dr. Seleem's report, the special master found that Ms. Sanchez did not report any "unusual arm movements or developmental issues" to Dr. Seleem. Dr. Seleem diagnosed Trystan with an ear infection and bronchitis, for which he prescribed an antibiotic.

Trystan returned to the clinic on May 13, 2009, at which time the examining pediatrician, Dr. Philip S. Brown, noted that Trystan's infection seemed to be resolving. Ms. Sanchez testified that she told Dr. Brown about "the weird movement, the contortion of the arm," and the issue with Trystan's head control. Dr. Brown's report of the visit did not include any reference to those neurological complaints, however, and the special master found that Trystan had not experienced any loss of skills at that point.

On August 17, 2009, Trystan was seen by physician's assistant Micaela Marin-Tucker for his one-year well-baby exam. Ms. Marin-Tucker's notes reflect that Trystan's mother said she had noticed a change in Trystan's development about two to three months earlier. Ms. Sanchez testified that Ms. Marin-Tucker's notes were wrong and that she told Ms. Marin-Tucker she had noticed a change in Trystan's development that began five to six months earlier. The special master credited Ms. Marin-Tucker's contemporary notes over Ms. Sanchez's testimony and found that Trystan began to lose skills only as of about the beginning of May 2009 at the earliest.

In the course of her examination, Ms. Marin-Tucker found that Trystan did not walk, stand, crawl, and hold his head up while sitting. She also found that Trystan did not attempt to move his lower extremities, and she noticed that

his extremities seemed generally soft, but rigid at times. Ms. Marin-Tucker referred Trystan to a neurologist.

During the August 2009 clinic visit, Trystan received another round of vaccinations. Following those vaccinations, Ms. Sanchez testified, Trystan “got sick again” and “started contorting his arm even more.”

Six weeks later, Trystan returned to the clinic for a follow-up visit. At that time, Ms. Marin-Tucker noted that Trystan had “no seizures, weakness, or tics.” In the report of her neurological examination, however, she stated that Trystan was “unable to grasp, sit, crawl, or make much eye contact.” She again urged the family to have Trystan examined by a neurologist.

In November of that year, Trystan was seen by a neurologist. Prior to that visit, Trystan began having tremors or twitching of his whole body. The neurologist recorded reports that Trystan was unable to sit independently, his hands stayed closed, and his feet went forward when he was at rest. His examination was positive for muscle spasms, weakness, and global developmental delay, among other problems. Based on his examination and Trystan’s history, the neurologist concluded that Trystan was suffering from “global developmental delay of unclear etiology, though a genetic predisposition is suspected based on the family history and a [central nervous system] cause is suggested by the physical exam findings.” An MRI performed in December 2009 revealed abnormalities in Trystan’s basal ganglia, and the treating physicians began to suspect a metabolic disorder.

During the ensuing five years, Trystan was examined on numerous occasions, without a firm diagnosis being reached. Genetic testing in December 2014, over a year after the special master’s initial factual findings, revealed that Trystan had two mutations in his SDHA gene. Based on those mutations, Trystan’s treating physician confirmed a diagnosis of Leigh’s syndrome.

## C

Following Trystan's diagnosis with Leigh's syndrome, the petitioners' theory changed. Rather than arguing that the vaccines directly caused his condition, they acknowledged that Trystan's Leigh's syndrome was the product of his genetic condition. They argued, however, that the first round of vaccinations Trystan received on February 5, 2009, either caused his genetic condition to be expressed or significantly aggravated the course of his disease. They also argued that Trystan's second set of vaccinations, on August 17, 2009, further aggravated the effects of his disease.

To address these issues, the special master held a second hearing in December 2017 at which experts for the parties testified. At that four-day hearing, two experts testified for the petitioners—Dr. Lawrence Steinman and Dr. Dmitriy Niyazov. Four experts testified for the government—Dr. Gerald Raymond, Dr. Stephen McGeady, Dr. Edward Cetaruk, and Dr. Dean Jones.

The petitioners' experts testified that Trystan's developmental regression began shortly after his first vaccinations on February 5, 2009. Dr. Niyazov testified that the symptoms Trystan experienced immediately after receiving those vaccines were evidence of an immune response. Because of Trystan's genetic mutations, which resulted in decreased mitochondrial function, the vaccines started an inflammatory response affecting Trystan's brain. That response, according to Dr. Niyazov, "triggered a gradual process of developmental regression" that became more evident around June 1, 2009.

Dr. Steinman similarly testified that the vaccines stressed the energy sources in Trystan's cells. Because of Trystan's mitochondrial disease, Dr. Steinman testified, Trystan was "on the edge all the time, and this vaccine trigger[ed] a downward cascade that began on February 5th when he got the vaccine." Dr. Steinman and Dr. Niyazov

testified that Trystan's inconsolable high-pitched crying and his jerking and arm contortions were evidence of neurodegenerative events, and were not consistent with a common cold.

Drs. Niyazov and Steinman also testified that Trystan suffered what is known as a "challenge-rechallenge." That is, his regression and dystonia following his initial vaccinations was repeated following his August 2009 vaccinations, except that his condition worsened significantly after that time. Dr. Steinman referred to the aftermath of Trystan's second set of vaccines as "an accelerated neurological degeneration due to a recall response." Dr. Niyazov agreed that the second set of vaccinations set Trystan back again.

One of the government's experts, Dr. McGeedy, testified that while Trystan's inconsolable crying on the day of his initial vaccinations "may very well have been" a response to the vaccines, the fever that he ran on February 16, 2009, was caused by the viral respiratory infection he suffered at that time. The other principal government expert, Dr. Raymond, testified that in his opinion, the evidence did not show that Trystan had a seizure on February 16. Instead, he testified that "[k]icking of the legs, resisting being held, is not, in my opinion, epileptic activity."

Following the December 2017 hearing, the special master entered his *Published Decision Denying Compensation*. In that detailed order, he reviewed his earlier factual findings and then turned to deciding the issue of compensation in light of the expert evidence adduced at the second hearing.

At the outset, the special master addressed the first of the three factors to be considered in assessing a vaccine compensation claim under this court's decision in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): whether the petitioners have shown "a medical theory causally connecting the vaccination and the injury." In this case, that factor required the special



master to determine whether the petitioners had shown that the vaccines Trystan received could have caused the manifestation or aggravation of his Leigh's syndrome.

After reviewing the expert testimony and the medical literature, the special master concluded that "though a link between vaccination and the onset of Leigh's syndrome has not been established to the standard of medical certainty," the evidence presented was "sufficient to conclude that the Sanchezes' theory is plausible insofar as it is consistent with contemporary understanding of the biological systems at play." The special master explained that the "first manifestation of Leigh's syndrome is known to follow an inter-current illness in many, if not most, cases." In particular, the special master concluded that the Sanchezes had presented "a plausible medical theory explaining how Trystan's vaccines may have caused his injury" by showing that it was more plausible than not that the vaccine that Trystan received "is known to sometimes cause fever," and that "fever can cause decompensation in someone with a pre-existing mitochondrial disease."<sup>1</sup> In light of the evidence before him, the special master concluded that the government had not rebutted either of those theories, and "that both premises are likely to be consistent with contemporary medical thought."

The special master then turned to the question whether the vaccine had in fact triggered or aggravated Trystan's Leigh's syndrome, for which his genetic mutations predisposed him. The special master noted that the petitioners and their experts argued that Trystan's neurological deterioration began on February 5, 2009, the day he received his vaccinations. The special master concluded, however, that the evidentiary record "does not support this

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<sup>1</sup> As the special master explained, "decompensation" is a period of regression or loss of skills frequently seen in children with Leigh's syndrome.

premise that is so central to the Sanchezes' argument." Instead, the special master found that "approximately three months passed between when Trystan received the February 5, 2009 vaccinations and the earliest possible onset of his neurological regression." Based on that finding, the special master asked whether a delay of that magnitude "is consistent with vaccine-causation." In light of the medical literature in evidence, he concluded that it was not. Instead, summarizing the literature, the special master concluded that regression would generally be expected to occur in such patients within about two weeks or less after the triggering event, such as a fever or infection.

The special master made a series of factual findings bearing on the issue. In particular, he found that in the hours after the February 5 vaccination, Trystan developed a fever and displayed inconsolable crying. The fever ebbed and flowed for a few days.

The special master found that the vaccines Trystan was given on February 5 caused him to develop a fever. He also found that fever, including fever following vaccination, can cause decompensation in a patient with a metabolic disease such as Trystan's.

On February 15, Trystan developed another fever and was crying inconsolably again. He "was congested and had difficulty breathing." In addition, the special master found, Trystan's "arms contorted and he was jerking around." However, the special master found that those movements "were of the type typically displayed by an infant suffering from a cold." The special master also found that Trystan's family did not convey to physician's assistant Luna, who examined Trystan the following day, that Trystan had displayed any symptoms consistent with a neurological injury as opposed to a cold, and Mr. Luna did not detect any signs in the course of his examination that were consistent with a neurological injury as opposed to a cold.

The special master also found that Trystan's parents took him to see Dr. Seleem on April 29, 2009, because of concern about his cough and congestion that had lasted for two weeks, and that they did not convey to Dr. Seleem that Trystan had displayed any symptoms consistent with a neurological injury. The special master further found that Dr. Seleem did not observe any signs that were indicative of neurological injury during the examination he performed on Trystan.

Finally, the special master credited the report prepared by physician's assistant Marin-Tucker, who stated that Trystan's mother had said during the August 17, 2009, visit that Trystan first started showing signs of loss of skills approximately two to three months earlier. Based on that evidence, the special master concluded that the first signs of Trystan's loss of skills occurred by the beginning of May 2009 at the earliest.

The special master then addressed the question whether the delay between the date of the vaccinations and when Trystan's parents noticed his loss of skills was attributable to the fact that in a child as young as Trystan, the loss of skills may not be immediately obvious. Based on the literature, the special master found that "there is some truth to that claim." In addition, the special master deemed that there is "a non-insignificant chance that the Sanchezes relayed a concern [about Trystan's development] at the May 13, 2009, visit with Dr. Brown that did not end up in the records." Nonetheless, the special master concluded, that possibility did not account for the three-month period during which the medical records "show[ed] no indication of Trystan having, or the parents being concerned about, a neurological condition." Instead, the special master found, the parents "appeared to be focused on Trystan's multiple colds."

The special master acknowledged that "if Trystan did not experience any other decompensating events between

the vaccination and the onset of his Leigh's syndrome, it may very well make his parents' claims of causation less improbable." However, the special master pointed out that during the three months "leading up to when his loss of skills first manifested, Trystan suffered from multiple upper respiratory infections." Such infections, the special master noted, "are known to precipitate mitochondrial decompensation." Trystan's upper respiratory infections between March and May of 2009, the special master concluded, "are entirely consistent with the infections being the intercurrent infection that induced his metabolic decompensation . . . ."

The special master further stated that the petitioners' failure to address "a conspicuous and probable alternate cause for the manifestation of Trystan's Leigh's syndrome weighs against a finding that the vaccination caused Trystan's injury." He determined that the presence of a probable alternative cause, "in combination with the unlikelihood of a multiple-month delay between the vaccine and the onset of his neurodegeneration, makes a finding that the vaccine was, more likely than not, a substantial factor in Trystan's Leigh's syndrome untenable." The special master therefore denied the petition for compensation.

#### D

The petitioners filed a motion for review of the special master's decision with the Claims Court. After conducting a detailed review of the evidence and the special master's findings, the court upheld the special master's decision denying compensation.

The Claims Court rejected petitioners' contention that the special master had erred in finding that Trystan's vaccine-related injury occurred within an acceptable time frame. The court declined the petitioners' "invitation to reweigh the evidence as to disease onset," because nothing in the allegations of fact or the expert opinions relied on by

the petitioners showed that the special master's findings as to disease onset were arbitrary or capricious.

The Claims Court also rejected the petitioners' argument that the special master had ignored their "challenge-rechallenge" argument based on the combined effect of the February and August 2009 vaccinations. The court found that the special master had "weighed the relevant evidence of rechallenge symptoms" but "found the evidence to be unpersuasive." For that reason, the court concluded, "it was not error for the special master to also find petitioners' expert testimony as to rechallenge to be so unpersuasive as to be unworthy of mention . . . ."

## II

On appeal, the petitioners challenge the special master's decision (and the Claims Court's affirmance of that decision) on three principal grounds. 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.

We are mindful that our authority to review factual findings made by the special master is extremely limited. As this court explained in *Paluck*, 786 F.3d at 1378, "we review findings of fact under the arbitrary and capricious standard." See also *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011).

## A

In *Paluck*, we affirmed the Claims Court’s decision overturning a special master’s denial of compensation to Vaccine Act claimants in circumstances similar in several respects to this case. We agree with the petitioners that this case has some features in common with *Paluck*, and that this court’s analysis in *Paluck* provides helpful guidance for the analysis of the merits of the petitioners’ claims in this case.

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 a mitochondrial disease can result in oxidative stress that can, in turn, cause progressive neurological deterioration over time. *See Paluck*, 786 F.3d at 1380–81. In fact, several of the scientific papers that the courts in *Paluck* pointed to as supporting the Palucks’ theory of liability were introduced by the Sanchezes in this case.

While there are similarities between this case and *Paluck*, there are differences as well, and because of those differences, this case cannot be decided based on *Paluck* alone. In particular, the Claims Court in *Paluck* rejected the special master’s conclusion that the child’s post-vaccination deterioration did not align with the medical theory on which the petitioners relied, in that the regression was not “linear” and the child did not manifest identifiable symptoms of neurologic injury within three weeks of his vaccinations. The court sustained the Claims Court’s ruling that the special master’s decision was arbitrary and capricious in that respect; the Claims Court held that the special master disregarded significant probative evidence that the child “experienced rapid and progressive neurological deterioration within a medically acceptable interval following his vaccinations.” 786 F.3d at 1380. In light of the “compelling evidence of post-vaccination neuro-

developmental regression,” this court concluded that the special master had “no reasonable basis for concluding that [the child] did not experience the progressive neurodegeneration predicted” by the petitioners’ medical theory. *Id.* at 1382.

This court in *Paluck* also concluded that the special master had erred by “setting a hard and fast deadline of three weeks between vaccination and the onset of clinically apparent symptoms of neurological injury,” which the court found was not supported by the medical literature in evidence. *Id.* at 1382–83. The court also found several of the inferences from the evidence drawn by the special master to be unsupported, and it concluded that the special master had improperly disregarded MRI evidence indicating progressive neurodegeneration and contemporaneous statements from the child’s treating physicians. *Id.* at 1384–86.

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. Instead, the special master considered the period of time, together with the other evidence of the progression of Trystan’s disease, in attempting to determine the issue of causation. 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. In fact, the special master in this case relied heavily on the observations (or the absence of observations) by the treating physicians in determining whether to credit the testimony given by Trystan’s parents. In sum, while there are substantial parallels between this case and *Paluck*, the differences between the two cases are such that the outcome of this case is not dictated by *Paluck*.

## B

We next turn to the petitioners’ challenge to the special master’s causation analysis. That issue requires a close examination of the evidence in the record.

The special master found the vaccines Trystan received on February 5, 2009, are known to cause fever, and fever can cause neural decompensation in someone with a preexisting mitochondrial disease. The special master concluded that Trystan clearly suffered a loss of skills after receiving the vaccine, and that the loss of skills was the manifestation of his Leigh's syndrome. The critical finding made by the special master as to the effect of the vaccination, however, was that the period of time between the vaccinations in February 2009 and Trystan's loss of skills no earlier than May 2009 was too long for the vaccinations to have been the likely trigger for his Leigh's syndrome. It is that finding that is the principal focus of the petitioners' challenge to the special master's ruling.

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.

A related issue that the special master should consider on remand has to do with the application of the second and third *Althen* factors: “(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. The special master treated those two factors together as being directed to the single issue of causation, on which the petitioners bore the burden of proof. While it is true that the entire *Althen* test is generally directed to the issue of causation, *Althen* distinguishes between the three factors that are necessary to make out a prima facie case (on which the petitioners bear the burden of proof) and the question whether the injury was caused by factors unrelated to the vaccine (on which the government bears the burden of proof). If petitioners make a prima facie case under the first three factors, they are entitled to prevail unless the government shows, by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine. *Althen*, 418 F.3d at 1278; see *Shalala v. Whitecotton*, 514 U.S. 268, 270–71 (1995); 42 U.S.C. § 300aa-13(a)(1)(B).

In this case, there is no question that Trystan suffered neurodegeneration beginning no later than May or June of 2009. But for the cold he suffered on February 16, 2009, and the other infections he suffered during the spring of that year, the vaccinations might have been prime suspects as the triggering mechanism for his mitochondrial disease to manifest itself. To be sure, there was a several-month delay between the initial vaccines and the time the special master found that Trystan’s loss of skills began to be noticed. But that delay, by itself, was not necessarily dispositive. As the special master noted, there is some force to the point that in a child as young as Trystan, loss of skills would not be immediately noticed.

For that reason, 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. If 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. But if the special master finds that the petitioners have met their burden of establishing a prima facie case as to the first issue, he must determine whether the government has met its burden as to the second.

### C

The petitioners also contend that the special master did not address the "challenge/rechallenge" claim raised by the petitioners' experts. That theory of causation was that the combined effect of the February and August vaccinations caused or aggravated Trystan's condition. Although that issue was raised in the petitioners' pre-hearing brief and by the evidence, the special master did not address that theory in his *Published Decision Denying Compensation*.

On review of the special master's ruling, the Claims Court held that it was not necessary for the special master to address that issue expressly, in that the argument appeared to have been implicitly rejected in the special master's factual findings. However, the findings that the special master made in his *Ruling Finding Facts* predated the testimony of the petitioners' experts, much of which focused on the challenge/rechallenge theory. Moreover, the special master based his factual conclusion that Trystan's condition did not deteriorate after the August 2009 vaccinations on the fact that the contemporaneous medical records did not corroborate the Sanchezes' testimony to that effect. The record closest in time to the August

vaccinations was the record prepared by Ms. Marin-Tucker regarding the August 17, 2009, visit when Trystan received his vaccinations. Based on that report the special master found that Trystan could not stand, walk, crawl, or hold his head up while sitting.

Six weeks later, when Trystan returned to the clinic for a follow-up visit. Based on Ms. Marin-Tucker's report for that visit, the special master found that Trystan was "unable to grasp, sit, crawl, or make much eye contact." While the two medical reports are generally similar, the special master's findings with regard to the two reports suggest that Trystan may have suffered at least some additional loss of skills during the period between August and October 2009, an issue the special master did not expressly address.

The challenge/rechallenge theory is not frivolous, and does not appear to have been implicitly rejected. For those reasons, we conclude that the special master should address that theory expressly on remand and decide whether it supports compensation in this case.

#### D

Finally, it may be necessary for the special master to address a question that was left open in the last two pages of the special master's decision denying compensation: 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.

This is a difficult issue on which the science has been developing rapidly. Each party's experts testified on this issue at the December 2017 hearing. In light of the speed with which medical understanding of the course of genetic disorders such as Leigh's syndrome has been expanding, however, 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

SANCHEZ v. HHS

21

hearing held by the special master two and one-half years ago.

For the reasons given, we vacate the judgment in this case and remand for further proceedings consistent with this opinion.

No costs.

**VACATED AND REMANDED**