In the United States Court of Federal Claims

FOR PUBLICATION

No. 16-1494V
(Filed: March 13, 2023*)

EBONIE WEAVER, *parent of T.M., a minor*, *Petitioner*, v. **SECRETARY OF HEALTH AND HUMAN SERVICES**, *Respondent*.	)	Vaccine Act, 42 U.S.C. § 300aa-10 *et seq.*; Off-Table Causation-in-Fact & Significant Aggravation Claims; Complex Febrile Seizure; Abnormal Screenings; Epilepsy

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OPINION AND ORDER

BONILLA, Judge.

Petitioner Ebonie Weaver, parent of a minor child identified herein as T.M., seeks review of a decision of the United States Court of Federal Claims Office of Special Masters (OSM) denying entitlement under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 *et seq.* Ms. Weaver claims a vaccine-induced complex febrile seizure caused T.M. to develop a chronic seizure disorder and, concomitantly, significantly aggravated T.M.'s preexisting developmental delay.

* This decision was initially filed under seal on February 24, 2023, in accordance with Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims, to allow the parties to propose redactions based upon privacy concerns. No proposed redactions were filed.

For the reasons set forth below, the Court finds the Chief Special Master improperly elevated petitioner's burden of proof by requiring contemporaneous medical screening evidence documenting brain injury under a "seizures beget seizures" theory of causation. The legal error further extended to petitioner's significant aggravation claim. Accordingly, Ms. Weaver's motion is GRANTED, the decision of the OSM is REVERSED-IN-PART and VACATED-IN-PART, and this matter is REMANDED for further proceedings consistent with this opinion.

BACKGROUND

I. Medical History

T.M. was born on March 29, 2013. No complications were reported during delivery (at 39½ weeks) and her Apgar scores for appearance (skin color), pulse (heart rate), grimace (reflexes), activity (muscle tone), and respiration (breathing rate and effort) totaled 9 out of 10 after one minute and, again, after five minutes.[1] T.M. was discharged from the hospital on March 31, 2013. During her April 3, 2013 follow-up wellness visit, healthcare providers found five-day-old T.M. to be in good health.

On July 15, 2013, during her four-month wellness visit, T.M. received the following vaccines: diphtheria, tetanus, and acellular pertussis (DTaP) (1st dose); haemophilus influenzae type b (Hib) (1st dose); hepatitis B (HepB) (2nd dose); inactivated poliovirus (IPV) (1st dose); rotavirus (RV) (1st dose); and pneumococcal conjugate (PVC) (1st dose). During T.M.'s physical examination, the healthcare provider checked the "well child" box under "Assessment" on the medical form but noted "Developmental Delay." *See* ECF 7-4 at 8. When asked about T.M.'s developmental progress using the Ages and Stages Questionnaires® (ASQ),[2] Ms. Weaver reported T.M. was not meeting the following milestones: pushing up to elbows, symmetrical movement, and rolling and reaching for objects. The healthcare provider documented their impression as "ASQ – Delay but is not 4 mo[nth]s yet." *See* ECF 7-4 at 8.

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[1] *See* JOHNS HOPKINS ALL CHILDREN'S HOSPITAL, https://www.hopkinsallchildrens.org/Patients-Families/Health-Library/HealthDocNew/What-Is-the-Apgar-Score (last visited Feb. 22, 2023) ("A baby who scores a 7 or above on the test is considered in good health. . . . Ten is the highest score possible, but few babies get it. That's because most babies' hands and feet remain blue until they have warmed up.").

[2] The Ages and Stages Questionnaires® are a screening tool used to measure developmental progress in children between the ages of one month and five years. *See* AGES AND STAGES QUESTIONNAIRES, https://agesandstages.com/products-pricing/asq3/ (last visited Feb. 22, 2023).

On December 6 and 10, 2013, nine-month-old T.M. returned for her six-month wellness visit.[3] During the December 10, 2013 visit, Ms. Weaver reported T.M. "was doing everything normal until 4 months and now she is not doing much." *See* ECF 7-8 at 4; *see also* ECF 11-1 at 70. Documenting developmental milestones, the healthcare provider noted T.M. occasionally meets 9 of the 16 milestones, is "babbling – little" and "smiles at mom," but she does not sit alone, roll from front to back or vice versa, pass a toy from hand to hand, imitate beginning consonant sounds, or say "mama" or "dada." ECF 7-8 at 4. The healthcare provider referred T.M. to a developmental clinic for further evaluation and early intervention treatment. During the December 10, 2013 wellness visit, T.M. received the following vaccines: HepB (3rd dose); DTaP (2nd dose); Hib (2nd dose); IPV (2nd dose); PVC (2nd dose); and RV (2nd dose). ECF 7-8 at 6. That evening, T.M. developed a fever which Ms. Weaver treated with Tylenol.

On December 11, 2013 at approximately 2:00 a.m.–less than 24 hours after receiving the vaccines–T.M. was taken by ambulance to the emergency room and treated for a complex febrile seizure lasting 35 minutes. Ms. Weaver reported the following symptoms to the paramedics and hospital staff: grunting, body shakes, clenched hands, curled toes, pulsating limbs, heavy drooling, and eyes rolled upward.[4] When examined at 4:00 a.m., T.M. presented with fever and shaking and "seizure-like activity." *See* ECF 11-1 at 8. Showing signs of respiratory distress, T.M. was intubated and placed on a ventilator. T.M.'s bloodwork showed an abnormally high white blood cell count; a flu panel, Computed Tomography (CT or CAT) brain scan, and chest x-ray yielded negative results. T.M. was given antibiotics and transferred to another hospital for treatment in the facility's pediatric intensive care unit. Following her hospital transfer, T.M.'s fever broke and she was extubated with no further seizure activity. An electroencephalogram (EEG) of T.M.'s brain activity performed that afternoon was interpreted to be normal. During evening rounds, a treating physician documented the likely diagnosis as complex febrile seizure. T.M. was discharged the following day.

Six days later, on December 18, 2013, T.M. returned to the emergency room after experiencing three episodes of vomiting and diarrhea, but no reported fever or additional seizures. By this time, Ms. Weaver had filed a Vaccine Adverse Event Reporting System (VAERS) report suggesting a link between T.M.'s febrile seizure

[3] The December 10, 2013 follow-up visit was necessary after healthcare providers were unable to verify T.M.'s vaccine history on December 6, 2013; consequently, no vaccines could be administered during the initial check-up.

[4] T.M.'s father also reported that T.M.'s tongue was swollen and confirmed the excess drooling.

and her recent vaccinations.[5] T.M. was prescribed a nausea medication, instructed to stay hydrated, and discharged. During a January 14, 2014 wellness visit, the treating physician documented their assessment of T.M.'s December 11, 2013 episode as a "DTaP induced versus febrile seizure." *See* ECF 7-4 at 5.

On March 18, 2014, T.M. returned to the emergency room after suffering a second febrile seizure and remained hospitalized overnight for observation. Medical staff flagged T.M.'s "significant developmental delay" and urged Ms. Weaver to seek early intervention for T.M. through prescribed physical and occupational therapy. *See* ECF 7-7 at 241; *accord id.* at 239–40. In early April 2014, healthcare providers continued to raise concerns that T.M. was not meeting developmental milestones.

On May 1, 2014, T.M. suffered a third febrile seizure while at daycare and again transported by ambulance to the emergency room. According to her daycare provider, T.M. "began to shake, foam at the mouth, and her eyes rolled into the back of her head while [the teacher] was holding her." *See* ECF 7-1 at 2. Prior to her discharge later that day, T.M.'s body temperature measured 102.2 degrees. Over the following week, T.M. was evaluated by the Illinois Bureau of Early Intervention and a pediatric neurologist. She was diagnosed as suffering from "[e]pileptic seizures, [f]ebrile seizures, [s]taring spell, and [d]evelopmental delay." *See* ECF 7-2 at 10. T.M. was prescribed a low dose of the anti-epileptic drug Keppra.

During a May 13, 2014 wellness visit, Ms. Weaver reluctantly authorized the administration of three more vaccines: measles, mumps, and rubella (MMR) (1st dose); varicella/chickenpox (1st dose); and hepatitis A (HepA) (1st dose). Two months later, on July 3, 2014, T.M. underwent a two-hour EEG. The results were found "within normal limits and appropriate for [the] patient['s] age"; however, the entry under "[a]bnormalities" reads: "slow wave activity was present throughout the recording and was unresponsive to stimulation." ECF 7-2 at 43.

Through the fall of 2014, T.M.'s overall development showed few signs of improvement. During a September 4, 2014 wellness visit, 17-month-old T.M. did not meet *any* of the 11 evaluated developmental milestones.[6] Concerned the vaccinations were causing or contributing to T.M.'s continuing health issues, Ms. Weaver declined to authorize additional scheduled vaccinations for T.M.

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[5] Co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA), VAERS "is a national early warning system to detect possible safety problems in U.S.-licensed vaccines." *See* VAERS, https://vaers.hhs.gov/about.html (last visited Feb. 22, 2023).

[6] Although T.M. was reportedly "rolling more frequently" and "up on her knees," she was not yet crawling. *See* ECF 7-3 at 71. Moreover, the healthcare provider checked "no" for the following developmental milestones: vocabulary 3 to 6+ words; listens to story; points to one or more body parts; gestures what they want; understands simple commands; walks, stoops, climbs stairs; stacks blocks; feeds self with fingers; drinks from a cup; looks for fallen objects; and social play. *Id.*

On December 30, 2014, T.M. suffered a breakthrough seizure and returned to the emergency room. The seizure reportedly "last[ed] for about ten minutes [and] then resolved on its own." *See* ECF 7-9 at 5. Hospital staff attributed the episode to T.M. missing her morning dose of Keppra. By the time T.M. was examined by a doctor two hours after her arrival at the hospital, she had returned to her baseline and discharged. T.M.'s development showed no documented signs of improvement throughout 2015 and into 2016.

On May 8, 2016, T.M. experienced an active afebrile seizure and was taken to the emergency room. Medical staff attributed the episode to T.M.'s reported congestion, exposure to viral illness, and a missed Keppra dose. A continuous-video EEG identified the following abnormalities: absent posterior dominant rhythm (PDR); excessive beta activity; and diffuse slowing. The EEG report further noted: "EEG is consistent with a global encephalopathy and drug-induced fast activity."[7] *See* ECF 9-4 at 62. An August 16-17, 2016 follow-up ambulatory (24-hour) EEG revealed the following abnormalities: "regional epileptiform discharges involving the posterior quadrant maximal over midline parieto-occipital region." *Id.* at 293-94. The results were deemed "consistent with an active epileptogenic source in the midline parieto-occipital region [of the brain]." *Id.*

Since then, T.M. has experienced several afebrile seizures resulting in additional trips to the emergency room and, in at least one instance, being admitted to the hospital. In diagnosing T.M., healthcare providers generally offer non-vaccine related explanations (e.g., recurrent ear infections, missed Keppra doses, exploring alternative treatments). Her current diagnoses include epilepsy and global encephalopathy (i.e., global developmental delay). Nearing her 10th birthday, T.M.'s global and profound developmental delays continue. She remains nonverbal, wears diapers, and continues to experience seizures.

II. Petition and OSM Decision

Ms. Weaver's petition presents a causation claim and significant aggravation claim, asserting the December 10, 2013 vaccines administered to T.M. caused her seizure disorder and significantly worsened her developmental delays. In support of her causation claim, Ms. Weaver relies upon the "seizures beget seizures" theory, asserting that T.M.s' initial vaccine-induced febrile seizure lowered her seizure threshold, paving the way for her chronic seizure disorder. The resulting brain damage from the attributable seizures, Ms. Weaver continues, significantly aggravated T.M.'s preexisting developmental delays.

[7] "Encephalopathy is a term for any disease of the brain that alters brain function or structure." *See* NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE, https://www.ninds.nih.gov/health-information/disorders/encephalopathy#:~:text=Encephalopathy%20is%20a%20term%20for,increased%20pressure%20in%20the%20skull (last visited Feb. 22, 2023). Although the parties dispute the import of this diagnosis, the OSM decision under review makes no mention of the May 8, 2016 EEG.

On September 23, 2022, the OSM issued a decision denying entitlement. The Chief Special Master found the December 10, 2013 vaccinations were responsible for T.M.'s ensuing fever and at least contributed to her initial febrile seizure. Citing the "absence of evidence that [T.M.'s] brain was likely damaged by the first febrile seizure," however, the Chief Special Master concluded T.M.'s subsequent seizures were not likely attributable to the first. *Weaver v. Sec'y of Health & Hum. Servs.*, No. 16-1494V, 2022 WL 12542485, at *1 (Fed. Cl. Spec. Mstr. Sept. 23, 2022). The Chief Special Master also held Ms. Weaver failed to establish that T.M.'s preexisting developmental delays were significantly aggravated by her initial vaccine-induced febrile seizure.

DISCUSSION

I. Standard of Review

In reviewing a Vaccine Act decision, this Court 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
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> (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 Federal Circuit clarified the applicable standards of review as follows: findings of fact are reviewed under the arbitrary and capricious standard; discretionary rulings are reviewed under an abuse of discretion standard; and legal conclusions are reviewed *de novo* under the "not in accordance with law" standard. *Turner v. Sec'y of Health & Hum. Servs.*, 268 F.3d 1334, 1337 (Fed. Cir. 2001) (citing *Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)).

II. Causation-In-Fact

To prove causation-in-fact for an injury not listed in the Vaccine Injury Table, 42 U.S.C. § 300aa–14(a) ("off-Table injury"), a petitioner must demonstrate by preponderant 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 v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). To satisfy this burden, a petitioner need not prove their claim to a medical or scientific certainty; rather, they must simply show that it is "more likely than not" that the vaccine caused the injury. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1322 (Fed. Cir. 2010).

The three *Althen* prongs comprise an overlapping analysis determining whether a vaccine more likely than not caused injury. *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) ("[T]he statute requires only that the claimant show that it is more likely than not that *this claimant's* [injury] was caused by the vaccine.") (emphasis in original). Under the first prong, petitioner must provide a reputable medical or scientific explanation for their theory of causal connection. *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2009) (quoting *Moberly*, 592 F.3d at 1322). To satisfy the second prong, petitioner must show how the facts of their case align with the medical theory presented and demonstrate a logical connection between the vaccine and the injury (i.e., a logical sequence of cause and effect). *See Capizzano*, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'") (quoting *Althen*, 418 F.3d at 1280) (citing 42 U.S.C. § 300aa–13(a)(1)). Finally, the third prong requires petitioner to show the injury occurred within the expected time frame of the proposed medical theory. *See de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

In this case, the Chief Special Master found Ms. Weaver satisfied *Althen* prongs one and three. In addressing prong one, the Chief Special Master found that Ms. Weaver provided a credible medical theory demonstrating how vaccines can cause a febrile seizure and, in turn, how a febrile seizure can cause a chronic seizure disorder. *See Weaver*, 2022 WL 12542485, at *25 ("I can easily determine herein that almost *any* vaccine, alone or grouped with others, could cause sufficient inflammation to trigger a single febrile seizure.") (emphasis in original); *id.* at *27 ("I emphasize again—the contention that a vaccine-caused febrile seizure *could* constitute the first 'domino' in a chronic seizure disorder is scientifically reliable.") (emphasis in original). Regarding prong three, the Chief Special Master credited testimony demonstrating the requisite timing between T.M.'s vaccination and her complex febrile seizure. *See id.* at *12 ("Finally, Dr. Huq addressed the timeframe between T.M.'s vaccinations and her first seizure, deeming it consistent with the short interval for initial inflammatory changes (which could occur within 24 hours to a few days after vaccination)."). Neither of these conclusions are contested here.

Accordingly, the Court focuses on the determination that Ms. Weaver did not satisfy the second *Althen* prong.

A. Contemporaneous Evidence of Brain Injury

The Chief Special Master improperly elevated Ms. Weaver's burden of proof under *Althen* prong two. In denying compensation, the Chief Special Master focused on the absence of abnormal screening results evidencing brain injury contemporaneous with T.M.'s first febrile seizure, finding:

> [T]he medical record *in this case* does not support the conclusion that T.M.'s December 2013 post-vaccination febrile seizure caused her epilepsy.
>
> Specifically, the record does not establish that the initial febrile seizure harmed T.M.'s brain sufficiently to conclude that it likely "explains" what transpired thereafter. On the contrary, persistent testing performed over the next two-plus years, whether in the form of EEGs or [magnetic resonance imaging (MRIs)], did not confirm the presence of a seizure-induced brain malformation or injury that could then (under a "seizures beget seizures" theory) be deemed causal of all subsequent seizures.

See Weaver, 2022 WL 12542485, at *25 (emphasis in original) (citing three EEGs, an MRI, and a CT scan yielding normal results between December 2013 and May 2016). The Chief Special Master noted that it was not until August 2016 that epileptiform activity in T.M.'s brain was corroborated by an EEG yielding abnormal results. *Id.* Upon these findings, the Chief Special Master concluded T.M.'s first vaccine-induced seizure could not be deemed responsible for her epilepsy "in the absence of record evidence corroborating the presence of brain injury that could credibly be attributed to the vaccine-induced febrile seizure." *Id.* at *27.

Requiring abnormal screening results to substantiate T.M.'s initial brain injury contradicts the spirit of the Vaccine Act and the standard to which petitioners are held. The preponderance of the evidence standard applicable under the Act does not require medical certainty. Rather, causation is determined on a case-by-case basis with "no hard and fast *per se* scientific or medical rules." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Moreover, under the National Vaccine Injury Program, close calls regarding causation are resolved in favor of injured claimants. *Althen*, 418 F.3d at 1280. The question whether T.M.'s brain was harmed by her initial vaccine-induced complex febrile seizure, leading to her chronic seizure disorder, is a close call and, as such, must be resolved in Ms. Weaver's favor.

Under the scientifically sound theory that a vaccine-caused complex febrile seizure could serve as the proverbial "first domino" to topple culminating in T.M.'s development of a chronic seizure disorder, the second *Althen* prong required Ms. Weaver to produce only a measure of reliable evidence that her brain was more likely than not harmed by the initial seizure. While a concurrent abnormal EEG or other medical screening may provide such evidence, the absence of an abnormal screening alone is not determinative.

The Federal Circuit has rejected the requirement that a petitioner satisfy the second *Althen* prong by presenting specific medical evidence or scientific proof to establish a logical sequence of cause and effect, concluding that such a requirement "impermissibly raises a claimant's burden under the Vaccine Act." *See Capizzano*, 440 F.3d at 1325–26. The court highlighted the inherent value of opinions from treating physicians and medical experts. *See id.* at 1325. Relevant circumstantial evidence may satisfy the preponderance standard. *Id.* In this case, T.M.'s treating physicians and medical expert opined that T.M.'s regression evidences the impact of her initial vaccine-induced seizure (and subsequent seizures) on her development. In contrast, expert witness testimony regarding the probative value of the initial EEGs and other screening tests were, at best, inconclusive.

1. Treating Physicians

"[Medical opinion] testimony is 'quite probative' since 'treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1375 (Fed. Cir. 2009) (quoting *Capizzano*, 440 F.3d at 1326) (additional citations omitted). Indeed, "in certain cases, a petitioner can prove a logical sequence of cause and effect between a vaccination and the injury (*Althen* prong two) with a physician's opinion to that effect where the petitioner has proved that the vaccination can cause the injury (*Althen* prong one) and that the vaccination and injury have a close temporal proximity (*Althen* prong three)." *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1333 (Fed. Cir. 2016) (citing *Capizzano*, 440 F.3d at 1326).

Under Ms. Weaver's scientifically reliable seizures beget seizures theory of causation, children who experience febrile seizures–particularly complex febrile seizures–are more likely to develop seizure disorders, including epilepsy. The proffered theory is sufficiently borne out by the circumstantial evidence presented. The causal link between T.M.'s December 10, 2013 vaccinations and her initial complex febrile seizure within 24 hours is well documented in T.M.'s contemporaneous emergency room records. Further, the medical opinions of T.M.'s pediatric neurologist connected T.M.'s initial febrile seizure and her currently diagnosed seizure disorder. Contemporaneous medical records prepared by other healthcare professionals further document T.M.'s developmental regression and

substantiate a causal connection between T.M.'s initial febrile seizure and her current diagnosis.

In the days and months following T.M.'s third febrile seizure over the course of five months, pediatric neurology specialist Lubov Romantseva, MD, noted T.M.'s developmental plateaus and regressions occurred contemporaneously with T.M.'s vaccinations and the onset of her febrile seizures. *See, e.g.*, ECF 7-2 at 15, 16, 76. To this point, the frequency of T.M.'s febrile seizures and the possible impact of the antiseizure medication prescribed immediately following T.M.'s third febrile seizure proves corroborative. Prior to taking a daily dose of Keppra, T.M. suffered febrile seizures on December 11, 2013, March 18, 2014, and May 1, 2014. Her subsequent December 30, 2014, and May 8, 2016 febrile seizures occurred on days when T.M. did not take her medication. Dr. Romantseva continues to treat T.M. and, based on the record presented, her opinions supply substantiated evidence of causation. *See Mondello v. Sec'y of Health & Hum. Servs.*, 132 Fed. Cl. 316, 323 (2017) ("Medical records 'warrant consideration as trustworthy evidence' because these records are 'generally contemporaneous to medical events,' and 'accuracy has an extra premium.'") (citing *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993)).

T.M.'s developmental evaluations timeline further supports the conclusion that T.M. experienced developmental regression as a result of her vaccine-induced December 11, 2013 complex febrile seizure and subsequent febrile seizures. At her December 10, 2013 wellness visit–during which T.M. received the vaccine regimen at issue–she was reported to meet some (but not all) developmental milestones. *See* ECF 7-8 at 4. During a 12-month wellness visit conducted on April 8, 2014–one month after T.M. suffered a second febrile seizure in three months–Lester Hockenberry, MD, documented that T.M. met only 1 of 13 developmental milestones. *See* ECF 7-3 at 85–86. By September 4, 2014, Dr. Hockenberry reported that T.M. did not meet a single developmental milestone. *See* ECF 7-3 at 71. The Court finds the contemporaneous medical opinions regarding T.M.'s developmental regression probative in determining T.M. suffered a brain injury after her first vaccine-induced febrile seizure.

Relevant here, the Chief Special Master seemingly conflated T.M.'s pre-seizure developmental concerns with her post-seizure developmental regression. *See Weaver*, 2022 WL 12542485, at *26 ("The fact that T.M.'s seizures occurred in the context of established developmental concerns also weighs against a conclusion that her first seizure caused what followed."). As expert witnesses for both parties explained, there is a significant difference between developmental delay and regression. Pediatric Neurologist John Zempel, MD, for example, distinguished between the "many kids who have development delay," and the "uncommon" phenomenon of regression, which requires immediate evaluation and treatment by a neurologist. *See* ECF 72 at 251. In turn, Pediatric Neurologist Ahm M. Huq, MD,

explained that a loss of once-mastered skills is "unusual" and, in the absence of evidence of illness or degenerative condition, is compelling evidence of harm to the brain. *Id.* at 105–06. Dr. Huq further noted the adverse impact brain seizures can have on child development, particularly during their early years of critical development. *See id.* at 107.

Notwithstanding the negative screenings cited by the Chief Special Master, discussed *infra*, the Court finds sufficient evidence in the record to support Ms. Weaver's contentions that T.M.'s December 11, 2013 vaccine-induced complex febrile seizure made her more susceptible to future seizures and that indications of a lowered seizure threshold were partially masked by the prescribed antiseizure medication. The Court notes the plausibility of this explanation for why T.M.'s allegedly lower seizure threshold did not result in significantly more seizures: it would strain credulity to suggest it is merely coincidental that on the two reported days T.M. missed a Keppra dosage, she suffered additional seizures. T.M.'s ensuing developmental regression further evidences the brain damage she suffered.

In reaching these conclusions, the Court finds several similar OSM decisions instructive. *See, e.g.*, *Silverio v. Sec'y of Health & Hum. Servs.*, No. 15-235V, 2019 WL 6694020 (Fed. Cl. Spec. Mstr. Nov. 14. 2019) (complex febrile seizure triggered propensity for additional seizures; *Althen* prong two satisfied by treating physician's testimony despite normal EEG, MRI, and CT scans; first abnormal reading occurred two years after initial complex febrile seizure using a continuous EEG); *Fuller v. Sec'y of Health & Hum. Servs.*, No. 15-1470V, 2019 WL 7576382 (Fed. Cl. Spec. Mstr. Dec. 17, 2019) (complex febrile seizure increased risk of developing epilepsy under seizures beget seizures theory; *Althen* prong two satisfied in part by expert testimony; first conclusively abnormal EEG was conducted three years after the initial seizure); *Ginn v. Sec'y of Health & Hum. Servs.*, No. 16-1466V, 2021 WL 1558342 (Fed. Cl. Spec. Mstr. Mar. 26, 2021) (considering normal MRI results as evidence ruling out alternative causes under *Althen* prong two, but not ruling out vaccinations as the potential cause). Put simply, requiring contemporaneous abnormal screening evidence to prove brain injury under a "seizures beget seizures" theory of causation improperly elevates a petitioner's burden under the second *Althen* prong.

2. EEGs and Other Screenings

As noted in the Chief Special Master's decision, medical experts for both parties testified to the limitations of EEGs and other screening tests in detecting brain injury or abnormality. *See, e.g.*, ECF 72 at 250 (Dr. Zempel: "If you have epileptiform abnormalities, that makes it more likely that you have a diagnosis of epilepsy. A normal EEG does not rule out that you have epilepsy."); *id.* at 44–45, 148–49 (Dr. Huq: "a short-term EEG has a 30 percent chance of capturing the abnormal. A long-term EEG usually have [sic] 60 percent, 60 or 70 percent. So a

positive EEG is helpful, and negative EEG cannot rule out the diagnosis. It's always a clinical diagnosis."). Moreover, in reviewing T.M.'s abnormal August 2016 EEG results, Dr. Zempel reiterated:

> I think that this is the first time we've seen evidence of epileptiform activity on an EEG. Again, I think that means it's more likely in the future that there could be recurrent unprovoked seizures, but there are children out there who have these abnormalities and don't have epilepsy, *and there are children who have epilepsy and don't have any abnormalities*.

Id. at 255 (emphasis added). Regarding T.M.'s normal screening results during the first two years following her initial complex febrile seizure, Dr. Huq opined on their limited import because "[t]here are patients who have seizures every day and can have normal EEG[s]." *Id.* at 148–49. As noted above, Dr. Huq explained that the short-term EEGs performed in the two years following T.M.'s initial complex febrile seizure have only a 30 percent chance "of capturing the abnormal[,]" whereas long-term EEGs–like the one performed in May 2016 (and August 2016)–capture abnormalities in 60 to 70 percent of individuals. *Id.* at 143, 148–49. Overall, both experts agreed that T.M.'s abnormal August 2016 EEG was consistent with epilepsy, and Dr. Huq, in particular, opined that her multiple EEGs (including those that were normal) were consistent with this diagnosis.

With respect to MRIs, Dr. Huq explained they would not likely detect molecular changes in the brain that occur after status epilepticus or a complex febrile seizure, and that the molecular changes might not be detectable for years. *See id.* at 93. In turn, although highlighting an MRI's ability to detect prolonged seizures and significant brain injuries, Dr. Zempel declined to opine that an MRI would detect all injuries in 100% of cases. *See* ECF 73 at 7–8. As for CT scans, Dr. Zempel testified he was "much less confident that a significant injury would appear on CT scan." *Id.* at 6.

Consistent with the Federal Circuit's decision in *Capizzano*, the nature and extent of the Chief Special Master's reliance upon EEG and other screening evidence was in error. *See* 440 F.3d at 1325–28. While abnormal screening results may be probative, the law does not require abnormal screening results to prove a particular injury under the Vaccine Act.

B. Burden to Eliminate Alternative Causes

To the extent the Chief Special Master assigned Ms. Weaver the burden of eliminating alternative independent potential causes for T.M.'s injury as part of her prima facie causation claim, the burden shift constitutes legal error. Under the Vaccine Act, once a petitioner has met their burden on causation, the burden shifts

to the Secretary to establish by a preponderance of the evidence that the injury or harm was unrelated to the vaccine. *See Walther v. Sec'y of Health & Hum. Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007) (citations omitted). As stated by this Court:

> The Act only requires a showing of "but for" causation and that the vaccine was a "substantial factor," not that the vaccine was the only cause. Thus the coincidence of another potential causal agent is not fatal to a claim under the Act. If petitioner meets its burden on causation, then it is the government's burden to prove that some other cause is to blame, not petitioner's to disprove it.

Mondello, 132 Fed. Cl. at 325.

Importantly, while evidence of other possible sources of injury can be relevant in the causation analysis, the Federal Circuit has clarified:

> first, that a special master may not require the petitioner to shoulder the burden of eliminating all possible alternative causes in order establish a prima facie case[;] and second, that a special master may find that a factor other than a vaccine caused the injury in question only if that finding is supported by a preponderance of the evidence.

Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1380 (Fed. Cir. 2012) (internal citations omitted).[8]

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[8] The Secretary seeks to apply the holding in *Stone* to this case. Readily distinguishable from this case, in *Stone*, the special master concluded that the children's SCN1A gene mutation was the *sole cause* of their severe myoclonic epilepsy of infancy (SMEI) (also known as Dravet syndrome), and that the petitioners failed to establish the existence of any brain damage. *See* 676 F.3d at 1375, 1377–78, 1385. In affirming the OSM's decision, the Federal Circuit held: "[t]he special master did not reject the petitioners' evidence of brain damage on the ground that it was circumstantial; rather, he found that [the expert's] inference of brain damage, in the face of clinical records showing no brain damage, was unpersuasive and that it was therefore insufficient to carry the petitioners' burden on causation." *Id.* at 1385. It is also worth noting that in *Stone*, unlike here, the burden of proof shifted to the respondent to demonstrate by a preponderance of the evidence that the gene mutation "was 'more likely than not the "but for" and "substantial factor" that caused' the SMEI in both children." *Id.* at 1377 (citations omitted).

Here, it is undisputed–and confirmed by both parties' experts–that T.M.'s August 2016 EEG was abnormal, demonstrated global encephalopathy, and is consistent with T.M.'s epilepsy diagnosis. *Compare* ECF 9-4 at 293–94 *and* ECF 72 at 145–46, 254–55 *with Stone*, 676 F.3d at 1382 n.2, 1385 (finding EEG evidence "questionable"; petitioner's expert witness unpersuasive). Additionally, the Court finds T.M.'s medical records—particularly the medical opinions of her pediatric neurologist and contemporaneous developmental assessments—amply support the conclusion that T.M. experienced developmental regression, which is probative circumstantial evidence of brain injury in this case.

In this case, rather than hold the Secretary to their shifted burden of proof, the Chief Special Master faulted Ms. Weaver for not refuting or otherwise addressing the notion that T.M.'s developmental delay could have caused or increased her risk or propensity for seizures. *See Weaver*, 2022 WL 12542485, at *26 ("Although I do not purport to find that T.M.'s developmental issues explain her subsequent seizure activity and epilepsy, Petitioner did not persuasively rebut this kind of evidence, and it therefore further diminishes the possibility that the initial febrile seizure *alone* explained why T.M. continued to experience seizures afterward.") (emphasis added); *id.* ("*[T]he record in this case* paints a picture of a child likely susceptible to seizure activity generally, but whose course could not be deemed inevitable once the first febrile seizure occurred. T.M.'s initial febrile seizure was likely vaccine-caused—but that seizure in turn was not the cause of what followed.") (emphasis in original). The law is clear: Ms. Weaver is not required to prove that T.M.'s initial vaccine-induced complex febrile seizure was the sole or predominant cause of her epilepsy. *See Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999) (petitioners must demonstrate vaccine was *a* but-for cause of and *a* substantial factor in the resulting injury; petitioners are not required to establish the vaccine was the only or predominate cause of the injury).

III. Significant Aggravation

Under the Vaccine Act, claimants may seek compensation for preexisting injuries that were "significantly aggravated" by vaccination. 42 U.S.C. § 300aa-11(c)(1)(C)(i-ii). To prove an off-Table significant aggravation claim, petitioners must satisfy the six-prong test adopted in *Loving v. Sec'y of Health & Hum. Servs.*, 86 Fed. Cl. 135, 143–44 (2009). Under the *Loving* framework, a petitioner must establish by a preponderance of the evidence:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Id. at 144. Here, Ms. Weaver argues T.M.'s vaccine-induced complex febrile seizure and resulting seizure disorder exacerbated her preexisting developmental delay.

In addressing the significant aggravation claim, the Chief Special Master found that T.M.'s contemporaneously documented pre-vaccine developmental issues "*literally* worsened" and became "more pronounced" in the months and years after she was vaccinated, thereby satisfying the first three *Loving* factors. *See Weaver*, 2022 WL 12542485, at *27 & n.21 (emphasis in original). Turning to the fourth factor, the Chief Special Master "assum[ed] that a vaccine-induced febrile seizure could cause sufficient brain injury to worsen preexisting developmental issues."[9] *See id.* at *27.

In assessing the fifth *Loving* factor, the Chief Special Master relied upon his findings under the second *Althen* prong, concluding that T.M.'s initial vaccine-induced complex febrile seizure was similarly not "the source of worsening" for her developmental delay. *See Weaver*, 2022 WL 12542485, at *27. The Chief Special Master explained: "My finding with respect to a lack of sufficient 'did cause' proof that the first, vaccine-caused febrile seizure T.M. experienced was causal of her overall epilepsy also bears on Petitioner's claim that her pre-existing developmental delays were exacerbated by the December 2013 vaccinations." *See id.*; *accord id.* at *28 ("[T]he initial, undoubtedly vaccine-related febrile seizure has not been shown to be the 'linchpin' to what followed."). Given the Court's conclusion reversing the causation determination under *Althen* prong two, the extension of the erroneous finding in analyzing the *Loving* factors necessitates a reevaluation on remand.[10]

CONCLUSION

For the foregoing reasons, Petitioner's Motion for Review (ECF 83) is **GRANTED**, the Decision Denying Entitlement issued by the Office of Special Masters (ECF 77 & 81) is **REVERSED-IN-PART** and **VACATED-IN-PART**, and this case is **REMANDED** for further proceedings consistent with this opinion.

It is so **ORDERED**.

Armando O. Bonilla
Judge

[9] The assumption is presumably based on the Chief Special Master's findings regarding *Althen* prong one (i.e., the counterpart to the third *Loving* factor).

[10] On remand, the Chief Special Master must also address the sixth *Loving* factor (i.e., proximate temporal relationship between the vaccination and the significant aggravation)–the counterpart to the third *Althen* prong–as his initial decision is silent on that issue. The Court declines to make these factual findings in the first instance on petitioner's motion for review. *See, e.g.*, *Mondello*, 132 Fed. Cl. at 325.