In the United States Court of Federal Claims

No. 16–738 V
(Filed Under Seal: March 9, 2023)
(Reissued for Publication: April 4, 2023)*

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THEODORE MARTINEZ *and* **SARAH MARTINEZ,** *as parents and natural guardians of W.M.*,

Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant.

* * * * * * * * * * * * * * * * * * * *

David John Carney, Green & Schafle, Philadelphia, PA, for Petitioners.

Naseem Kourosh, U.S. Department of Justice, Washington, DC, for Respondent.

OPINION AND ORDER

SOMERS, Judge**.**

Before the Court is a motion for review of the Chief Special Master's decision denying compensation under the National Vaccine Injury Compensation Program, filed by Petitioners, Theodore and Sarah Martinez ("Petitioners"), as parents and guardians of their daughter, W.M. *See* ECF Nos. 109 ("Motion") and 111 ("Pet. Brief"). The Secretary of Health and Human Services ("Respondent") filed a response to Petitioners' Motion, *see* ECF No. 113 ("Oppo."), and the Court held oral argument on December 21, 2022, ECF No. 114.

In their motion for review, Petitioners contend that W.M. developed Transverse Myelitis ("TM") caused by the diptheria-tetanus-acellular pertussis ("DTaP") vaccine and seek

* Pursuant to Vaccine Rule 18(b), included in Appendix B of the Rules of the Court of Federal Claims, the parties have 14 days from the date of this decision to object to the public disclosure of (1) trade secrets or other sensitive financial or commercial information that is privileged or confidential, or (2) medical information that would constitute "a clearly unwarranted invasion of privacy." Neither party objected to the public disclosure of any information included in this Opinion and Order, and the Court hereby publicly releases it in full.

compensation pursuant to the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa–10 to 34. The Chief Special Master denied Petitioners' claim, concluding that: (1) Petitioners did not establish causation based on an acceptable medical theory, and (2) Petitioners' proposed onset of W.M.'s TM was not medically acceptable. Petitioners now seek review of that decision. For the reasons provided below, the Court finds that Petitioners have not met the high burden imposed under the Vaccine Act to set aside the Chief Special Master's decision and, therefore, denies Petitioners' motion for review.

BACKGROUND

A. Factual History

This case involves the Petitioners' infant daughter, who developed acute TM[1] shortly after receiving the DTaP vaccination. The facts, witness testimony, and other evidence relevant to this case are comprehensively detailed in the Chief Special Master's Entitlement Decision, *see Martinez v. Sec'y of Health & Hum. Servs.*, No. 16–738–V, 2022 WL 4884923, at *1–20 (Fed Cl. Spec. Mstr. Sept. 9, 2022) ("Entitlement Decision"), and as a result, the Court will only provide a summary of the relevant events and evidence.

On the afternoon of June 26, 2013, W.M., and her twin sister, R.M., received the DTaP vaccine, and Mrs. Martinez reported that afterward, both sisters "were tired, a bit cranky and had sore legs from the injections." *Id.* at *2. After a few days, however, W.M. continued to be lethargic and appeared unable to move her legs while her twin sister had seemingly recovered from any initial reaction to the injection. *Id.* In a 2016 declaration, Mrs. Martinez stated that, because W.M.'s condition was not improving, Mr. Martinez took W.M. to the Affinity Clinic urgent care facility on June 29, 2013. *Id.* However, there is no record of the visit because Mr. Martinez "only briefly spoke with a doctor in the waiting room." *Id.* On July 1, 2013, W.M. returned to the clinic that administered her DTaP vaccine, and Petitioners told "treaters that she was constipated, hypotonic (meaning low muscle tone), lethargic, not acting like herself, and had a fever of 100.9 degrees, and that her symptoms were not worsening but also not improving either." *Id.* at *1. According to Mrs. Martinez, these symptoms manifested after W.M. received the DTaP vaccine. *Id.* at *2. During the July 1, 2013, pediatric visit, W.M. was seen by Nurse Practitioner Ramona Cawley, and the exam records noted that W.M. would not bear weight on her legs, had tremors in her arms while reaching, and had limited active movement in her lower extremities. *Id.* As a result, W.M. was referred to neurology because her symptoms had "progressed" up to July 1, 2013. *Id.*

On July 3, 2013, W.M. saw pediatric neurologist, Yong Park, M.D., and he noted "spasticity and clonus" in W.M.'s lower extremities, as well as "hyporeflexia and brisk deep tendon reflexes . . . in the lower extremity, minimal reaction to stimulation on the left leg[,] and a wink in the anal sphincter tone." *Id.* The neurologist's "assessment was spastic paraparesis 'acute in onset since 2nd [DTaP] vaccination.'" *Id.* (alteration in original). He then immediately

[1] "Transverse myelitis is a neurological disorder caused by an abnormal immune response resulting in inflammation across both sides of one level of the spinal cord that interrupts communications between the nerves in the spinal cord and the rest of the body." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1342 (Fed. Cir. 2010).

transferred W.M. to the hospital for further testing, including a spinal tap/lumbar puncture and an MRI. *Id.*

Once at the hospital, Mrs. Martinez provided the following information regarding the onset of W.M.'s symptoms:

> [Mrs. Martinez] again suggested an onset close in time to the vaccination date. W.M., she reported, had received the DTaP and rotavirus vaccines on June 26, 2013, and after returning home developed a decreased activity level (including less rolling) that evening, and had a temperature of 99 degrees. By the next morning (June 27, 2013), both of W.M.'s legs were limp, and she continued to not move her lower extremities or stand on her legs. In addition, W.M. now had a temperature of 100.9 degrees, which continued through that day. And as of June 28, 2013, both of W.M.'s legs were stiff, and at some point around this time, her stools became more frequent and of lesser quantity, although her urination pattern was normal.

Id. (internal citations to the record omitted). During the July 3, 2013, hospital visit, George Lazari, M.D., PGY1,[2] examined W.M. and observed, *inter alia*, spasticity and decreased movements in W.M.'s lower body. *Id.* at *3. Treating physicians believed that W.M. had either Guillain-Barré Syndrome ("GBS") or TM. *Id.* On the same day, W.M. had an MRI done, which "showed thoracic spinal cord intermedullary enhancement at T3-T4 that was concerning for early stages of acute TM." *Id.* Later that day, pediatric neurologist Suzanne Strickland, M.D., evaluated W.M. and officially diagnosed her with TM. *Id*.

After being diagnosed with TM, W.M. was administered a high dose of methylprednisolone over the next five days. *Id*. "Her lower extremity movement began to improve on the second day, and her neurological exam improved slightly each day, but she was still moving significantly less than normal." *Id*. On July 7, 2013, she was discharged from the hospital "with a diagnosis of TM and instructions to continue oral steroids." *Id*.

Several post-discharge medical visits are relevant to this Court's review. On July 12, 2013, W.M. was taken to outpatient physical therapy by her parents who "reported that within hours of receiving a DTaP vaccine, W.M. developed extreme weakness, tremulousness, and lethargy." *Id.* On August 1, 2013, Petitioners took W.M. to the Affinity Clinic where she was seen by pediatrician Dixie Griffin, M.D. *Id.* During that visit, Dr. Griffin spoke with Mrs. Martinez about the possibility of a vaccination causing W.M.'s TM. *Id.* Dr. Griffin suggested that she did not believe the DTaP vaccine caused W.M.'s TM because symptoms occurred two days after vaccination, and most studies indicate that TM symptoms typically do not arise until two or three weeks after an inciting event. *Id.* On August 5, 2013, neurologist Sheisa Claudio-Sandoval, M.D. evaluated W.M., and Petitioners informed her that W.M. "manifested symptoms associated with TM within a few hours of receiving a DTaP vaccine." *Id.*

In the months following her TM diagnosis, and up until at least the filing of the petition, she has continued to demonstrate progress, but

[2] "PGY1" refers to a physician in "Postgraduate Year 1." *See* Entitlement Decision at *3 n.5.

> continues to have pain and displays difficulty walking long periods of time or long distances; difficulty running; [gait] issues and concerns; balance issues and concerns; short tendons and tight muscles; hip joint concerns; some bladder and constipation concerns and frequently asks to wear a pull up; issues dressing and undressing and poor balance and flexibility.

Id. at *4 (internal quotations omitted). As of the date of the hearing before the Chief Special Master, W.M. was eight years old and used assistive devices, like orthotics and forearm crutches, to get around. *Id.* at *6.

B. Witness Testimony

The Court will summarize the testimony of the fact and expert witnesses, which is comprehensively recounted in the Chief Special Master's decision. *See id.* at *4–20.

1. Petitioners' witnesses

Sarah Martinez

W.M.'s mother testified about W.M.'s and R.M.'s medical and vaccination history. *Id.* at *4. She recalled the twins receiving the DTaP vaccine on June 26, 2013, and described their ensuing reactions. *Id.* She noted a divergence in the twins' symptoms on June 28, 2013—while R.M. presented fewer post-vaccination symptoms, W.M. continued to exhibit irritability, tiredness, and a fever. *Id.* at *5. Mrs. Martinez contacted the pediatrician's nurse hotline and was told that W.M.'s symptoms were normal. *Id.* Mrs. Martinez reported that on the following day, June 29, 2013, R.M. greatly improved and was seemingly back to full health, while W.M. still had the aforementioned symptoms. *Id.* Mrs. Martinez testified that, as a result, Mr. Martinez took W.M. to the Affinity Clinic urgent care center that same day. *Id*. Mrs. Martinez also testified that on June 30, 2013, the day after Mr. Martinez took W.M. to the urgent care clinic, W.M. developed severe constipation that caused bleeding. *Id.* During the July 1, 2013, visit to the Affinity Clinic, Mrs. Martinez indicated that Dr. Griffin recommended that W.M. be evaluated by a pediatric neurologist but told her that it was not an urgent issue. *Id.* Mrs. Martinez testified that after leaving the Affinity Clinic, W.M. began, for the first time, "straightening out her legs rigidly then bending her knees" repeatedly. *Id*. She claimed that this was the first time she had concerns with W.M.'s leg movements. *Id.*

Regarding the July 3, 2013, visit with pediatric neurologist Dr. Park (following the referral from Dr. Griffin), Mrs. Martinez testified that she explained W.M.'s behavior since the July 1, 2013, clinic visit. *Id*. Dr. Park expressed concern that W.M. might have acute TM and recommended testing. *Id.* Mrs. Martinez said that she now viewed W.M.'s condition as urgent and she took W.M. to the hospital for various tests. *Id*. After a spinal tap and an MRI, the doctors officially diagnosed W.M. with TM. *Id.*

Particularly relevant here, Mrs. Martinez also contested some of the medical records as they relate to the onset of W.M.'s symptoms. *Id.* She took issue with Dr. Claudio-Sandoval's history that notes "[W.M.] was admitted to PICU on July 3, 2013, *after develop[ing] low*

extremity weakness after a few hours of receiving second DTaP dose." *Id.* (alterations in original). She also suggested that records from a January 30, 2015, visit with William Taft, M.D., were inaccurate in noting that "[p]arents report that [W.M.] was doing well *until the day after she received her DTaP. That night she began to exhibit flaccid weakness* of her legs on both sides." *Id.* (alterations in original). Mrs. Martinez contends that she did not notice any lower extremity abnormalities immediately following vaccination. *Id.*

Theodore Martinez

W.M.'s father also testified, and according to the Chief Special Master, his testimony was largely consistent with Mrs. Martinez's recollection of events. *Id.* However, on June 29, 2013, Mr. Martinez took W.M. to urgent care and saw Teresa Stewart, M.D. *Id.* There are no records of the visit, and according to Mr. Martinez, Dr. Stewart briefly examined W.M. from her car seat in the lobby of the urgent care facility. *Id.* According to Mr. Martinez, Dr. Stewart deemed W.M.'s reflexes normal and recommended that W.M. see Dr. Griffin on July 1, 2013, if symptoms persisted. *Id.*

Justin Willer, M.D.

Dr. Willer, one of Petitioners' experts, is a neurologist with a subspecialty in neuromuscular diseases and epilepsy. *Id.* at *7. He submitted four reports on behalf of Petitioners, and he opined that the "temporal relationship between W.M.'s onset and date of vaccination [is] consistent with causation by the DTaP vaccine." *Id.* at *7–8.[3] He testified that TM is a swiftly developing disease, and after an inciting event, a patient reaches nadir sometime between four and twenty-one days. *Id.* at *8. Typically, according to Dr. Willer, someone diagnosed with TM first exhibits hypotonia (*i.e.*, reduced muscle tone and decreased resistance to movement), which then progresses to hypertonicity (*i.e.*, muscle rigidity), and then spastic paraparesis (*i.e.*, increased tone and weakness in two arms or two legs). *Id.* He also testified that TM may include other sensory symptoms, such as "weakness, bowel or bladder complaints, urinary retention, constipation, or pain." *Id.*

Even though his expertise was focused on the issue of onset, Dr. Willer concluded that the DTaP vaccine may have caused W.M.'s TM because there was no evidence of any other illness prior to vaccination, and he also suggested that an idiopathic etiology (*i.e.*, meaning no cause is identified) is unlikely in such a young infant. *Id.* Indeed, he opined that the onset of symptoms was consistent with the conclusion that the DTaP vaccine caused W.M.'s TM. *Id.* According to Dr. Willer, based on several case reports, "TM could begin after a vaccine trigger any time between three to four days to a few weeks post-vaccination, although onset within two days was also possible." *Id.*

Turning to W.M. specifically, Dr. Willer proposed that her symptoms most likely began on June 30, 2013, four days after receiving the DTaP vaccine. *Id.* at *9. Of particular relevance to Dr. Willer was Petitioners' testimony that W.M. experienced bleeding from severe

[3] Dr. Willer focused on the onset of W.M.'s TM and did not offer an opinion regarding the "can cause" causation issue underlying prong one of the *Althen* test discussed later in this Opinion. *See id.* at *7.

constipation on June 30, 2013, because to him, this indicated an "outward manifestation of the neurologic harm attributable to TM." *Id.* Supporting his onset date of June 30, 2013, Dr. Willer explained that the notes from W.M.'s July 1, 2013, visit to the Affinity Clinic, did not identify "stiff legs, clonus, hypertonicity, or spastic paraparesis," which he would have expected had the onset of TM occurred close to the day that W.M. received the DTaP vaccine. *Id.* Additionally, he referred to the notes from the July 3, 2013, visit with Dr. Park, at which point W.M. was noted to have displayed spasticity. *Id.* To Dr. Willer, this indicated a progression of W.M.'s TM symptoms, such that she was approaching nadir. *Id.*

Dr. Willer "could not identify medical record evidence to corroborate his contention that W.M. had *not* likely experienced TM-associated symptoms sooner than July 1[, 2013]," but he suggested that the totality of the record supported this later onset. *Id.* at *10. Indeed, he testified that earlier symptoms indicated a "nonspecific, malaise-like reaction" that was no different than what her twin sister exhibited. *Id.* To support his opinion, he challenged the accuracy of some of the medical records, particularly Dr. Lazari's progress note from the July 3, 2013, hospital visit, which indicated an onset close to the time in which W.M. received the DTaP vaccine. *Id.* Particularly, he posited that if W.M.'s TM actually began on June 26 or June 27, 2013, "then she should have reached nadir sooner than what the record actually suggested had occurred." *Id.* He acknowledged that medical records and prior statements from witnesses may suggest an earlier onset, but "he deemed the Petitioners' descriptions during the hearing more reliable than the medical records made closer in time to W.M.'s injury." *Id.*

Eric Gershwin, M.D., MACR, MACP

Dr. Gershwin, Petitioners' second expert witness, is "a board-certified immunologist with expertise in internal medicine, rheumatic disease, allergy, and immunology." *Id.* at *11. He offered "the opinion that the DTaP vaccine can cause TM." *Id.* According to the Chief Special Master, Dr. Gershwin took note of several points in the medical record that support his opinion that the DTaP vaccine caused W.M.'s TM. *Id.* He testified that "the record provided no evidence of a genetic predisposition, environmental trigger, or immunological insult other than vaccination," and "there was no evidence of another autoimmune neurologic disease either." *Id.*

As far as the actual mechanism by which the DTaP vaccine could have caused W.M.'s TM, Dr. Gershwin proposed molecular mimicry. *Id.* at *12. The Chief Special Master summarized Dr. Gershwin's theory of molecular mimicry as follows:

> As he explained, a foreign antigen (specifically the amino acid sequences that comprise its proteins), can sometimes resemble a protein structure found in the person's body. Thus, in addition to provoking an immune response, antigens in a vaccine can cause a cross-reaction in which antibodies produced in reaction to the vaccine attack self tissues (here, the spinal cord). This occurs in the context of inflammation (featuring a variety of infiltrating T cells, B cells, and other monocytic population) that leads to local nerve damage.

Id. (citations to the record omitted). Dr. Gershwin also testified that molecular mimicry, no matter how reliable it is as a theory, is very difficult to study or observe. *Id.* According to the

Chief Special Master, Dr. Gershwin "was able to marshal little in the way of direct scientific or medical literature," and he also testified that epidemiological studies did not show a link between vaccination and TM. *Id.* In addition to criticizing Respondent's causation expert, *id.* at *13, Dr. Gershwin also testified that his theory of causation meshed with Dr. Willer's proposed onset date of July 1, 2013, *id.*

2. Respondent's witnesses

Timothy Lotze, M.D.

Respondent put forth two expert witnesses; the first, Dr. Lotze, a pediatric neurologist, opined "on what might constitute W.M's onset—and whether the vaccine could be implicated in the timeframe he favored." *Id.* at *14. First, although he is not the Respondent's causation expert, Dr. Lotze suggested that an association between vaccination and TM was unlikely given the absence of literature discussing such a connection. *Id.* at *15–16.[4] Turning to onset, Dr. Lotze suggested that W.M.'s symptoms likely would have "evolved over the course of a two-to-four-day timeline," and he opined that TM would typically reach its nadir roughly five to six days after onset. *Id.* at *16. As a result, as summarized by the Chief Special Master, "[t]he relevant medical record revealed that in W.M.'s case, TM onset had most likely occurred within 24 hours (between June 26-27) of her vaccination with nadir arriving four days later—a timeframe Dr. Lotze deemed not medically reasonable for causation under the circumstances." *Id.*

In making his onset determination, Dr. Lotze looked to contemporaneous medical records and testimony to determine whether the apparent onset time was consistent with the DTaP vaccination causing W.M.'s TM. *Id.* Specifically, he testified that various treater notes suggested that W.M.'s initial TM symptoms began on the evening of June 26, 2013, the day on which W.M. received the DTaP vaccine. *Id.* Additionally, he found it critical that W.M. appeared to be unable to move her legs on June 27, 2013, which distinguished her condition from a normal vaccination reaction as outlined in the DTaP package insert and experienced by R.M. *Id.* at *17. Dr. Lotze also testified that W.M.'s June 30, 2013, episode of constipation was consistent with an onset of June 26, 2013, because bowel issues related to TM typically do not present immediately and are secondary to other symptoms. *Id.* Finally, Dr. Lotze testified that W.M.'s leg straightening and stiffening following the July 1, 2013, clinic visit was "evidence that W.M. was by this point evolving into the next stage of TM, where weakness and low tone is replaced by spasticity, increased tone, and increased reflexes." *Id.*

James Moy, M.D.

Respondent offered Dr. Moy, an attending physician specializing in allergy and immunology, as its causation expert, and "[h]e sought to rebut Petitioners' argument that the DTaP vaccine can cause TM." *Id.* He posited that TM usually occurs after a patient has an infection, but it can also be idiopathic, meaning there is no apparent cause. *Id.* at *18. In

[4] Additionally, Dr. Lotze thought that the record potentially supported that an infection caused W.M.'s TM because she "had been reported to be experiencing a low-grade fever, and displayed enlarged lymph nodes, shortly after vaccination." *Id.* at *16.

arguing that the DTaP vaccine did not cause W.M.'s TM, Dr. Moy criticized the case reports and contended that epidemiological studies did not suggest that the DTaP vaccine could cause TM. *Id.* He pointed to a separate study linking GBS and the flu vaccine, "noting that epidemiological studies were available to reliably establish an increased incidence of GBS following flu vaccination," and he explained that no similar studies existed demonstrating a DTaP-TM connection. *Id.* Dr. Moy disagreed with Dr. Gershwin's theory that molecular mimicry was the mechanism by which the DTaP vaccine caused TM. *Id.* He also "rejected Dr. Gershwin's contention that TM could arise as the product of an immediate, innate immune response (rather than the secondary, more immune memory-oriented adaptive response)." *Id.* at *19.

Dr. Moy then testified that three aspects of the medical records in this case also supported his conclusion that the DTaP vaccine did not cause W.M.'s TM. *Id.* First, he deemed it significant that W.M.'s twin sister did not develop TM post-vaccination; in so finding, he disagreed with Dr. Gershwin and opined that "the twins likely shared the same genetics, [so] their immune responses to the vaccine should have been identical, but were not, undermining the possibility that the vaccine itself was the causal factor." *Id.* Second, Dr. Moy testified that it was telling that W.M. received prior doses of the DTaP vaccine without issue. *Id*. In his mind, it was "unlikely that the dose at issue had triggered autoimmunity where prior doses had not." *Id.* Finally, he observed that W.M. did not have an infection or illness prior to receiving the final dose of the DTaP vaccine. *Id*. He explained that a prior infection "might have had the secondary impact of causing the kind of blood-brain barrier weakening or breach that would be necessary to allow the antigen of antibodies to get across the [central nervous system]." *Id.* Because there was no evidence of infection, and thus no evidence of a weakening or breach of the blood-brain barrier, this also ruled out the DTaP vaccine in his opinion. *Id*. According to Dr. Moy, there is nothing offered in this case "establishing how immune cells can get into the [central nervous system] in the absence of an actual 'break' in the blood-brain barrier." *Id.*

C. Procedural History

Petitioners filed their petition for compensation under the National Vaccine Injury Compensation Program on June 22, 2016. ECF No. 1. After the parties filed their evidence, reports, and briefs, the Chief Special Master held a two-day entitlement hearing on November 16 and 17, 2021. ECF Nos. 91–92. After post-hearing submissions, the Chief Special Master issued his Entitlement Decision on September 9, 2022, denying compensation under the Vaccine Act. *See* ECF No. 107. After giving the parties an opportunity to propose redactions, the decision was made public on October 4, 2022. ECF No. 108.

Petitioners timely filed their motion for review on October 9, 2022, ECF No. 109. They seek review of the Chief Special Master's Entitlement Decision based on two principal objections:

1. The Chief Special Master's holding that minor Petitioner's transverse myelitis began on the same day as the vaccination is based on a faulty understanding of the clinical course of transverse myelitis, a misreading of the medical evidence attributable to transverse myelitis versus minor Petitioner's local side effects from the vaccination, and irrational inferences from the evidence, all of which

amount to an interpretation of the medical evidence that was arbitrary and capricious and an abuse of discretion.

2. Given the specificity of the demonstrated homologies between tetanus toxoid constituents of the vaccine and myelin components of the central nervous system, as well as the proximity of the time frame (four days) from vaccination to onset of the transverse myelitis, the Chief Special Master's holding that Petitioner[s] had failed to establish by a preponderance *Althen* Prong 1 (a "can it cause" medical theory causally connecting the vaccination and the injury) due largely to the Chief Special Master's consideration of an epidemiological study that simply did not rule out causation between vaccination and the rare incidence of acute transverse myelitis, was arbitrary and capricious, an abuse of discretion, contrary to law and violative of due process of law.

   Furthermore, the Chief Special Master thereby improperly heightened the burden of proof required of Petitioner, contrary to law, by requiring an improper and impossible-to-reach level of specificity in connection with Petitioner's showing of the well-established theory of molecular mimicry.

Motion at 1–2. Respondent filed its Response to Petitioners' Motion on November 7, 2022, *see* Oppo., and the Court held oral argument on December 21, 2022, *see* ECF No. 114.

DISCUSSION

A. Standard of Review of a Special Master's Decision

Under the Vaccine Act, this Court has jurisdiction to review the decisions of vaccine special masters. *See* 42 U.S.C. § 300aa–12(e)(1). In reviewing a special master's decision, the 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
>
> (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). In other words, "[u]nder the Vaccine Act, the Court of Federal Claims reviews [a special master's] decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.'" *Markovich v. Sec'y of Health & Hum. Servs.*, 477 F.3d 1353, 1355–56 (Fed. Cir. 2007), *cert. denied*, 552 U.S. 816 (2007) (citing 42 U.S.C. § 300aa–12(e)(2)(B)).

With regard to factual determinations, the Court does not "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). "[A]s long as a special master's finding of fact is 'based on evidence in the record that was not wholly implausible, [the Court is] compelled to uphold that finding as not being arbitrary or capricious.'" *Id.* (quoting *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1363 (Fed. Cir. 2000)). Under the "not in accordance with law" standard, the Court may *de novo* review statutory or other purely legal issues. *H.L v. Sec'y of Health & Hum. Servs.*, 129 Fed. Cl. 165, 169 (2016); *accord Hines v. Sec'y of Health & Hum. Servs.*, 940 F.2d 1518, 1527 (Fed. Cir. 1991) ("The 'not in accordance with the law' aspect of the standard of review is . . . involved [in cases in which there is a] dispute over statutory construction or other legal issues.").[5]

In short, the Chief Special Master is afforded a great deal of deference with regard to factual conclusions and how the evidence is weighed, and Petitioners face an incredibly heavy burden to overturn his factual and evidentiary decisions. The Vaccine Act "provide[s] for a limited standard for appeal from the [special] master's decision" and its legislative history shows "that this procedure [should not] be used frequently, but rather in those cases in which a truly arbitrary decision has been made." H.R. Rep. No. 101-386, at 517 (1989) (Conf. Rep.), reprinted in 1989 U.S.C.C.A.N. 3018, 3120. "If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, *reversible error will be extremely difficult to demonstrate*." *Hines*, 940 F.2d at 1528 (emphasis added); *see also Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed Cir. 1993) ("[O]n review, the Court of Federal Claims is not to second guess [a s]pecial [m]aster[']s fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process."); *see also Munn*, 970 F.2d at 870 (arbitrary and capricious standard applied to "both fact-findings and fact-based conclusions . . . is a standard well understood to be the most deferential possible").

B. Legal Standard for Non-Table Injuries

Under the Vaccine Act, a petitioner may seek compensation for two different types of vaccine injuries. First, a petitioner is entitled to compensation "when an injury or condition listed in the Vaccine Injury Table . . . begins to manifest itself within the time specified in the Table for the vaccine in question." *Hines*, 940 F.2d at 1524 (citing 42 U.S.C. §§ 300aa–

[5] "An abuse of discretion may be found when (1) the court's decision is clearly unreasonable, arbitrary, or fanciful; (2) the decision is based on an erroneous conclusion of the law; (3) the court's findings are clearly erroneous; or (4) the record contains no evidence upon which the court rationally could have based its decision." *Simmons v. Sec'y of Health & Hum. Servs.*, 875 F.3d 632, 635 (Fed. Cir. 2017) (citing *Hendler v. United States*, 952 F.2d 1364, 1380 (Fed. Cir. 1991)). However, the abuse of discretion is not frequently applied in vaccine appeals. *See Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992) (abuse of discretion standard "will rarely come into play except where the special master excludes evidence"); *see also Caves v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 119, 131 (2011) (abuse of discretion is "applicable when the special master excludes evidence or otherwise limits the record upon which he relies"). The Chief Special Master here did not exclude evidence or limit the record in any way; therefore, the abuse of discretion standard is not applicable here.

11(c)(1)(C)(i), 300aa–14(a)). In these so-called "table injury cases," causation is presumed. *Id.* Second, "for injuries not listed in the Table, or which do not occur within the time period stipulated in the Table, the Vaccine Act authorizes recovery only if the petitioner proves actual causation." *Id.* at 1524–25 (citing 42 U.S.C. § 300aa–11(c)(1)(C)(ii)). A petitioner bears the burden of establishing actual causation in a non-table case by a preponderance of the evidence. *Broekelschen*, 618 F.3d at 1345. If a petitioner satisfies his or her burden, then the burden shifts to the respondent to prove "[by] a preponderance of the evidence that [the petitioner's injury] is due to factors unrelated to the administration of the vaccine described in the petition." *See* 42 U.S.C. § 300aa–13(a)(1)(B); *accord Walther v. Sec'y of Health & Hum. Servs.*, 485 F.3d 1146, 1150 (Fed. Cir. 2007). Indeed, if a petitioner makes out a prima facie case, "she bears no burden to rule out possible alternative causes." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008) (citing *Walther*, 485 F.3d at 1149–50).

Petitioners here assert a "non-table" injury. In order to prove actual causation in a non-table case by a preponderance of the evidence, they must demonstrate the following:

> (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) ("*Althen*"). Here, the Chief Special Master determined that Petitioners failed to meet their burden with regard to prongs one and three of the *Althen* test.

To meet prong one, demonstrating a medical theory causally connecting vaccination and injury, "a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" *Broekelschen*, 618 F.3d at 1345 (quoting *Knudsen v. Sec'y of Health & Hum. Servs.,* 35 F.3d 543, 548–49 (Fed. Cir. 1994)). Petitioners need not establish a plausible medical theory with conclusive evidence. *See Solak v. Sec'y of Health & Hum. Servs.*, No. 14–869–V, 2020 WL 9173158, at *19 (Fed. Cl. Spec. Mstr. Feb. 19, 2020) ("A petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstrations of a specific mechanism, or a generally accepted medical theory."). Nonetheless, a theory "that lacks any empirical support will have limited persuasive force." *Caves*, 100 Fed. Cl. at 134.

The third *Althen* prong requires that Petitioners provide a "medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury." *Althen*, 418 F.3d at 1281. Specifically, Petitioners need to submit "proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan*, 539 F.3d at 1352. The third prong closely links with the first prong because the acceptable timeframe must coincide with a petitioner's theory of how a vaccine can cause the injury. *Id.* In reality, the third *Althen* prong can be broken down into two steps: (1) "establish the timeframe for which it is medically acceptable to infer causation, that is, the timeframe in which symptoms would be expected to arise if the [disorder] was caused

by the vaccination" and (2) "show that the onset of [the disorder] occurred during this causation period." *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011).

C. Analysis

As stated above, the Chief Special Master determined that Petitioners failed to meet their burden of proof with regard to two of the three *Althen* prongs. Accordingly, in order to successfully challenge the Chief Special Master's determination, they must demonstrate that his decision with regard to *both* prong one and prong three of the *Althen* test was irrational. Because the Court determines that Petitioners failed to demonstrate that the Chief Special Master's fact-intensive determination with regard to prong three was in error, the Court must deny their motion for review.

Althen prong three requires Petitioners to establish a "timeframe for which it is medically acceptable to infer causation." *Shapiro*, 101 Fed. Cl. at 542–43. This case is unique with regard to onset because the Chief Special Master found that the record demonstrated an onset that was too early for W.M.'s TM to have been caused by the DTaP vaccine. Entitlement Decision at *27–28. Normally, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *de Bazan*, 539 F.3d at 1352 ("[T]he present case presents an unusual situation in that the basis for the special master's finding that [petitioner] had failed to prove a proximate temporal relationship was that the onset of her [disorder] was too *early* to be attributable to the vaccine."). In any event, cases in which onset occurs too early fail *Althen* prong three because, as with late onset cases, "the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Jagoe v. Sec'y of Health & Hum. Servs.*, No. 08–678–V, 2012 WL 13036265, at *28 (Fed. Cl. Spec. Mstr. Aug. 3, 2012) (determining that twenty-four hours between vaccination and the onset of TM symptoms was not a medically appropriate timeframe for vaccine causation). "If any petitioner fails to satisfy the third prong of *Althen*, *i.e.*, prove appropriate timing for credible causation from the vaccine, that petitioner will similarly fail to prevail on entitlement." *Mosely v. Sec'y of Health & Hum. Servs.*, No. 08–724–V, 2015 WL 2354316, at *19 (Fed. Cl. Spec. Mstr. Apr. 27, 2015).

In their brief, Petitioners broadly contend that the "Chief Special Master's decision finding a same day onset of transverse myelitis is predicated on a confusing and faulty analysis of the medical records, and it failed to consider critical testimony from [Petitioners], the identical symptoms that [W.M.'s] twin sister had, who was not diagnosed with transverse myelitis, and the onset of severe constipation that is a symptom of [TM]." Pet. Brief at 35. They then offer several fact-based arguments as to why the Chief Special Master's decision was unreasonable. *See id.* at 35–53. However, Petitioners' assertions regarding the Chief Special Master's onset determination are not supported by a review of the Chief Special Master's opinion. Moreover, their assertions, rather than demonstrate unreasonableness, as is required, essentially request that the Court conduct a *de novo* review of the facts and the Chief Special Master's fact-based findings regarding onset. Unfortunately for Petitioners, simply relitigating the facts is insufficient at this point in the case, because the Chief Special Master's factual determinations regarding onset are entitled to significant deference. *Hodges*, 9 F.3d at 961 ("[T]he Court of Federal Claims is not to second guess the Special Master[']s fact-intensive conclusions . . . .

That level of deference is especially apt in a case in which the medical evidence of causation is in dispute."). Petitioners' argument, at its core, simply takes issue with how the Chief Special Master weighed the evidence. But reweighing the evidence is not the Court's role in adjudicating a motion for review. *See Oliver v. Sec'y of Health & Hum. Servs.*, 900 F.3d 1357, 1362 (Fed. Cir. 2018) ("[Petitioners] repeatedly fault the Chief Special Master for failing to afford greater weight to their expert's testimony and supporting evidence. . . . We cannot review such challenges."); *see also O.M.V. v. Sec'y of Health & Hum. Servs.*, 157 Fed. Cl. 376, 387 (2021) ("The reviewing court does not reweigh the evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses because all of these matters are within the purview of the factfinder." (citing *Broekelschen*, 618 F.3d at 1349)).

First, Petitioners contend that the Chief Special Master erred by finding that medical records substantiate that onset began within twenty-four hours of W.M. receiving the DTaP vaccine. Pet. Brief at 36. Specifically, they contend that he erred by "disregarding the testimony of [W.M.'s] parents and the Petitioner[s'] experts." *Id.* This argument, however, is simply inaccurate. The Chief Special Master's opinion clearly indicates that he considered all of the testimony. *See, e.g.*, Entitlement Decision at *4–20 (spending over fifteen pages recounting and summarizing all of the lay and expert testimony offered). And, rather than "disregarding" testimony, the opinion demonstrates that the Chief Special Master weighed the testimony and other evidence and concluded that Petitioners could "provide[] no compelling reason to find their subsequent testimony or statements more credible" than contemporaneous medical records. *Id.* at *27.

Furthermore, there is a great deal of contemporary documentation indicating an onset consistent with the Chief Special Master's conclusion. *See, e.g.*, *Hines*, 940 F.2d at 1528 ("If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate."). The Chief Special Master summarized that evidence as follows:

> Numerous medical records from different visits substantiate that onset began within 24 hours of vaccination, or not appreciably long thereafter. Evidence of onset the morning after vaccination, or sometime that day, is found in records prepared by many treaters, including NP Cawley and Drs. Griffin, Lazari, Strickland, Claudio-Sandoval and Carrol. Ex. 8 at 43-44, 54-55; Ex. 9 at 7; Ex. 10 at 24, 62, 149. These records preponderantly establish clear concern for W.M.'s lack of leg movement as soon as *the day of* vaccination. In particular, the July 1, 2013, and July 3, 2013[,] records (the earliest treatment evidence in this case after the vaccination date) refer to leg issues "since" vaccination, or having "progressed" up to July 1—all of which reasonably suggests an onset *before* July 1. Ex. 8 at 43; Ex 9 at 7.
>
> Then, subsequent records from W.M.'s hospitalization memorialize statements by the Petitioners (in recounting W.M.'s history) that they had observed leg-related symptoms by the morning of June 27—and these were the symptoms that later impelled them to seek treatment for W.M. (as opposed to her twin, whose initial vaccine malaise improved). *See* Ex. 10 at 24, 448. The record by itself is thus

> consistent in reporting neurologic-like symptoms prior to June 30—and closer to the morning of June 27.

Entitlement Decision at *26. And from these medical records he concluded that,

> [w]hile these presenting issues cannot be neatly separated from the post-vaccination malaise that both twins appear to have experienced, it can be determined on this record that by June 27, 2013, W.M.'s leg issues had more likely than not manifested, and were notably distinguishable—enough to prompt Petitioners to seek care for W.M., and to express concerns that went beyond the fact that she was taking longer to recover from malaise than her twin.

Id. Respondent also outlined all of this evidence in detail in its opposition brief. *See* Oppo. at 6 (collecting and summarizing medical record evidence detailing the beginning of W.M.'s lower extremity issues prior to June 30, 2013).

In short, it is not the case that the Chief Special Master "disregard[ed] the testimony of [W.M.'s] parents and the Petitioner[s'] experts," Pet. Brief at 36; rather, he simply gave more weight to the contemporary medical records, which indicate an earlier onset than is alleged by Petitioners. Indeed, the Chief Special Master specifically observed that Petitioners "*have not provided a persuasive reason to discount the overall contemporaneous record*, which consistently points to an onset prior to June 30. Petitioners simply cannot simply gainsay these contemporaneous records, given the consistent picture they paint, and *have provided no compelling reason to find their subsequent testimony or statements more credible*." Entitlement Decision at *27 (emphasis added). And, Petitioners have failed to show here that there was anything irrational about the weighing of the evidence by the Chief Special Master. In fact, "[s]pecial masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony." *Vergara v. Sec'y of Health & Hum. Servs.*, No. 08-882 V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. May 15, 2014). This is because, as the Federal Circuit has observed, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Second, Petitioners contend that the Chief Special Master inappropriately relied on hospital records that they believe do not comport with contemporaneous medical records. Pet. Brief at 39–50. Basically, they argue that records from W.M.'s July 3, 2013, hospital visit are at odds with the "only medical chronology that makes sense," which is that "[W.M.'s] transverse myelitis began on June 30, 2013[,] with the severe constipation and rectal bleeding, followed by hypotonia on July 1, 2013, and a progression to hypertonia between July 1, 2013 and July 3, 2013 and spastic paraparesis on July 3, 2013." *Id.* at 46. However, Petitioners admit that this chronology required the Chief Special Master to accept "that the hospital recorded the correct sequence of events but documented the wrong onset date." *Id.* at 44. Again, there is documentation from the July 1, 2013, pediatric visit, the July 3, 2013, neurology visit, the July 3,

2013, hospital visit, and other subsequent appointments in which Petitioners themselves reported to health care providers an onset of W.M.'s symptoms that supports the Chief Special Master's prong three finding. Entitlement Decision at *26 ("Numerous medical records from different visits substantiate that onset began within 24 hours of vaccination, . . . or sometime that day, is found in records prepared by many treaters, including N[urse] P[racticioner] Cawley and Drs. Griffin, Lazari, Strickland, Claudio-Sandoval and Carrol.").

Finally, Petitioners make several other arguments, all of which essentially amount to disagreements with the Chief Special Master's factual findings. They assert that the Chief Special Master:

1. failed to consider the post-vaccination symptoms of W.M.'s twin, Pet. Brief at 37–41;

2. improperly found that Mrs. Martinez's call to the nurse hotline on June 28, 2013, supported an inference of an earlier onset, *id.* at 36–37;

3. failed to consider that constipation may have been W.M.'s first symptom of TM, *id.* at 38–39; and

4. disregarded Dr. Willer's opinion regarding the phasing of hypotonicity to hypertonicity in a patient with TM and argued that his theory of onset did not mesh with TM's nadir in W.M., *id.* at 48–53.

However, the Chief Special Master addressed each issue:

1. He explicitly considered the post-vaccination symptoms of R.M. (W.M.'s twin sister) and determined a divergence in symptoms as supported by the record. *See* Entitlement Decision at *26 ("While these presenting issues cannot be neatly separated from the post-vaccination malaise that both twins appear to have experienced, it can be determined on this record that by June 27, 2013, W.M.'s leg issues had more likely than not manifested, and were notably distinguishable—enough to prompt Petitioners to seek care for W.M., and to express concerns that went beyond the fact that she was taking longer to recover from malaise than her twin.").

2. The Chief Special Master did not focus on the call to the nurse hotline, but rather found that Petitioners taking W.M. to the urgent care clinic for a car seat exam on June 29, 2013, was "supportive of the conclusion that by this time, W.M.'s symptoms were alarming enough to seek additional treatment, thus bulwarking the inference that her neurologic symptoms had begun before early July." *Id.* at *27.

3. Again, the Chief Special Master addressed Dr. Willer's theory that W.M.'s constipation (on June 30, 2013) was the initial presenting symptom of her TM. He explained that "[i]t simply cannot be concluded from the record that this is what drove Petitioners to bring W.M. to see treaters on July 1 or 3 (let alone why she was later hospitalized)." *Id.* He also weighed the contrasting opinions of Drs. Willer and

Lotze and found Dr. Lotze's explanation—that constipation was more likely a secondary symptom of TM—to be more credible. *Id.*; *see O.M.V.*, 157 Fed. Cl. at 387 (quoting *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993)) ("The special master has broad discretion in determining the credibility of witnesses and weighing the evidence, and these credibility determinations are 'virtually unreviewable' by the reviewing court.").

4. Finally, he considered the evidence and testimony and "did not find compelling Petitioners' arguments attempting to pinpoint when W.M. displayed hypertonicity versus hypotonicity, and/or what stage she had reached in her disease process as of July 1." Entitlement Decision at *27; *see also* Oppo. at 11–12.

In total, these additional arguments, much like Petitioners' medical records argument, ask the Court to evaluate the Chief Special Master's factual findings and his weighing of the evidence *de novo*. Although this is understandable, given that shifting the date of onset by only a few days would change the outcome on this *Althen* factor (and thus even a minor disagreement in the weight to assign evidence between the undersigned and the Chief Special Master could theoretically make a difference), "neither the Court of Federal Claims nor the Federal Circuit can substitute its judgment for that of the special master merely because it might have reached a different conclusion." *See Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed Cl. 706, 718 (2009). Rather, the Court can only set aside the Chief Special Master's factual findings or fact-based conclusions if he "relied on factors which Congress has not intended to be considered, or has entirely failed to consider an important aspect of the problem, or has offered an explanation of the decision that runs counter to the evidence, or is so implausible it could not be ascribed to a difference in view or a product of expertise." *Sharpnack v. Sec'y of Health & Hum. Servs.*, 27 Fed. Cl. 457, 459–60 (1993). The Court cannot so find based on the Entitlement Decision's consideration of the record and reasonable conclusions regarding onset. While both Petitioners and Respondent proposed onset theories that appear to be credible, the Chief Special Master appropriately weighed the evidence, including Petitioners' and their experts' testimony, to determine that Respondent's theory was better supported by the record.

CONCLUSION

For the foregoing reasons, the Court finds that the Chief Special Master's Entitlement Decision with regard to *Althen* prong three was reasonable. Accordingly, Petitioners' Motion for Review is **DENIED,** and the decision of the Chief Special Master is **SUSTAINED**. The Clerk of the Court shall enter judgment accordingly.

IT IS SO ORDERED.

s/ Zachary N. Somers
ZACHARY N. SOMERS
Judge