

In the United States Court of Federal Claims

No. 05-579V

Filed Under Seal: October 23, 2018

Reissued for Publication: November 27, 2018*

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HOLLY AUSTIN, <i>parent of K.A., a</i>))	
<i>minor,</i>))	
))	
Petitioner,))	National Childhood Vaccine Injury Act,
))	42 U.S.C. § 300aa–1 to –34 (2012);
v.))	Vaccine Rule 8; Waiver; Diphtheria
))	Tetanus Acellular Pertussis Vaccine;
SECRETARY OF HEALTH AND))	Inactivated Polio Vaccine; Haemophilus
HUMAN SERVICES,))	Influenza Type B Vaccine; Pneumococcal
))	Vaccine; Encephalopathy; Autism.
Respondent.))	
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MEMORANDUM OPINION AND ORDER

GRIGGSBY, Judge

I. INTRODUCTION

Petitioner, Holly Austin, seeks review of the May 15, 2018, Decision of the special master (the “May 15, 2018 Decision”), denying a claim for compensation brought on behalf of her minor son, K.A., under the National Childhood Vaccine Injury Act (“Vaccine Act”), 42 U.S.C. § 300aa–1 to –34 (2012). Petitioner has also moved to exceed the page limitations with

* This Memorandum Opinion and Order was originally filed under seal on October 23, 2018 (docket entry no. 138). The parties were given an opportunity to advise the Court, by November 26, 2018, of their views with respect to what information, if any, should be redacted. On November 26, 2018, the parties filed a joint status report informing the Court that no redactions were required (docket entry no. 140). And so, the Court reissues the Memorandum Opinion and Order, dated November 27, 2018, without any redactions.

respect to her motion for review (docket entry no. 132). For the reasons set forth below, the Court: (1) **GRANTS** petitioner's motion for leave to exceed the page limitations; (2) **DENIES** petitioner's motion for review of the special master's May 15, 2018, Decision; and (3) **SUSTAINS** the decision of the special master

II. FACTUAL AND PROCEDURAL BACKGROUND¹

A. Factual Background

In this Vaccine Act matter, petitioner, Holly Austin, alleges that her son, K.A., suffered an encephalopathy as a result of the diphtheria-tetanus-acellular pertussis ("DTaP"), inactivated poliovirus vaccine ("IPV"), Haemophilus influenza type B ("HiB"), and pneumococcal vaccinations administered on July 28, 2003; the flu vaccine administered on December 15, 2003; and the Diphtheria-Tetanus ("DT") vaccine administered on June 1, 2004. *See generally* Pet'r Am. Pet. On May 15, 2018, the special master denied petitioner's claim for compensation under the Vaccine Act. *Austin v. Sec'y of Health & Human Servs.*, No. 05-579V, 2018 WL 3238608 (Fed. Cl. Spec. Mstr. May 15, 2018).

1. Petitioner's Medical History

K.A.'s medical history is discussed in detail in the special master's May 15, 2018, Decision and is summarized here. *See generally Austin*, 2018 WL 3238608. K.A. was born on January 24, 2003, following a normal pregnancy. Pet'r Ex. 3 at 1. K.A. received the Hepatitis B ("Hep. B") vaccine on February 5, 2003; the initial round of childhood vaccinations on March 27, 2003; and the second round of childhood vaccinations on June 13, 2003. Pet'r Ex. 8 at 26-29; Pet'r Ex. 14 at 2-3.

a. 2003 Vaccinations And Symptoms

On July 12, 2003, petitioner took K.A. to the emergency room at Franklin Memorial Hospital to report that K.A. had experienced what K.A.'s treating physicians described as an "acute life-threatening event." Pet'r Ex. 11 at 2. Petitioner revealed that the episode included

¹ The facts recounted in this Memorandum Opinion and Order are taken from the petitioner's amended petition ("Pet'r Am. Pet."); petitioner's motion for review ("Pet'r Mot. for Rev."); petitioner's motion for leave to file a memorandum exceeding 20 pages accompanying a motion for review ("Pet'r Mot. for Leave"); petitioner's memorandum in support of her motion for review of the special master's decision ("Pet'r Mem."); petitioner's exhibits ("Pet'r Ex."); and the special master's May 15, 2018, Decision ("May 15, 2018, Decision"). Except where otherwise noted, the facts recited herein are undisputed.

staring and limpness. *Id.* K.A. was transferred to Eastern Maine Medical Center, where doctors performed several tests to determine possible causes of these symptoms. *Id.* at 4-6, 19-20, 45-47. Following these tests, the doctors determined that K.A.'s vitals were stable, and diagnosed him with an "acute life-threatening event, presumptive gastrointestinal reflux, and left otitis media." *Id.* at 2. Medical notes from this visit do not include twitching or spasm activity. *Id.* at 4-7.

On July 28, 2003, K.A. received his third round of childhood vaccinations at Penobscot Pediatrics, and a few hours later, he experienced acute onset seizures. *Austin*, 2018 WL 3238608, at *2, *3. K.A. was taken to Eastern Maine Medical Center on the same day, where he was seen by Dr. James Sears. *Id.* at *3; Pet'r Ex. 11 at 63-65. On July 29, 2003, doctors performed an electroencephalogram ("EEG") test and a magnetic resonance imaging ("MRI") test, both of which returned normal results. Pet'r Ex. 11 at 53. In light of K.A.'s July 12, 2003 acute life-threatening event, Dr. Sears explained that K.A. may be experiencing complex partial seizures and he prescribed K.A. the anti-seizure medications fosphenytoin and phenobarbital. *Id.* at 63-65. Dr. Sears also recognized that K.A. had experienced these seizures on the same day that K.A. received several vaccinations, but he noted that the vaccines did "not appear to be [a] substantial element" of K.A.'s seizure episode. *Id.* at 64. K.A. was released from the medical center on July 31, 2003. *Id.* at 52.

Thereafter, K.A. received a third round of IPV on October 31, 2003 at Penobscot Pediatrics. Pet'r Ex. 14 at 2. K.A. did not experience seizures following this vaccination. Pet'r Ex. 8 at 14.

On December 15, 2003, K.A. received the flu vaccine at Pine Tree Pediatrics. *Austin*, 2018 WL 3238608, at *3. Eight days later, on December 23, 2003, petitioner reported that K.A. had experienced seizure activity the previous night. Pet'r Ex. 8 at 11. Petitioner described the seizure as lasting five seconds, and Dr. John Hickey recommended that she continue administering phenobarbital. *Id.* Subsequent medical records provide additional details regarding this seizure episode and reveal the seizure activity occurred over a period of four days. *Austin*, 2018 WL 3238608, at *3.

b. 2004 Vaccinations And Symptoms

On January 6, 2004, petitioner took K.A. to Maine Medical Partners, where he saw Dr. Stephen Rioux. *Austin*, 2018 WL 3238608, at *4. Dr. Rioux opined that K.A. likely had a

“generalized seizure” disorder and that it was possible that “quinolones transmitted to the child through breast milk, as well as subsequent immunizations lowered the seizure threshold and may have been responsible for the timing of [K.A.’s] seizures.” Pet’r Ex. 5 at 7. But, Dr. Rioux explained that it was “unlikely that either of these interventions or agents are responsible for his ongoing seizure difficulties.” *Id.*

K.A. visited his pediatricians at Pine Tree Pediatrics and Penobscot Pediatrics for various symptoms unrelated to seizures on February 12, 2004; March 4, 2004; March 10, 2004; and March 29, 2004. Pet’r Ex. 8 at 12-14; Pet’r Ex. 14 at 30. During the March 4, 2004 visit, Dr. Hickey noted that he would “wait for clearance from Dr. Rioux” before administering any vaccines to K.A. without further explanation. Pet’r Ex. 8 at 14. On April 26, 2004, K.A. returned to Penobscot Pediatrics for a routine check-up and he had no developmental issues. *Austin*, 2018 WL 3238608, at *4.

During a follow-up visit on May 6, 2004—and at petitioner’s request—Dr. Rioux recommended that K.A.’s vaccines be spread out temporarily. Pet’r Ex. 8 at 21. Thereafter, between May 24, 2004 and May 28, 2004, petitioner began calling Penobscot Pediatrics to request that K.A.’s vaccination schedule be adjusted. Pet’r Ex. 14 at 42. In light of these changes, K.A. “received the IPV vaccine on May 25, 2004, a third dose of HiB on June 1, 2004, and the DT vaccine on June 8, 2004.” *Austin*, 2018 WL 3238608, at *4.

On July 5, 2004—approximately one month after K.A. received his third dose of HiB—K.A. experienced additional seizures while taking a therapeutic level of phenobarbital. Pet’r Ex. 14 at 43. Petitioner took K.A. to see Dr. Michael Ross on July 9, 2004. *Id.* at 35-36. Following this seizure episode, K.A.’s doctors began to observe signs of developmental regression. *Id.* The regression included a “steady decrease [in vocabulary] back to wordless mumbling,” decreased attention span, failure to regard faces, constant looking away, lingering blank looks, frequent head and ear rubbing, aimless wandering, and unsteady gait. *Id.* at 35. Dr. Ross diagnosed K.A. with a “seizure disorder and significant developmental delay” and recommended, among other things, that K.A. receive another EEG test and be evaluated for developmental problems. *Id.* at 36.

On September 9, 2004, K.A. was evaluated by the Maine General Medical Center’s Developmental Evaluation Clinic. *Austin*, 2018 WL 3238608, at *5. During this visit, Dr. Anne

Uecker observed that K.A. “exhibited all six critical indicators for autism.” *Id.*; Pet’r Ex. 25 at 11-12. This assessment provided several other possible diagnoses, including seizure disorder, severe receptive and expressive language delays, severe articulation delay, mild gross motor delay, and internal tibial torsion and femoral anteversion. Pet’r Ex. 25 at 2-3. Thereafter, on September 14, 2004, K.A. saw a new pediatrician, Dr. Melissa Burch, at Norumbega Medical Pediatrics, where his health history officially included “autistic regression.” *Austin*, 2018 WL 3238608, at *6; Pet’r Ex. 6 at 2. Dr. Burch referred K.A. to the metabolic clinic at Tufts Medical Center to determine if K.A.’s autism had a metabolic etiology. Pet’r Ex. 4 at 10. K.A. was evaluated at the Center on March 3, 2005, by Dr. Cheryl Garganta, who noted that a vaccination exemption “might be possible,” but emphasized that it would be made in an abundance of caution because K.A.’s health problems “were very likely unrelated to his immunizations.” Pet’r Ex. 4 at 13. During a May 3, 2005 check-up with Dr. Burch at Norumbega Medical Pediatrics, Dr. Burch indicated that she would wait to administer two vaccines but Dr. Burch provided no explanation for this decision. Pet’r Ex. 6 at 3.

Petitioner commenced this action on May 27, 2005. *See generally* Pet. Since filing this case, petitioner has sought additional medical treatment for K.A. to determine the cause of K.A.’s condition. *Austin*, 2018 WL 3238608, at *7. To that end, on February 16, 2015, K.A. was examined by Dr. Fran Kendall, who explained that, although the onset of K.A.’s symptoms appeared to be temporally related to his vaccines, “the science is not sophisticated enough to prove any absolute [theory] as to why” his symptoms began. Pet’r Ex. 29 at 4. K.A.’s doctors have consistently agreed with Dr. Kendall’s assessment of K.A.’s condition and rejected petitioner’s view that K.A.’s autism was a result of his childhood vaccinations. Pet’r Ex. 15 at 1; Pet’r Ex. 18 at 4.

2. Proceedings Before the Special Master

Petitioner commenced this Vaccine Act case on May 27, 2005, as part of the Omnibus Autism Proceedings (“OAP”), and she claimed that various vaccines caused K.A. to suffer autism. *Austin*, 2018 WL 3238608, at *15. On January 12, 2011, petitioner’s claim was removed from the OAP, in light of her desire to proceed on an alternate theory. *Id.*

On November 23, 2015, petitioner submitted an expert report by Dr. Yuval Shafir in which Dr. Shafir analogized autism to epilepsy and contended that the diseases' similar origins and course of development explained K.A.'s post-vaccination symptoms. *Id.* at *8-*11.

On February 2, 2016, the Secretary of Health and Human Services ("Secretary") filed an expert report by Dr. Gregory Holmes, arguing that Dr. Shafir failed to provide a compelling theory regarding how K.A.'s vaccines caused developmental regression. *Id.* at *13-*15. On May 3, 2016, petitioner filed a supplemental expert report by Dr. Shafir, in which Dr. Shafir clarified that the vaccines do not cause autism, but that the vaccines cause autoimmune phenomena with developmental regression as a secondary injury. *Id.* at *12-*13.

On August 11, 2017, petitioner filed an amended petition, alleging that K.A. suffered seizures and rapid developmental regression due to the DTaP, Hep. B, and pneumococcal vaccines that K.A. received on July 28, 2003; the flu vaccine that K.A. received on December 15, 2003; and the HiB vaccine that K.A. received on June 1, 2004. Pet'r Am. Pet. at 1-2, 22.

On October 12, 2017, the Secretary responded to petitioner's amended petition and filed a motion for a decision dismissing the petition on the record and memorandum in response to petitioner's brief. *See generally* Resp't Mot. On November 14, 2017, petitioner filed a reply to the Secretary's motion for decision dismissing the petition on the record and memorandum in response to petitioner's brief. *See generally* Pet'r Resp.

3. The Special Master's May 15, 2018, Decision

On May 15, 2018, the special master issued a decision denying petitioner's Vaccine Act claim. *See generally Austin*, 2018 WL 3238608. In the May 15, 2018, Decision, the special master found that: (1) K.A. had not experienced a post-vaccination encephalopathy; (2) petitioner failed to establish a reliable or persuasive causation theory; (3) petitioner failed to establish that K.A.'s vaccinations caused an encephalopathy or seizures resulting in autism; (4) petitioner had not shown that the timeframe of K.A.'s injuries was medically acceptable; and (5) an evidentiary hearing was unnecessary. *Id.* at *23-*29. And so, the special master determined that the evidentiary record "does not support petitioner's contention that the vaccines K.A. received could, or did, cause his developmental regression, seizure disorder, or autism" and the special master dismissed petitioner's claim. *Id.* at *29.

Specifically, the special master determined, as an initial matter, that K.A. did not experience a post-vaccination encephalopathy. *Id.* at *23-24. In this regard, the special master found that petitioner’s claim depended upon a factual finding that K.A. “suffered from an encephalopathy prior to his alleged regression and/or seizures.” *Id.* at *23. But, the special master determined that K.A.’s medical records did not support a finding that K.A. “experienced any kind of encephalopathy reaction after his July 28, [2003], vaccinations (or subsequent vaccinations...)” *Id.* (emphasis original).

The special master also observed that K.A. appeared to be “healthy and normal” before, during, and immediately after his July 28, 2003, vaccinations, and that K.A.’s July 28, 2003 EEG and MRI tests showed no signs of neurological damage. *Id.* at *24 (citing Pet’r Ex. 8 at 30, 57; Pet’r Ex. 11 at 53; Pet’r Ex. 14 at 5). The special master further observed that the seizures that K.A. experienced in December 2003, occurred several days after K.A. received a different set of vaccines than those he received prior to experiencing seizures in July 2003. *Id.*

In addition, the special master observed that K.A.’s neurologist specifically noted that K.A.’s July 2003 seizures were unlikely to have been caused by the vaccines. *Id.* (citing Pet’r Ex. 5 at 7). Lastly, the special master observed that K.A.’s June 2004 medical record—which was more proximate in time to the manifestation of K.A.’s developmental problems—lacked evidence of symptoms “that could be interpreted as indicia of encephalopathy.” *Id.* (citing Pet’r Ex. 14 at 35-36). And so, based upon this evidence, the special master concluded that “[t]he overall record simply does not support the conclusion that K.A. ever experienced a post-vaccination encephalopathy at any time.” *Id.*

Second, the special master determined that petitioner did not established a reliable or persuasive causation theory in this case. *Id.* at *24-*26. In this regard, the special master considered the causation theory advanced by petitioner’s medical expert, Dr. Yuval Shafir, who “maintained that a component in the DTaP vaccine could initiate an autoimmune process and thereby produce an encephalopathy... sufficient to result in developmental regression a year later.” *Id.* at *24. But, the special master noted that Dr. Shafir did not put forward any persuasive medical studies to support this theory, and instead relied upon a “loose chain of circumstantial propositions” that were themselves insufficiently supported with reliable scientific evidence. *Id.* at *25. In this regard, the special master found Dr. Shafir’s medical theory

lacking because, among other things, certain medical literature offered to support this theory involved a different injury and vaccine than the injuries and vaccines at issue in this case. *Id.* The special master also found that the medical literature did not support petitioner's causation theory, because the literature "centered on a pathologic process reasonably understood to be autoimmune – something that cannot possibly be said for autism or developmental regression." *Id.* And so, the special master concluded that the gap between the science and Dr. Shafrir's expert opinion was "quite wide in this case." *Id.*

The special master also found petitioner's medical articles "were simply too broad in focus to constitute persuasive support" for Dr. Shafrir's causation theory. *Id.* In addition, the special master observed that petitioner's argument regarding post-vaccination symptoms leading to an encephalopathy bears a "striking similarity to theories universally rejected in the Vaccine Program," including in both autism cases and cases where petitioners sought compensation for post-vaccination encephalopathy accompanied by subsequent developmental regression. *Id.* at *26. And so, the special master concluded that petitioner's causation theory was unreliable and unpersuasive. *Id.*

Third, the special master determined that petitioner failed to establish that K.A.'s vaccines caused either an encephalopathy or seizures resulting in autism. *Id.* at *26-*27. In this regard, the special master recognized that, even if K.A. had experienced an encephalopathy, petitioner would not be entitled to compensation in this case because "[t]here is no evidence in the record that K.A. was undergoing an autoimmune process of the kind [that petitioner's] causation theory suggests he should have been experiencing." *Id.* at *26. Notably, the special master observed that K.A.'s first seizure episode on July 12, 2003, occurred before the first vaccinations that petitioner claims resulted in an encephalopathy on July 28, 2003. *Id.* at *27. And so, the special master determined that, to the extent that K.A.'s treating physicians recommended spreading out K.A.'s vaccinations, this decision was "based on parental concerns about possible negative effects" and had "no [scientific] explanation at all." *Id.* (emphasis original).

Fourth, the special master determined that petitioner had not shown that the timeframe for the development of K.A.'s injuries was medically acceptable. *Id.* at *27-*28. Specifically, the special master observed that the scientific literature provided by Dr. Shafrir was inconsistent

with K.A.'s reaction and that "[t]hese inconsistencies are not adequately resolved in Dr. Shafrir's reports." *Id.* at *27.

The special master also observed that, in light of the incontrovertible facts from K.A.'s medical history "it is impossible to discern an explanation in this case that can credibly and persuasively harmonize the varying response times at issue." *Id.* at *28. In this regard, the special master also observed that K.A. experienced seizure symptoms on the same day as the July 28, 2003, vaccinations; none following the October 2003 vaccinations; one week after the December 15, 2003 vaccinations; and one month after the two June 2004 vaccinations. *Id.* The special master further observed that petitioner did not explain why there was no evidence of developmental regression with regards to K.A. before July 2004—a year after the first alleged reaction to a vaccine. *Id.* And so, the special master concluded that petitioner had not established a "reasonable, reliable framework" to explain the inconsistencies regarding the timing of K.A.'s symptoms. *Id.*

Lastly, the special master determined that an evidentiary hearing was not necessary in this case, because the written record was "expansive and contained sufficient evidence" to resolve petitioner's claim. *Id.* The special master also observed that Dr. Shafrir "offered opinions regarding autism or developmental regressions as a vaccine injury - consistent with theories that have previously been deemed scientifically unreliable and unpersuasive." *Id.* Given this, the special master found an evidentiary hearing to be unnecessary, because he had already heard Dr. Shafrir's testimony in a similar context in another case. *Id.* And so, the special master declined petitioner's request to hold an evidentiary hearing. *Id.*

B. Procedural Background

On June 14, 2018, petitioner filed a motion for review of the special master's May 15, 2018, Decision and a motion for leave to file a memorandum exceeding 20 pages accompanying a motion for review. *See generally* Pet'r Mot. for Rev.; Pet'r Mot. for Leave. On July 16, 2018, the Secretary filed a response to petitioner's motion for review. *See generally* Resp't Resp.

III. STANDARDS FOR DECISION

A. Vaccine Act Claims

The United States Court of Federal Claims has jurisdiction to review the record of the proceedings before a special master and, upon such review, may:

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa–12(e)(2).

The special master's determinations of law are reviewed *de novo*. *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009). The special master's findings of fact are reviewed for clear error. *Id.* (citation omitted); *see also Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (“We uphold the special master's findings of fact unless they are arbitrary or capricious.”) The special master's discretionary rulings are reviewed for abuse of discretion. *Munn v. Sec'y of Dep't of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

In addition, a special master's findings regarding the probative value of the evidence and the credibility of witnesses will not be disturbed so long as they are “supported by substantial evidence.” *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citation omitted); *see also Burns by Burns v. Sec'y of Dep't of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is “uniquely within the purview of the special master”). This “level of deference is especially apt in a case in which the medical evidence of causation is in dispute.” *Hodges v. Sec'y of Dep't of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). And so, the Court will not substitute its judgment for that of the special master, “if the special master has considered all relevant factors, and has made no clear

error of judgment.” *Loneragan v. Sec’y of Dep’t of Health & Human Servs.*, 27 Fed. Cl. 579, 580 (1993).

Under the Vaccine Act, the Court must award compensation if a petitioner proves, by a preponderance of the evidence, all of the elements set forth in 42 U.S.C. § 300aa–13(a)(1). A petitioner can recover either by proving an injury listed on the Vaccine Injury Table (the “Table”), or by proving causation-in-fact. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C)(i)-(ii); *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). And so, to receive compensation under the National Vaccine Injury Compensation Program, a petitioner must prove either that: (1) the petitioner suffered a “Table Injury” that corresponds to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) the petitioner’s illnesses were actually caused by a vaccine. *See* 42 U.S.C. §§ 300aa–11(c)(1)(C)(i)-(ii), 300aa–14(a); *see also Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006).

In addition, in Table and non-Table cases, a petitioner bears “a preponderance of the evidence” burden of proof. 42 U.S.C. § 300aa–13(a)(1)(A); *Althen*, 418 F.3d at 1278 (citing *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)). And so, a petitioner must offer evidence that leads the “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact’s existence.” *Moberly*, 592 F.3d at 1322 n.2 (brackets existing) (citations omitted); *see also Snowbank Enters. v. United States*, 6 Cl. Ct. 476, 486 (1984) (finding that mere conjecture or speculation is insufficient under a preponderance standard).

To establish a prima facie case, a petitioner must “prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface*, 165 F.3d at 1352. In addition, petitioner must prove by a preponderance of the evidence: “(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. But, medical or scientific certainty is not required. *Knudsen by Knudsen v. Sec’y of Dep’t of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994).

The Federal Circuit addressed the three elements to prove causation-in-fact in *Althen*. *Althen*, 418 F.3d at 1278. The Federal Circuit has also held that all three of these elements “must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). In addition, if a petitioner establishes a *prima facie* case, the burden shifts to the respondent to show, by a preponderance of the evidence, that the injury was caused by a factor unrelated to the vaccine. *See* 42 U.S.C. § 300aa–13(a)(1)(B); *Shalala v. Whitecotton*, 514 U.S. 268, 270–71 (1995). But, regardless of whether the burden of proof shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case. *See Stone v. Sec’y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[E]vidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a *prima facie* showing has been made that the vaccine was a substantial factor in causing the injury in question.”); *De Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1353 (Fed. Cir. 2008) (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner’s evidence on a requisite element of the petitioner’s case[-]in-chief.”).

B. Vaccine Rule 8

Vaccine Rule 8(d) provides that,

[a] special master may decide a case on the basis of written submissions without conducting an evidentiary hearing. Submissions may include a motion for summary judgment, in which event the procedures set forth in RCFC 56 will apply.

RCFC App. B, Vaccine Rule 8(d) (“Vaccine Rule”); *see also Simanski v. Sec’y of Dept. of Health & Human Servs.*, 671 F.3d 1368, 1371 (Fed. Cir. 2012) (Noting that “the Vaccine Rules provide that the special masters can decide cases on written submissions, including, in appropriate cases, by summary judgment.”).

Vaccine Rule 8(f) addresses the waiver of a fact or argument on review of a special master’s decision. Specifically, this rule provides that:

(f) Waiver of a Fact or Argument.

(1) In General. Any fact or argument not raised specifically in the record before the special master will be considered waived and cannot be raised by either party in proceedings on review of a special master's decision.

(2) Exception. This rule does not apply to legal arguments raised by the party that stands in the role of the appellee on review.

Vaccine Rule 8(f). The Federal Circuit has held that any argument that is not raised specifically in the record before the special master will be considered waived under Vaccine Rule 8(f) and cannot be raised by either party in proceedings on review of a special master's decision. *Davis v. Sec'y of Health & Human Servs.*, 409 Fed. App'x 342, 344 (Fed. Cir. 2011) (declining to consider arguments challenging the constitutionality of the Vaccine Act's statute of limitations on appeal because the arguments were not raised before the special master); *Weddel v. Sec'y of Dep't of Health & Human Servs.*, 23 F.3d 390, 390 n.2 (Fed. Cir. 1994) (noting that any argument not raised before the special master shall be considered waived under Vaccine Rule 8(f)); *see also McMillan v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 357, 358-59 (1992) (holding that respondent waived his right to raise specific objections to a fee petition under Vaccine Rule 8(f), when respondent failed to raise any objections to the petition during the proceedings before the special master).

IV. LEGAL ANALYSIS

In her motion for review, petitioner raises four objections to the special master's May 15, 2018, Decision denying her claim for compensation. First, petitioner argues that the special master abused his discretion by ignoring or incorrectly representing and interpreting factual matters in finding that: (1) there was no connection between K.A.'s post-vaccine seizures and his neurological decline; (2) imposing an inflexible requirement for an appropriate time frame between K.A.'s vaccinations and seizures; and (3) finding that K.A.'s treating physicians rejected the role of the vaccinations in causing K.A.'s seizures. Pet'r Mem. at 20-26. Second, petitioner argues that the special master abused his discretion by improperly classifying K.A.'s case as an autism case and inappropriately analyzing the facts of the case. *Id.* at 26-28. Third, petitioner argues that the special master abused his discretion by finding that K.A. had not experienced an encephalopathy. *Id.* at 28-31. Lastly, petitioner argues that the special master

abused his discretion by declining to hold a hearing on the issue of entitlement to compensation in this case. *Id.* at 31-33.

In addition, petitioner maintains that she is entitled to compensation under the Vaccine Act because she has met her burden to prove causation under *Althen*. *Id.* at 33-38. Petitioner has also filed a motion for leave to exceed the page limitations of a memorandum in support of her motion for review of the special master's decision. *See generally* Pet'r Mot. for Leave. As relief, petitioner requests that the Court either set aside the special master's May 15, 2018, Decision and grant her claim for compensation, or, alternatively, hold an evidentiary hearing in this matter. Pet'r Mem. at 40.

The Secretary counters that the special master correctly determined that the evidentiary record in this matter does not support petitioner's claim that K.A. suffered a post-vaccination encephalopathy and that petitioner failed to show that K.A.'s vaccinations can, or did, cause his injuries. Resp't Resp. at 9-16. Specifically, the Secretary argues that the special master appropriately dismissed this matter based upon the evidentiary record because, among other things, K.A.'s medical records do not contain sufficient evidence to show that K.A. suffered the characteristic symptomology of an encephalopathy and these records also reveal temporal irregularities with respect to the timing of K.A.'s vaccinations and the onset of his seizures. *Id.* at 12-14. The Secretary also argues that the special master did not abuse his discretion in resolving this matter without holding an evidentiary hearing, because the evidentiary record contains sufficient evidence upon which the special master could base his decision. *Id.* at 17-19. And so, the Secretary requests that the Court deny petitioner's motion for review and sustain the decision of the special master. *Id.* at 19-20.

For the reasons discussed below, the evidentiary record before the Court shows that the special master did not abuse his discretion, or act contrary to law, in reaching the decision to deny petitioner's Vaccine Act claim and to dismiss this matter based upon the record evidence. And so, the Court: (1) **GRANTS** petitioner's motion for leave to exceed the page limitations; (2) **DENIES** petitioner's motion for review of the special master's May 15, 2018, Decision; and (3) **SUSTAINS** the decision of the special master.

A. Petitioner's Objections To The Special Master's Findings Of Fact Are Not Supported By The Evidentiary Record

1. The Special Master Reasonably Found No Connection Between K.A.'s Seizures And The Vaccinations

As an initial matter, petitioner's objection that the special master abused his discretion in finding no connection between K.A.'s post-vaccination seizures and his neurological decline—and in finding that K.A. had not experienced an encephalopathy—is not supported by the record evidence. The Court reviews the special master's findings of fact for clear error. *Andreu*, 569 F.3d at 1373.

In the May 15, 2018, Decision, the special master found that petitioner's Vaccine Act claim depended upon a factual finding that K.A. suffered from a post-vaccination encephalopathy in 2003 or 2004. *Austin*, 2018 WL 3238608, at *23. To determine whether K.A. had in fact suffered an encephalopathy during this time period, the special master examined K.A.'s medical records during the 2003 and 2004 time period for evidence showing that K.A. experienced common symptoms indicative of an encephalopathy, including crying, anorexia, insomnia, fever, irritability, or depression. *Id.* at *23-*24. As a result of this review, the special master determined that there was no evidence of any such symptoms in the medical records. *Id.* at *24. And so, the special master concluded that K.A. had not experienced an encephalopathy.

The special master's finding is supported by the record evidence. As the special master observed in the May 15, 2018, Decision, K.A.'s medical records during the time of the July 28, 2003, vaccinations showed that: (1) K.A. appeared "healthy and normal" before, during, and immediately after his vaccinations; (2) K.A.'s July 28, 2003, EEG and MRI test results showed no signs of neurological damage; and (3) K.A.'s neurologist, Dr. James Sears, concluded that K.A.'s seizures were unlikely to have been caused by the vaccines. *Id.*; Pet'r Ex. 8 at 30; Pet'r Ex. 11 at 53; Pet'r Ex. 14 at 5. The record evidence is also devoid of any evidence to show that K.A. suffered an encephalopathy after receiving another vaccination on December 15, 2003. *Austin*, 2018 WL 3238608, at *24; Pet'r Ex. 8 at 11. In addition, K.A.'s June 2004 medical records similarly contain no evidence indicating an encephalopathy. Pet'r Ex. 14 at 35-36. And so, the special master's finding that K.A. did not experience an encephalopathy during 2003 and 2004 is supported by the record evidence in this case.

Petitioner's claim that the special master ignored key evidence in making this factual finding also lacks evidentiary support. In petitioner's memorandum in support of her motion for

review, petitioner argues that the special master ignored facts in determining that K.A. did not suffer an encephalopathy regarding K.A.'s development, namely: (1) K.A.'s loss of language in June 2004; (2) K.A.'s decreased attention span; and (3) Dr. Michael Ross's report that K.A. had seizures and episodes of blank staring in July 2004. Pet'r Mem. at 21. But, a careful review of the record evidence makes clear that the special master specifically addresses this evidence in the May 15, 2018, Decision and he concluded that K.A.'s developmental issues were too distant in time from the vaccinations that K.A. received to support a finding of a post-vaccination encephalopathy. *Austin*, 2018 WL 3238608, at *24 n.23 (distinguishing cases where a claimant successfully established an encephalopathy from the record in this matter, which contains no evidence "establishing any sort of proximate temporal reaction to the vaccines" supportive of a finding of an encephalopathy).

Given this, the record evidence shows that the special master carefully considered and analyzed the facts contained in K.A.'s medical records regarding K.A.'s neurological condition before finding that K.A. did not suffer an encephalopathy during 2003 and 2004. And so, the Court concludes that the special master did not err in making this finding and that the special master reasonably determined that "[t]he overall record simply does not support the conclusion that K.A. ever experienced a post-vaccination encephalopathy at any time." *Id.* at *24.

2. The Special Master Properly Considered The Factual Record In Examining The Time Frame Between K.A.'s Vaccinations And Seizures

Petitioner's claim that the special master ignored facts and abused his discretion by finding that the timeframe for the development of K.A.'s injuries was not medically acceptable is also unsubstantiated by the evidentiary record. Pet'r Mem. at 22-24. In the May 15, 2018, Decision, the special master determined that petitioner had not shown that the timeframe for the development of K.A.'s injuries was medically acceptable, because of the wide variances between the timing of K.A.'s vaccines and the onset of K.A.'s symptoms. *Austin*, 2018 WL 3238608, at *27-*28. Specifically, the special master found that the medical records showed that K.A. experienced: (1) seizure symptoms on the same day that he received the July 28, 2003 vaccinations; (2) no seizures following the October 2003, vaccinations; (3) seizures one week after the December 15, 2003, vaccinations; and (4) seizures one month after receiving vaccinations in June 2004. *Id.* at *28. The special master also observed that petitioner provided no explanation for why there was no evidence of developmental regression in K.A.'s medical

history before July 2004—a year after K.A.’s first alleged reaction to a vaccine. *Id.* And so, the special master reasonably concluded that, in light of the incontrovertible facts in K.A.’s medical history, “it is impossible to discern an explanation in this case that can credibly and persuasively harmonize the varying response times at issue.” *Id.*

The Court is also unpersuaded by petitioner’s argument that the special master incorrectly interpreted her construction of the facts in this case to support a “rechallenge scenario” and that the special master improperly discounted that K.A. was receiving significant doses of the seizure medication phenobarbital in finding that petitioner failed to establish a medically acceptable time frame. Pet’r Mem. at 22.

First, to the extent that petitioner seeks to argue that K.A.’s medications impacted the timing of the onset of his post-vaccination seizures, petitioner has waived this argument, because she did not present the argument during the proceedings before the special master. *Id.*; *see generally* Pet’r Am. Pet. It is well-established that Vaccine Rule 8(f) provides that any fact or argument not raised by the party before the special master cannot be considered on review by this Court. Vaccine Rule 8(f); *see, e.g., Davis*, 409 Fed. App’x. at 344. The evidentiary record here contains no evidence to indicate that petitioner argued that phenobarbital impacted the time frame for development of K.A.’s injuries. *See generally* docket no. 94, 124. And so, petitioner may not raise this argument on review.

In addition, while petitioner argues that the special master incorrectly imposed a “hard and fast rule for temporal proximity of injury to vaccination” to fit a challenge-rechallenge scenario, a careful reading of the May 15, 2018, Decision shows that the special master did not categorize petitioner’s argument as supportive of a rechallenge scenario. *Austin*, 2018 WL 3238608, at *28. Rather, the special master simply observed that the irregularity in the timing of the onset of K.A.’s seizures following the vaccinations did not make sense within the context of a “‘challenge-rechallenge’ theory, where reactions to a series of vaccines should occur in increasingly shorter intervals.” *Id.* And so, again, the record evidence shows that the special master reasonably determined that petitioner did not establish a medically acceptable timeframe for the development of K.A.’s injuries.

3. The Special Master Properly Found That K.A.'s Treating Physicians Rejected The View That K.A.'s Vaccinations Caused His Seizures

Lastly, petitioner claims that the special master ignored facts and abused his discretion in finding that K.A.'s doctors rejected her theory that the subject vaccinations caused K.A.'s seizures is also not supported by the record evidence. In petitioner's memorandum in support of the motion for review, petitioner points to certain statements made by several of K.A.'s doctors to demonstrate that these physicians believed that K.A.'s vaccinations were a possible cause of his symptoms. Pet'r Mem. at 24-26. Specifically, petitioner argues that the examination notes of K.A.'s physician, Dr. Stephen Rioux, show that Dr. Rioux believed it was possible that K.A.'s immunizations were responsible for the timing of K.A.'s seizures. *Id.* at 24-25. Petitioner also correctly notes that Dr. Rioux's handwritten notes state that "if possible spread immunizations out over time to reduce stimulus to immune system. This may reduce risk of seizures." Pet'r Ex. 8 at 21.

But, as the special master observed in the May 15, 2018, Decision, the record evidence includes several other notes written by Dr. Rioux that negate the possibility that the vaccines actually caused K.A.'s seizure activity. *Id.* For example, the record evidence shows that Dr. Rioux qualified the statement that it was possible that K.A.'s immunizations lowered his seizure threshold, by noting that it was "*unlikely that . . . these interventions or agents are responsible for his ongoing seizure difficulties.*" Pet'r Ex. 5 at 7 (emphasis supplied); *Austin*, 2018 WL 3238608, at *4. The record evidence also shows that K.A.'s parents encouraged Dr. Rioux and other physicians to adjust K.A.'s vaccine schedule and that this encouragement—rather than a belief that the vaccines actually caused K.A.'s seizures—heavily influenced Dr. Rioux's recommendation to spread out K.A.'s vaccinations. Pet'r Ex. 14 at 8; Pet'r Ex. 8 at 20-21; Pet'r Ex. 5 at 7-8. Given this evidence, the special master reasonably determined that Dr. Rioux did not find that K.A.'s vaccines had a causal relationship to his seizures. *Austin*, 2018 WL 3238608, at *27.

Petitioner's argument that the special master misconstrued the medical notes of Dr. Fran Kendall is also unsubstantiated by the record evidence. *Austin*, 2018 WL 3238608, at *7 (citing Pet'r Ex. 29 at 1). Petitioner argues that Dr. Kendall's statement in the examination notes dated February 16, 2005, that "while the onset of [K.A.'s] symptoms appear to be temporally related to his vaccines, the science is not sophisticated enough to prove any absolute [theory] as to why this

regression would occur in mitochondrial disease other than due to immunological stress,” shows that Dr. Kendall believed that “immunological stress” explained how the vaccines may have caused K.A.’s seizures. Pet’r Mem. at 25-26; Pet’r Ex. 29 at 4. But, Dr. Kendall refutes petitioner’s theory of causation in these medical notes by acknowledging that the “science is not sophisticated enough” to prove that K.A. suffered from anything other than immunological stress. Pet’r Ex. 29 at 4. Dr. Kendall also observes in these notes that K.A.’s condition ultimately “offers no clear [proof] of causation.” *Id.* And so, the record evidence supports the special master’s finding that Dr. Kendall believed that “no clear proof of causation” existed between K.A.’s vaccinations and his seizures. *Austin*, 2018 WL 3238608, at *7.

Petitioner’s claim that the special master ignored key facts regarding the findings of Dr. John Hickey and Dr. Melissa Burch are similarly without merit. In petitioner’s memorandum in support of the motion for review, petitioner argues that that the special master erroneously disregarded: (1) key observations made by K.A.’s pediatrician, Dr. Hickey, in a March 4, 2004 note to “wait for clearance from Dr. Rioux” before giving K.A. his MMR and Varicella-Zoster Virus (“VZV”) vaccinations and (2) Dr. Burch’s advice that K.A. should “wait on MMR and VZV”. Pet’r Mem. at 26; Pet’r Ex. 8 at 14; Pet’r Ex. 6 at 3. But, there is no evidence in the record to show that Dr. Hickey disagreed with Dr. Rioux’s assessment that K.A.’s vaccinations did not cause seizure symptoms. *See generally* Pet’r Ex. 8. A review of the evidentiary record also makes clear that Dr. Burch’s March 3, 2005, handwritten note does not state that the vaccines caused K.A.’s seizures. Pet’r Ex. 6 at 3. In light of this evidence, the Court concludes that the special master did not err in declining to cite to the statements of Dr. Hickey and Dr. Burch in the May 15, 2018, Decision.

Finally, petitioner’s argument that the special master ignored key facts regarding the findings of Dr. Cheryl Garganta must also fail. Petitioner correctly observes that Dr. Garganta described K.A. as a “young boy with autism who had neurological changes and regression after 2 different immunizations.” Pet’r Mem. at 26 (quoting Pet’r Ex. 4 at 3). But, the evidentiary record makes clear that Dr. Garganta also noted in her examination notes that, “I did reassure them that [K.A.’s] health problems... were very unlikely to be related to his immunizations.” Pet’r Ex. 4 at 13. And so, again, the special master’s finding that Dr. Garganta also believed that “K.A.’s health problems were unrelated to his immunizations” is supported by the record evidence. *Austin*, 2018 WL 3238608, at *6.

Because the record evidence supports the special master's finding that K.A.'s doctors did not believe the vaccination caused his seizures, the Court will not disturb the findings of the special master.

B. The Special Master Did Not Classify Or Analyze This Matter As An Autism Case

Petitioner's second objection—that the special master improperly classified and analyzed this matter as an autism case—is equally unavailing. Pet'r Mem. at 26-28. In petitioner's memorandum in support of the motion for review, petitioner argues that the special master “arbitrarily interpreted the medical record as supportive of autism” and ignored evidence regarding K.A.'s post-vaccination seizures in determining whether K. A. experienced an encephalopathy. *Id.* at 27-28. But, a review of the May 15, 2018, Decision and the record evidence makes clear that the special master did not analyze this matter as an autism case, nor did the special master address K.A.'s autism when he analyzed petitioner's claims and concluded that K.A. did not suffer from a vaccine-induced encephalopathy. *Austin*, 2018 WL 3238608, at *23-*27.

Indeed, while it is undisputed that K.A. was diagnosed with autism in 2004, the special master focused his analysis on whether there was evidence in K.A.'s medical records to show that K.A. experienced an encephalopathy during 2003 and 2004. *Austin*, 2018 WL 3238608, at *24; Pet'r Ex. 25 at 11-12. In doing so, the special master reasonably concluded that the medical records did not support a finding that K.A. experienced an encephalopathy after his July 28, 2003, vaccinations, or after any subsequent vaccinations. *Austin*, 2018 WL 3238608, at *24. In addition, the May 15, 2018, Decision makes clear that the special master cited to several autism cases in connection with the discussion of petitioner's causation theory solely for the purpose of explaining why, in comparison, petitioner's causation theory in this case was unpersuasive. *Id.* at *26. In this regard the special master observed in the May 15, 2018, Decision that petitioner's causation theory was “strikingly similar” to theories universally rejected in the Vaccine Program for autism cases and he cited to, among other cases, *Hardy v. Sec'y of Health & Human Servs.*, No. 08-108V, 2015 WL 7732603, at *4-*5 (Fed. Cl. Spec. Mstr. Nov. 3, 2015). *Id.* There is no indication in the record evidence, however, that the special master analyzed this matter as an autism case. And so, the evidentiary record simply does not substantiate petitioner's objection.

C. The Special Master Did Not Abuse His Discretion In Finding that K.A. Had Not Experienced An Encephalopathy

For many of the same reasons, petitioner's third objection—that the special master abused his discretion in evaluating the evidence related to the issue of whether K.A. experienced an encephalopathy—is also unsubstantiated by the record evidence. Petitioner argues in her memorandum in support of the motion for review for the first time that K.A. satisfies the criteria set forth in the *Graus* paper for: (1) “subacute onset” and “altered mental status” and (2) “seizures not explained by a previously known seizure disorder.” Pet'r Mem. at 29. And so, petitioner further argues that the special master erred by not considering the theory articulated in the *Graus* paper in analyzing her Vaccine Act claim. *Id.* at 30-31. Petitioner's argument lacks merit for two reasons.

First, to the extent that petitioner seeks to rely upon the *Graus* paper to support her claim for compensation, she has waived this argument by failing to adequately present it before the special master. As discussed above, under Vaccine Rule 8(f) any fact or argument not raised by the party before the special master cannot be considered on review by this Court. Vaccine Rule 8(f); *see, e.g., Davis*, 409 Fed. App'x. at 344. In this case, petitioner does not point to—and the Court does not find—any evidence in the record to show that petitioner presented an argument regarding the application of the *Graus* paper to the facts of this case during the proceeding before the special master. Pet'r Mem. 30-31; *see generally* docket no. 94, 124. In fact, the evidentiary record makes clear that petitioner did not submit the *Graus* paper as evidence during the proceedings before the special master. *See generally* docket no. 94, 124. Given this, petitioner cannot properly present the argument that K.A. satisfies the criteria set forth in the *Graus* paper on review. Vaccine Rule 8(f); *Davis*, 409 Fed. App'x. at 344.

Second, as discussed above, a careful review of the record evidence also shows that the special master reasonably determined that K.A. did not suffer an encephalopathy. K.A.'s medical records show that K.A. appeared to be “healthy and normal” before, during, and immediately after his July 28, 2003, vaccination, and that K.A.'s July 28, 2003, EEG and MRI tests showed no signs of neurological damage. *Austin*, 2018 WL 3238608, at *24 (citing Pet'r Ex. 8 at 30, 57; Pet'r Ex. 11 at 53; Pet'r Ex. 14 at 5). In addition, as the special master observed in the May 15, 2018, Decision, K.A.'s neurologist specifically noted at the time that K.A.'s July 2003 seizures were unlikely to have been caused by the vaccines. *Id.* (citing Pet'r Ex. 5 at 7).

Notably, the special master observed that K.A.'s June 2004 medical records lacked evidence of symptoms "that could be interpreted as indicia of encephalopathy." *Id.* (citing Pet'r Ex. 14 at 35-36). And so, the Court sustains the special master's reasonable conclusion that "[t]he overall record simply does not support the conclusion that K.A. ever experienced a post-vaccination encephalopathy at any time." *Id.*

D. The Special Master Reasonably Declined To Hold An Entitlement Hearing

The evidentiary record in this matters also makes clear that the special master did not abuse his discretion in declining to hold an entitlement hearing before resolving petitioner's Vaccine Act claim. *Munn*, 970 F.2d at 870 n.10. Petitioner argues in her memorandum in support of the motion for review that the special master should have held an entitlement hearing in this case because K.A.'s medical condition and the medical theory put forward by petitioner's medical expert are complex. Pet'r Mem. at 32-33. But, as petitioner acknowledges, the Vaccine Act and the Vaccine Rules endow the special master with broad discretion in determining whether to hold an entitlement hearing. *Id.* at 32.

In this case, the special master reasonably declined to hold an entitlement hearing because there was an extensive and detailed evidentiary record already before him. As the special master observed in the May 15, 2018, Decision, the record evidence in this case includes, medical records from several of K.A.'s treating physicians, numerous medical articles submitted by petitioner, two expert reports from petitioner's medical expert, an expert report from the Secretary's expert, and the parties' briefs in connection with the Secretary's motion for a ruling on the record dismissing the petition. *Austin*, 2018 WL 3238608, at *28; docket entry nos. 72; 89; 90; 94-98; 102; 105-107. As the special master also observed in the May 15, 2018, Decision, petitioner received several extensions of time to obtain a medical expert and to formulate her causation theory in this case. *Id.*; see docket entry nos. 66, 69, 71 and 79. And so, the ample evidentiary record provided an adequate basis for the special master to resolve this dispute.

In addition, while petitioner correctly argues that her medical expert did not have the opportunity to provide oral testimony during the proceedings before the special master, the special master reasonably concluded that he did not need to consider this oral testimony because the special master had previously considered similar testimony by petitioner's medical expert and there was no need to obtain information not contained in the evidentiary record. *Austin*,

2018 WL 3238608, at *28. Given the extensive medical evidence and written expert testimony before the special master, the special master properly exercised his discretion in determining that a hearing was not necessary to resolve petitioner's claim. *Austin*, 2018 WL 3238608, at *28-29; 42 U.S.C. 300aa-12(d); Vaccine Rule 8(d).² And so, the Court will not set aside the special master's sound decision.

E. Petitioner Has Not Proven That She Is Entitled To Compensation

As a final matter, petitioner also has not met her burden to prove that she is entitled to compensation in this Vaccine Act case. *Althen*, 418 F.3d at 1278. In petitioner's memorandum in support of the motion for review, petitioner alleges that she is entitled to receive compensation on behalf of K.A. because she has satisfied all three prongs under *Althen*. Pet'r Mem. at 33-40. Alternatively, she requests that the Court conduct an entitlement hearing on her claim. *Id.* at 40.

Petitioner's argument is not substantiated by the evidentiary record. As discussed above, the record evidence in this case shows that K.A. did not experience an encephalopathy at any time since his first vaccinations in July 2003. Pet'r Ex. 5 at 7; Pet'r Ex. 8 at 14, 30, 57; Pet'r Ex. 11 at 53-54; Pet'r Ex. 14 at 3-6, 26, 36-37. And so, as a threshold matter, petitioner has not established that K.A. experienced an encephalopathy that could be connected to any of his vaccinations.

Petitioner has similarly failed to put forward a plausible medical theory showing that any of K.A.'s vaccinations caused an encephalopathy. *Althen*, 418 F.3d at 1278 (holding that, under Prong 1 of the *Althen* standard, petitioner must establish by a preponderance of the evidence "a medical theory causally connecting the vaccination and the injury" (citation omitted)). As the special master observed in the May 15, 2018, Decision, Dr. Shafrir did not put forward any persuasive medical studies to support the theory that a component in the DTaP vaccine could initiate an autoimmune process and thereby produce an encephalopathy sufficient to result in developmental regression one year later. *Austin*, 2018 WL 3238608, at *24. Notably, some of the medical literature that Dr. Shafrir offered to support this theory involved a different injury and vaccine than the vaccines and injuries at issue in this case. *Austin*, 2018 WL 3238608, at *25; docket entry no. 96, attachment 4 (discussing the flu vaccine and narcolepsy).

² For these same reasons, petitioner has not shown that she is not entitled to an entitlement hearing on her claims on review.

And so, the Court concurs with the special master's conclusion that a wide gap exists between the science and Dr. Shafir's expert opinion on causation. *Austin*, 2018 WL 3238608, at *25.

Petitioner also has not established 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 (citations omitted). As discussed above, the special master found no evidence in the record to show that K.A. experienced the kind of autoimmune process that is contemplated by petitioner's causation theory. *Austin*, 2018 WL 3238608, at *26. More importantly, the special master correctly noted in the May 15, 2018, Decision that there is evidence in the record to suggest that K.A. actually experienced seizure-like symptoms *before* he received his first set of vaccinations on July 28, 2003—thus, further calling into doubt petitioner's causation theory. *Id.* at *27 (emphasis supplied). Given this, the Court does not find that the record evidence supports a logical sequence of cause and effect favoring causation in this case.

Lastly, petitioner also fails to show "a proximate temporal relationship between vaccination and injury" in this case. *Althen*, 418 F.3d at 1278. The scientific literature provided by Dr. Shafir to support petitioner's causation theory indicates that a reaction to the vaccines at issue could not have occurred in the brief timeframe between K.A.'s July 2003, vaccinations and the subsequent acute onset of his seizures. Pet'r Ex. 35 at 5. In addition, as discussed above, K.A.'s medical records make clear that K.A. experienced seizure symptoms a varying periods of time after receiving the subject vaccinations, and petitioner provides no explanation for why there was no evidence of developmental regression in K.A.'s medical history before July 2004. Given these concerns, petitioner simply has not established a reasonable and reliable framework to explain the inconsistencies regarding the timing of the onset of K.A.'s symptoms following the vaccinations. And so, the Court sustains the sound decision of the special master to deny compensation in this case.

V. CONCLUSION

In sum, the evidentiary record before the Court shows that the special master did not abuse his discretion, or act contrary to law, in finding that: (1) there was no connection between K.A.'s post-vaccination seizures and his neurological decline; (2) petitioner failed to show a medically acceptable timeframe for the onset of K.A.'s symptoms; and (3) K.A.'s treating physicians rejected the role of the vaccinations in causing K.A.'s seizures. In addition, the record evidence also shows that the special master did not classify or analyze this matter as an

autism case, nor abuse his discretion in finding that K.A. had not experienced an encephalopathy and that the special master reasonably declined to hold an entitlement hearing. Finally, petitioner has not met her burden to prove that she is entitled to compensation on behalf of K.A. in this Vaccine Act case. Pet'r Mem. at 33-40.

And so, for the forgoing reasons, the Court:

- (1) **GRANTS** petitioner's motion for leave to exceed the page limitations;
- (2) **DENIES** petitioner's motion for review of the special master's May 15, 2018, Decision; and
- (3) **SUSTAINS** the decision of the special master.

The Clerk shall enter judgment accordingly.

Some of the information contained in this Memorandum Opinion and Order may be considered privileged, confidential or sensitive personally-identifiable information that should be protected from disclosure. And so, this Memorandum Opinion and Order shall be **FILED UNDER SEAL**. The parties shall review the Memorandum Opinion and Order to determine whether, in their view, any information should be redacted prior to publication. The parties shall also **FILE**, by **November 26, 2018**, a joint status report identifying the information, if any, that they contend should be redacted, together with an explanation of the basis for each proposed redaction.

IT IS SO ORDERED.

s/Lydia Kay Griggsby
LYDIA KAY GRIGGSBY
Judge