

Golkiewicz denied compensation on the grounds that Petitioner had not established by preponderant evidence that the vaccine caused A.H.'s injuries.

In her motion for review, Petitioner asserts that the Special Master's decision should be reversed because he improperly weighed the evidence and misapplied the relevant legal standards. Because the Court finds that the Special Master's factual findings are supported by substantial evidence and that he correctly applied the relevant legal standards, Petitioner's Motion for Review is denied.

I. Background

The facts upon which the experts and the Special Master relied are derived from three independent sources, plus an October 15, 2010 fact hearing. Because the various sources of evidence are inconsistent at times, this opinion will follow the Special Master's lead in summarizing the facts described in, and differences between, the various parts of the record, including the testimony of the Petitioner's and Respondent's experts, Drs. Ronald I. Jacobson and Max Wiznitzer, respectively. The Special Master's conclusions as to disputed facts are included in the facts, where appropriate.

A. Medical Records

A.H. was born on ***, 2005. Prior to the vaccination at issue, A.H.'s newborn check-ups were normal. However, Petitioner frequently contacted A.H.'s pediatrician to inquire as to whether A.H.'s frequent and prolonged episodes of crying and fussiness were normal. For example, the Special Master cited one instance in the records – prior to A.H.'s immunizations – that noted that “mom needs lots of assurance! Feels she's a ‘bad mom’ as A.H. has so many issues!” Decision at 4. On October 21, 2005, Petitioner called the pediatrician and reported that A.H. had been crying off and on for eighteen hours. A note on the same page indicates that A.H. cried for four hours, followed by sleep for five hours. *Id.* The Record is replete with references to calls placed by the Petitioner throughout October and November. *See id.* (referencing calls on October 3, 21 and 25, and November 9, 16, 17, 18, 22 and 23). In each instance, excessive crying was reported.

On December 1, 2005, A.H. had her two month well-child visit. Concerns were expressed over A.H.'s sleeping and diarrhea, but the examination was normal in other respects. It was during this visit that A.H. received the vaccinations at issue: Pediarix (a combination vaccine including DTaP, IPV polio, and hepatitis B), hemophilus influenza type b, and pneumococcal conjugate. *Id.* The relevant events in this matter occurred over the next four weeks. These events are the subject of some dispute.

Later on December 1, the day of the vaccinations, Petitioner called the pediatrician's office “in a panic,” indicating that A.H. had slept for four hours following the vaccinations and had become increasingly irritable since awakening. This call was followed by an episode on December 2, 2005. During the episode, Petitioner was evidently driving A.H., who was “crying really hard in her car seat.” Petitioner reported that A.H. was making a strange face and “shaking her head a little bit.” Petitioner pulled over and checked on A.H., who reportedly had a

blank look on her face. Petitioner “touched [A.H.’s] face and she was okay again.” The doctor’s notes indicate that the pediatrician believed the strange face was “that catching breath from crying so hard look.” *Id.*

Petitioner contacted the pediatrician’s office several more times after these initial post-vaccination calls. On December 12, 2005, Petitioner contacted the pediatrician to report that A.H.’s left eye was wandering and sticking. On December 15, she called to report fussiness. Finally, on December 19, 2005, Petitioner took A.H. to see the pediatrician to address concerns that A.H. “cries all the time,” but she did not report any other symptom or sign of illness. Upon exam, A.H. was found to be “fussy, engaging and active.” *Id.*

On December 28, 2005 – more than a week after the latest episode – A.H. was admitted to the emergency room (“ER”) of Porter Hospital. The “Chief Complaint” was “lethargy.” It was noted in the history that A.H. was in “her usual state of health until this morning.” Under “Past Medical History,” it was noted that “[t]here has not been any problems as far as mother can recall.” Petitioner reported that, prior to A.H.’s admission to the ER, she was not breast feeding well and she had vomited four times within the hour prior to admission. Other reported symptoms included holding her body stiffly and intermittent sleepiness. The examination notes indicate that A.H. had poor muscle tone. *Id.* at 5.

A.H. was then transferred to the Fletcher Allen Health Care Hospital (“FAHC”). The admission notes at FAHC indicate that A.H. was not acting out of the ordinary until “right before noon,” when she became fussy and began “screaming so loud we had to leave the restaurant.” Outside the restaurant, A.H. vomited, choked, and turned white. No shaking was reported. Petitioner described a similar episode about two weeks prior, during which A.H. looked “odd and was shaking her head back and forth.” *Id.* This is presumably a reference to the December 2 incident.

On the third day of her admission, December 30, 2005, she was witnessed having a seizure which included a sudden cessation of crying, left head and eye deviation, drooling, staring, and flexed and rhythmic shaking lasting about two minutes. An electroencephalography (“EEG”) showed clinical and subclinical seizure activity. The assessment was “a right basal ganglia hemorrhage, and hemorrhage in the deep white matter of the right frontal lobe.” *Id.*

Following the assessment, A.H. was transferred to the pediatric intensive care unit (“PICU”), where she was treated for her seizures. After her treatment, no further seizure activity was observed and A.H.’s health continued to improve throughout the remainder of her hospital stay. A.H. was discharged on January 10, 2006, with instructions to avoid pertussis vaccination. *Id.* at 6.

On January 11, 2006, A.H. saw her pediatrician for a follow-up appointment. On January 12, A.H. was noted as having a fifty-second seizure witnessed by a home health aide. This was her first seizure since the December 30 episode. An overnight EEG was negative for seizures. A.H. was referred to a neurologist, Dr. Kalsner. The diagnosis of hemorrhage in the right basal ganglia was confirmed, and the most typical causes were noted as being a venous angioma or an arteriovenous malformation (“AVM”). The Petitioner provided Dr. Kalsner with several

typewritten sheets detailing the medical events, and these sheets were allegedly placed into the medical record. It does not appear, however, that the typewritten sheets were included in the medical records. *Id.*

The records reflect further interactions between Petitioner and A.H. and the doctors. These interactions took place on February 6, February 13, March 7, and April 11, 2006. (*Id.* at 6-7). One of the notes related to the follow-up with FAHC states that “[Petitioner] had many questions regarding [the bleed’s] proximity to recent immunization. We counseled her that this would be a rare event but **certainly not improbable.**” *Id.* at 7 (emphasis added by Special Master). A recent MRI showed the hemorrhage resolving. *Id.*

On September 18, 2006, A.H. attended a follow-up consultation at FAHC. No major seizures were noted, but Dr. Kalsner’s notes indicated that Petitioner had observed occasional dazed looks from A.H.. FAHC sent a letter after a November 3, 2006 visit which reported that A.H. was “doing great and developmentally seems very on target.” *Id.*

Seeking a second opinion, Petitioner took A.H. to Children’s Hospital Boston on May 18, 2007. Petitioner had captured some of A.H.’s odd movements on video, including “one striking episode” in which A.H. slowed her movements and shook her left arm. In other video clips, no abnormal movements could be ascertained. Although the doctor suspected the episodes were seizures, he noted that “[a]rguing against seizure ... is that they [the episodes] are often bilateral without clear loss of consciousness.” He therefore suggested the possibility that the movements could be a movement disorder resulting from the basal ganglia injury.

B. Petitioner’s Exhibit 9 and the October 15, 2010 Fact Hearing

Along with A.H.’s medical records, Petitioner also submitted “Exhibit 9,” which consists of five typed pages and is entitled “Seizures.” There is no date or signature on the document, but reference was made on the January 23, 2006 visit to “several typewritten sheets.” These “sheets” and Exhibit 9 are presumably one and the same. Indeed, Petitioner testified that the first four pages, up to the “UPDATE” on page 4, were given to the doctor on the January 23 visit. *Id.* at 7 (citing Transcript of October 15, 2010 Hearing). The remaining events recorded in Exhibit 9 were added later.

The Special Master noted several differences between the events recorded on Exhibit 9 and the contemporaneous medical records. For example, where the medical records from both December 2 and December 28 indicate that on December 2, A.H.’s head shook “a little bit,” and the December 2 record indicates the shaking stopped when Petitioner touched A.H.’s face, Exhibit 9 – recorded *after* the events on December 28 and 30 – states that, in addition to A.H.’s head shaking, her arms and hands also shook. The post-diagnosis recording is the first time where the arm and hand shaking appears in the record. Exhibit 9 likewise lacked any reference, with respect to the December 2 incident, to the fact that A.H.’s odd behavior ceased when Petitioner touched her face. As the Special Master stated, “[t]hese are meaningful facts for the medical analysis of the case.” *Id.* at 8.

Exhibit 9 also refers to two additional “seizures.” It states that the “2nd seizure took place again in the car.” The third “seizure” occurred when Petitioner’s aunt was visiting. The Special Master observes that the seizures are not referenced in the medical records.² He also noted that Petitioner stated, on December 28, when A.H. was being admitted, that there had been one similar incident about a month ago, not two or three incidents. *Id.*

In order to clarify the circumstances surrounding Exhibit 9, the Special Master held a hearing on October 15, 2010. Petitioner described the alleged second seizure in much the same terms as the first, and that the third involved A.H.’s eye “suddenly moving to one side and then the other ‘and just st[icking] there.” According to the testimony, Petitioner’s mother was present for this third seizure. Despite this, there was no mention of the eye issue at the December 19 visit. *Id.* at 9-10.

With respect to the December 15 call, the records merely indicate “fussiness.” Yet Petitioner’s testimony was that A.H. “has been pressing her hands against her forehead and just screaming like someone was stabbing her with needles.” Again with respect to the visit on December 19, the record indicates that the parents reported A.H. crying all of the time, but it notes “no illness.” Petitioner’s testimony is once again at odds with the record, as Petitioner claims that A.H. had been screaming and “she had her hands in a ball pressed up against her forehead.” *Id.* at 9.

Petitioner also testified that she told the doctors at Porter Hospital that “my daughter’s been having seizures for weeks now. And I told them that she first had the seizure the next day right after her vaccines.” Once again, this is directly contradictory to the medical records. The records show that Petitioner described an abrupt onset about an hour prior to her admission, but until that point, there “has not been any problems as far as mother can recall.” *Id.* at 10.

Given the foregoing, the Special Master found the records “the most logical and reliable descriptor of the events in question.” Not only was the testimony markedly different from any of the contemporaneous evidence, but Petitioner’s notes include medical conclusions regarding the alleged seizures, and such conclusions are not reliable coming from a lay person. This is not to say that the Special Master believed that Petitioner was falsifying anything; rather, he suggested that the events of December 28 and 30 may have retrospectively influenced Petitioner’s view of prior events.

C. Petitioner’s Exhibit 30

On August 27, 2010, Petitioner filed an affidavit “which differs greatly from the contemporaneous medical records and from the mother’s notes filed as petitioner’s Exhibit 9.” This affidavit varies greatly both from the medical records and from Exhibit 9. For example, in

² The medical records do demonstrate that Petitioner made phone calls on December 12 and 15, and the Special Master recognized these calls, as well as the December 19 check up. Decision at 8. However, the Special Master also noted that “Petitioner, who had a pattern of calling the doctors, did not contact the doctors regarding these ‘seizures.’ There is no mention of these events during the two phone calls to the doctors or during the one visit in December.” *Id.* (internal citation omitted).

contradiction of both earlier records, Exhibit 30 states that, after immunization, A.H. never stopped crying, and in fact, “she continued to scream every day, every night.” Exhibit 30 also states that the Petitioner made numerous trips to the doctors, but she was given “every excuse in the book,” while the records indicate that petitioner called the doctors twice and visited them once between the immunizations and A.H.’s eventual hospitalization. Given the time between the actual events and the extreme difference between events recorded contemporaneously and in Exhibit 30, the Special Master did not find Exhibit 30 credible. He also observed that the Petitioner’s expert did not even rely on the affidavit in reaching his opinion, so the lack of credibility with respect to the affidavit was “virtually meaningless.” *Id.* at 9.

D. The Expert Witnesses

1. Dr. Jacobson

Petitioner’s expert, Dr. Jacobson, testified as an expert in pediatric neurology. He testified that he is the Chief of Pediatric Neurology at New York Medical College, while his CV reflects that he is an Associate Clinical Professor of Neurology and Pediatrics at NYMC.³ He is board certified in Neurology, with special qualifications in Child Neurology. Nothing in Dr. Jacobson’s testimony indicated the extent of his experience with AVMs.

Dr. Jacobson’s amended report contains a one-paragraph summary of the events following immunization. According to the Special Master, this summary appeared to be derived from a combination of the medical records and Exhibit 9. Based on this summary, Dr. Jacobson opined that A.H.’s incessant crying and screaming after her vaccinations caused “transient intracranial pressure, increased intracranial venous pressure, and blood pressure alterations.” In Dr. Jacobson’s opinion, these alterations led to the hemorrhage, which then produced the seizures. Decision at 12.

Dr. Jacobson opined that the records demonstrate a “stuttering presentation” of symptoms, including the doctor contact on December 12 for eye wandering, December 15 for fussiness, and December 19 for crying, as well as Petitioner’s notations describing the alleged second and third seizures. This presentation culminated in the December 28 hospitalization and subsequent seizure diagnosis on December 30. *Id.*

2. Dr. Wiznitzer

Dr. Wiznitzer, Respondent’s expert, is a child neurologist at Rainbow Babies and Children’s Hospital in Cleveland, Ohio. His certifications include pediatrics, child neurology and neurodevelopment disabilities. Dr. Wiznitzer disagreed with Dr. Jacobson on several key issues. For example, Dr. Wiznitzer described the December 2 event as nothing more than drowsiness or a brief breath-holding spell. He also observed that the alleged second and third seizures are documented nowhere in the medical records. Finally, he noted that A.H. had several episodes of prolonged crying prior to the immunizations, and he observed that none of these episodes precipitated her hemorrhage. *Id.* at 12-13.

³ The Special Master found that this discrepancy had no bearing on the case. Decision at 12.

II. Standard of Review

Under the Vaccine Act, a court may set aside a Special Master's findings of fact or conclusions of law only if they are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B). With respect to findings of fact, the Special Master has broad discretion to weigh expert evidence and make factual determinations. See *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). "If the special master has considered the relevant evidence of the record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). This Court ought not to second-guess the Special Master's fact-intensive conclusions, particularly in cases "in which the medical evidence of causation is in dispute." *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). In such cases, which often involve expert testimony, the Federal Circuit has "unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act." *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011). "Such credibility determinations are 'virtually unreviewable'" on appeal. *Id.* at 1251. With respect to questions of law, legal rulings are reviewed *de novo* under the "not in accordance with law" standard. See, e.g., *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

III. Discussion

This Court's task on review is to determine whether the Special Master properly considered the relevant evidence in the record before him, came to factual conclusions based on plausible inferences, and provided a reasoned explanation for his conclusions and his decision. *Hines*, 940 F.2d at 1528.

Here, the Special Master expressly relied on two findings in reaching his conclusion. The first, answered in the negative, was whether the December 2 event was a seizure. The Special Master found this issue dispositive because Dr. Jacobson's entire opinion "hinged on the December 2 event being a seizure." The second issue, also answered in the negative, was whether it was logical, based on the evidence available, to conclude that whatever happened on December 2 was medically connected to the December 28 event and hospitalization. Because the Special Master determined that the December 2 event did not constitute a seizure, and that no logical causal connection could be drawn between the December 2 and December 28 events, the Special Master determined that Petitioner had failed to prove by preponderant evidence that the vaccinations caused A.H.'s injuries.

In her brief challenging these findings, Petitioner raises six objections to the Special Master's decision:

1. The Special Master disregarded statements of treating doctors regarding opinions that the petitioner's vaccinations may have caused her injury.
2. The Special Master failed to issue a dispositive ruling on petitioner's medical theory as required by Vaccine Rule 3.
3. The Special Master failed to follow the standards of *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005) and other Federal Circuit cases, by requiring scientific certainty of vaccine causation, increasing petitioner's burden of proof.
4. The Special Master failed to give adequate weight to petitioner's notes found in Exhibit 9, and relied too heavily upon the medical records, which did not contain the complete medical history.
5. The Special Master's clear bias in favor of respondent's expert was contrary to the evidence and imposed an improper legal burden upon petitioner.
6. The Special Master did not rule on petitioner's significant aggravation claim.

Mot. at 3. In light of the Special Master's detailed and reasoned decision, this Court concludes that none of these arguments provides a basis for this Court to set aside the Special Master's decision.

A. The Special Master did not “disregard” statements of treating doctors.

Petitioner's first argument is that the Special Master disregarded several statements in the medical records which support Petitioner's claim of vaccine injury. Petitioner relies on nine quotes from A.H.'s medical records to support her argument. Although Petitioner's attorney made no effort to put these quotes in context, a review of the record sheds some light on where each of these excerpts may be found.

It is clear that the excerpts refer, respectively, to: the December 1 phone call; the December 12 phone call; December 30 hospital stay; the January 10 discharge summary (which repeats the December 30 statements); the Dartmouth-Hitchcock visit on January 23; a February 13, 2006⁴ record; the April 11 visit to FAHC; a record from an October 2, 2006 visit stating “[i]ntracranial bleed @ 3 mos. old. ? caused by immunizations,”⁵ Pet. Ex. 3 at 94; and the May 18 visit to Children's Hospital Boston.

Notably, all but one of these records is expressly cited by the Special Master. For example, the Petitioner emphasizes from the April 11 recording that “[t]he mother had many questions regarding its proximity to recent immunization. We counseled her that this would be a rare event but certainly not improbable.” Mot. at 4 (emphasis in brief). The Special Master's decision refers to the *exact same passage*, observing that the record “noted that ‘mother had many questions regarding [the bleed's] proximity to recent immunization. We

⁴ This particular reference does not appear to be cited in the Special Master's report. The record states, as past history, that A.H. has a “[s]eizure history (- diagnosed after 2 month shots). (‘bleed in her brain’ per mom @ 3 months).” Pet. Ex. 3 at 196. That particular record also clearly reflects the following: “Historian: patient and family.”

⁵ This reference does not appear in the Special Master's discussion of the medical records, but is addressed in his analysis. *See* Decision at 24.

counseled that this would be a rare event but **certainly not improbable.**” Decision at 7 (emphasis and modification in Decision).

To say that the Special Master disregarded the records which he cited is to question his finding of fact. This Court sees nothing arbitrary or capricious here, for several reasons. First, not one piece of evidence cited by Petitioner shows a treating physician diagnosing a seizure prior to the late December hospitalization. The December 2 and December 12 references describe nothing more than a crying baby with a wandering eye, which the Special Master reasonably found not to be seizures based on (1) the medical records and (2) Dr. Wiznitzer’s testimony. The December 30 reference diagnoses seizures “[s]ince admission” and states that A.H. “had one similar episode about one month ago,” but the descriptions of the early and late December events are plainly distinguishable. In early December, A.H. allegedly screamed, ceased screaming and had a strange look on her face, began shaking her head “a little bit,” retained her color, and recovered as soon as Petitioner touched her face. Decision at 4. The description of the December 28 event makes clear that A.H. “turned white and [became] lifeless.” Respondent’s expert was able to explain why one of these events was a seizure and the other was not, and the Special Master found this explanation persuasive.

Continuing with the Petitioner’s other references which the Special Master discussed, the January 23 record does not diagnose the December 2 event as a seizure. Instead, it is merely a record of Petitioner’s conclusion – made in hindsight – that the event was a seizure. The same goes for the May 18 note: there is no diagnosis by a physician, but instead, the record clearly states that A.H.’s “***mother relates the onset of A.H.’s symptoms to her receiving her 2 month vaccinations.***” Mot. at 5 (bold in brief, italics added by the Court). The “Intracranial bleed @ 3 mos. old. ? caused by immunizations” is rejected as raised, at best, the “questionable role of the immunizations; at worst, it merely reflects historical information from sources unknown to us.” Decision at 24.

The Special Master referred to each of these records, but based on the medical records and the expert testimony, the Master concluded that the December 2 event was not a seizure. This Court will not substitute its judgment for that of the Special Master when the Special Master considered all of the pertinent evidence, including many of the particulars cited by Petitioner.

Turning to the reference in Petitioner’s brief that is not expressly cited in the Decision, the Court must once again find that the Special Master’s findings of fact are not arbitrary or capricious. It is clear that no diagnosis was made by a treating physician on the February 13 visit, but all of the pertinent facts raised by this record were included in the Special Master’s analysis. Taken as a whole, the February 13 record provides the following facts: (1) A.H. had some history of seizures; (2) these seizures were diagnosed some time after her two month shots; and (3) Petitioner thought that the December 2 incident was a seizure. All three of these facts are included elsewhere in the Special Master’s decision. Moreover, the only reference to a seizure in the February 13 record is derived from Petitioner’s review of A.H.’s health history, as noted by the fact that the “Historian” for the record is listed as “patient and family.”

To the extent that Petitioner instead argues that, “[i]f the special master had properly weighed these records [rather than disregarded them], there would have been adequate evidence to corroborate the mother’s notes in Exhibit 9, substantiating their credibility,” there are two

flaws in the argument. The first is that it complains about the weight given a piece of evidence by the Special Master, the consideration of which is beyond this Court's review. *See Bradley*, 991 F.2d at 1575. The second is that, logically speaking, not one of the records cited establishes that A.H. suffered from seizures prior to December 28. At best, they repeat the Petitioner's own lay speculation on that topic, and the records from prior to December 30 don't even do that much. This gives rise to the very same issue which the Special Master observed with respect to Exhibit 9. That is, all of Petitioner's references to seizures arise *after* A.H. was diagnosed with an actual seizure, and all are rooted in Petitioner's speculation, which the Special Master believed to be tainted by hindsight. *See* Decision at 11 (observing that "it is very possible that petitioner was influenced by the events of December 28 in retrospectively describing in her notes A.H.'s behavior over the month of December."). Thus, even if this Court were to give these records the weight which Petitioner argues they should be accorded, they do not corroborate the facts underlying Exhibit 9 in any meaningful way.

Based on the foregoing, the Court sees no reason to conclude that the Special Master "disregarded" or improperly weighed any of the cited portions of the record. Most of the evidence cited by Petitioner in her motion is actually cited by the Special Master. That evidence which is not cited in the Decision adds nothing new in the way of the analysis. Hence, this Court finds that Petitioner's motion should be denied on this ground.

B. The Special Master's failure to issue a dispositive ruling on Petitioner's medical theory is not "fatal" to his decision.

In order to make out a *prima facie* case under *Althen*, Petitioner must show by preponderant evidence that the vaccination caused A.H.'s injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. Petitioner asserts that she believes she has satisfied prongs two and three, and thus, the Special Master failure to rule on prong one is "fatal and renders the opinion arbitrary and capricious and contrary to law." Mot. at 7.

While Petitioner may believe she has established all of the necessary prongs under *Althen*, the Special Master made express findings which foreclose that possibility based on Petitioner's own medical theory. Petitioner's medical theory, as presented by Dr. Jacobson, is that the events beginning on December 2 – the day after vaccination – escalating throughout the month, and culminating in the hospitalization and seizures occurring between December 28 and 30 evidence a "stuttering presentation" of seizure-like symptoms that began immediately after the vaccinations. *See* Decision at 17 (describing Dr. Jacobson's theory, including "stuttering or episodic presentation"); *id.* at 25 (describing Dr. Jacobson's description of A.H.'s "stuttering presentation"). The theory is that A.H. has a preexisting AVM, which both experts agreed was unrelated to the vaccination. Decision at 17. Dr. Jacobson's testimony was that A.H.'s intense crying after vaccination led to the bleed, which in turn led to the seizures. *Id.* In Dr. Jacobson's words:

The incessant crying and significant intense screaming resulting from the vaccinations caused transient intracranial pressure, increased intracranial venous

pressure, and blood pressure alterations. These pressure alterations precipitated the intracranial hemorrhage from the vascular anomaly leading to the onset of seizures from the intracranial hemorrhage.

Decision at 32 (citing Pet. Ex. 31 at 2). The Special Master “found the medical theory may have some reliable support, but that the record was not sufficiently developed. Given that the case is resolved on two overriding issues under Prong II,” the Special Master did not rule on prong I. *Id.*

Despite Petitioner’s belief that she has made an adequate showing under *Althen*, the Special Master found that Petitioner had failed to establish prong II, on the basis of these two overriding issues. The first was that Dr. Jacobson admitted that it was critical to his theory that the December 2 event be a seizure. *See* Decision at 17. If that particular event was not a seizure, then Dr. Jacobson “would say that my opinion is no longer at the level of reasonable medical certainty.” *Id.* In light of the medical records and other evidence available, the Special Master found Dr. Wiznitzer’s explanation for why the December 2 event was *not* a seizure more persuasive than Dr. Jacobson’s explanation for why it was. Thus, removing the fact of a December 2 seizure from the analysis, Dr. Jacobson’s testimony was left “without the beginning of the story,” and his theory, by his own admission, was no longer reasonably medically certain.

In addition, regardless of whether the December 2 event was a seizure, the Special Master found that AVMs do not present consistently with Petitioner’s theory. The Special Master considered the testimony of both experts, who described their views on presentation of AVM bleeds. Once again, the Special Master found Dr. Wiznitzer’s testimony the more persuasive. This led to the conclusion that Petitioner had failed to produce preponderant proof of “the so-called stuttering presentation of AVM.” Thus, a second key element linking the vaccines to A.H.’s injury was missing from Dr. Jacobson’s testimony.

These conclusions are well-reasoned and supported by the evidence. This Court will not overturn the Special Master’s factual conclusions. In refusing to do so, the Court must reject Petitioner’s argument that the Special Master’s failure to address prong I is fatal to his decision. To some extent, the Special Master assumed prong I had been satisfied, because he analyzed the facts to see if they could support Petitioner’s medical theory. In the Special Master’s view, the facts were insufficient – even if the theory was upheld – to show “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Thus, his failure to rule on prong I is not fatal to his decision, because his findings on prong II are instead fatal to Petitioner’s theory. The motion is denied on this ground.

C. The Special Master did not require scientific certainty of vaccine causation.

Petitioner next complains that the Special Master failed to follow the standards set forth in *Althen* by increasing Petitioner’s burden of proof through reference to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Mot. at 8. Petitioner’s argument presents a question of law, as she asserts that the Special Master’s improper reliance upon *Daubert* led to the rejection of Dr. Jacobson’s testimony (and, presumably, reliance upon Dr. Wiznitzer’s testimony). She asserts that the Special Master’s use of the *Daubert* standards impermissibly revived the standard in *Stevens v. Sec’y of Health & Human Servs.*, No. 99-594V, 2001 WL

387418 (Fed. Cl. 2001). Mot. at 10-11. She claims that the Special Master's application of *Daubert* raised her burden by requiring medical certainty of her proposed theory.

To the extent that Petitioner argues that use of *Daubert* somehow revives *Stevens*, that argument is plainly specious. The Federal Circuit has repeatedly stated that the Special Master may refer to *Daubert* to assess reliability of expert testimony in vaccine cases. *See, e.g., Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338-39 (Fed. Cir. 2010); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *Andreu*, 569 F.3d at 1379; *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999); *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994); *Perreira v. Sec'y of Health & Human Servs.*, 33 F.3d 1375, 1377 n. 6 (Fed. Cir. 1994). There is nothing impermissible about the Special Master referring to *Daubert* to assess the reliability of Dr. Jacobson's testimony. Indeed, Dr. Wiznitzer's testimony was held to the same standard.

Petitioner was careful not to argue too stridently that *Daubert* may not be used in vaccine cases, as that proposition is clearly wrong. Instead, the thrust of her argument is directed at the Special Master's application of *Daubert*, and is divided between two topics: the level of proof necessary to show that the December 2 event was a seizure, and the allegation that medical literature supports Petitioner's case. With respect to the first, the Special Master found that Dr. Jacobson's testimony and the Petitioner's additional exhibits and testimony were insufficient to prove that A.H. suffered a seizure on December 2. Thus, contrary to Petitioner's position that the Special Master held that a contemporaneous diagnosis was dispositive, the Special Master actually held that the medical records, expert testimony, additional evidence and Petitioner's testimony combined were insufficient to demonstrate a seizure on December 2.

As to the second topic, Petitioner argues that the literature supports her position, and specifically points to her Exhibit 33 as an example of medical literature supporting Dr. Jacobson's testimony. Mot. at 12. Again, the Special Master gave consideration to, and provided analysis of, the literature and related expert testimony. *See* Decision at 27-31. The Special Master's findings on these articles and the related testimony are factual, and are adequately and reasonably explained by the Special Master. Once again, this Court sees no reason to tamper with the Special Master's findings of fact, as they are not arbitrary or capricious.

D. The Special Master did not fail to give adequate consideration to the Petitioner's notes in Exhibit 9, nor did he rely too heavily upon the medical records.

Next, Petitioner complains that the Special Master gave the medical records too much weight in his analysis, while he did not give sufficient weight to Petitioner's Exhibit 9. As such, Petitioner argues that it is contrary to the law to base a decision on vaccine compensation solely on the medical records. Mot. at 13.

As an initial point, Petitioner claims that the Special Master was incorrect in stating that Exhibit 9 "is not contained in th[e medical] history." *Id.* Petitioner refers the Court to Dr. Hyder's statement that he has included in record "several typewritten sheets" produced by the Petitioner. These sheets, says Petitioner, are Exhibit 9. Based on Petitioner's testimony, this statement is not entirely true, as she confirmed that the first four sheets, up to "UPDATE" on

page 4, were given to Dr. Hyder, and the remainder of page 4 and all of page 5 were produced at a later time. Decision at 7.

Regardless of whether or not Exhibit 9 was actually contained in A.H.'s medical records, the Special Master considered the Exhibit. He also considered Exhibit 30, as well as Petitioner's testimony at the October hearing. Given that each rendition of Petitioner's story was different, and the later recordings and testimony directly conflicted with the contemporaneous records, the Special Master found noted that "the medical records and petitioner's notes are contemporaneous." He also observed that contemporaneous records "are to be given greater weight, but that rule should not be applied reflexively." Decision at 11 (citing *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (Fed. Cl. 2006); *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 537-40 (Fed. Cl. 2011)). Thus, the Special Master clearly gave consideration to the non-medical record evidence, but based on common sense and logic, found the medical records to be the most persuasive written evidence.

But the Special Master's analysis did not stop there. The Special Master analyzed the expert testimony provided by both experts. These experts relied on the medical records, Petitioner's exhibits, medical literature, and the experts' experience in the field of pediatric neurology. Dr. Wiznitzer also considered Petitioner's testimony, and Dr. Jacobson was given the opportunity to do so, but did not. Decision at 10. It was after consideration of this testimony that the Special Master concluded no seizure had occurred on December 2, and that Petitioner was therefore unable to make the necessary showing under *Althen*.

Petitioner also attempts to paint the Special Master's decision as factually inaccurate for failure to recognize a third seizure in the medical records or for failing to rely upon Brenda Vaughan's⁶ ("Vaughan") testimony. These two challenges are, essentially, directed to the Special Master's findings that the December 2 and December 12 events were not seizures. Notably, Vaughan testified that, on December 2, Petitioner had called and described A.H. as reaching her hands to her head and shaking. Mot. at 15. Petitioner evidently views this as conclusive proof of a seizure on December 2, despite the fact that (1) this shaking, which is evidently now so key, does not appear in Petitioner's report to the doctors at the time of event; and (2) later episodes of shaking were recorded on video EEG, and they were not diagnosed as seizures. Dec. at 18. Thus, even accepting that the shaking did occur, there was a reasonable basis for the Special Master to conclude that the December 2 event did not constitute a seizure. Likewise with the December 12 event, which was adequately considered throughout the decision. Once again, the medical records and expert testimony provide a reasonable basis for these findings, and as such, they are not arbitrary or capricious.

E. The Special Master was not clearly biased in favor of respondent's expert.

Petitioner next argues that the Special Master was biased in favor of Dr. Wiznitzer. Petitioner's argument is largely just a summary of the two experts' competing opinions. Petitioner concludes that Dr. Wiznitzer's testimony relies solely upon the medical records, and

⁶ Petitioner's brief refers to Brenda Vaughan as "Brenda Vaughn."

that this “tunnel vision” renders his opinion, and the decision which relies upon it, contrary to law.

The Special Master’s reliance upon Dr. Wiznitzer’s testimony had nothing to do with the fact that it relied solely upon the medical record. Instead, it had to do with the weakness of Dr. Jacobson’s testimony. Petitioner selectively cites portions of the decision, but when taken in the context of the entire decision, it is clear that the Special Master found Dr. Jacobson evasive, and he believed Dr. Jacobson’s answers were frequently unsupported by fact. For example, the Special Master was incredulous about Dr. Jacobson’s explanation for why A.H. had stopped seizing when Petitioner touched her face: it was “coincidental,” said Dr. Jacobson. Decision at 19. Then, when asked what information he had relied upon in forming his opinion, Dr. Jacobson merely stated that “I’m talking about in broad terms whatever information we want to look at between the events.... Whatever information you choose.” “Whatever information” is not a reliable basis for forming an expert opinion.

In explaining why Petitioner only reported “eye wanders and sticks,” fussiness, and crying when there were – according to Exhibit 9 and later evidence – major issues with shaking and the like, Dr. Jacobson only responded that “it sometimes happens.” Then, as his explanation for why, on December 28, Petitioner only reported one similar episode rather than multiple other episodes, Dr. Jacobson observed that “it’s unusual” for two such different recollections.

Evidently recognizing that his argument was not carrying the day, Dr. Jacobson changed his tune. No longer were the two intervening events necessary to demonstrate a stuttering presentation between December 2 and December 28. Instead, the intervening events did not need to be seizures, but instead showed that A.H. was not “acting perfectly well.” His answers to questioning along these lines left the Special Master feeling that Dr. Jacobson was being evasive. Decision at 22.

That the Special Master “was far more impressed and persuaded by the testimony of Dr. Wiznitzer” does not show any bias, and shows that the Special Master in fact did exactly what the Federal Circuit has admonished special masters to do in vaccine cases. *See Porter*, 663 F.3d at 1250 (“Indeed, this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act.”). The decision shows that the Special Master considered the testimony of both experts, and indeed, it recaps a significant amount of information from both experts, but in the end, the Master concluded that Dr. Wiznitzer was the more trustworthy. The Special Master, as fact finder, “has broad discretion in determining credibility because he saw the witnesses and heard the testimony.” *Bradley*, 991 F.2d at 1575. For this reason, the Special Master’s determination on credibility is “virtually unreviewable,” *Porter*, 663 F.3d at 1251, and to the extent that it is reviewable, this Court sees nothing arbitrary or capricious in the Special Master’s findings here.

F. The Special Master did not expressly rule on Petitioner’s significant aggravation claim, but that failure is not fatal to his decision because such a ruling is implicit in the Special Master’s decision.

Petitioner's final attempt to overcome the Special Master's decision is a challenge to the Special Master's failure to address Petitioner's significant aggravation claim. Under the Vaccine Act, a "significant aggravation" is "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. 300aa-33(4). The Special Master concluded that "Petitioner raised for the first time in her post hearing brief the alternative legal theory of significant aggravation." Decision at 13 n. 6. Petitioner points to her Prehearing Memorandum and Notice of Filing Exhibits as proof that she raised the issue. That memorandum, as far as this Court can discern, includes the following as the extent of Petitioner's argument for significant aggravation:

Petitioner will be able to show preponderant evidence of a reliable medical theory, a logical sequence of cause and effect showing that the December 1, 2005 vaccinations were the cause of **(or significant aggravation of)** A.H.'s bleeding resulting in a permanent seizure disorder, and a medically acceptable temporal association between the vaccinations and A.H.'s injuries.

Mot. at 22 (citing Petitioner's Prehearing Memorandum and Notice of Filing Exhibits 18-31) (emphasis added). Whether or not that single statement is sufficient to raise a claim of significant aggravation, the Special Master also concluded that Petitioner did not "produce any evidence to support a finding of significant aggravation." Decision at 13 n. 6. Petitioner challenges this finding, as well.

This Court need not address whether Petitioner timely raised her significant aggravation claim because it is clear that Petitioner has not met her evidentiary burden here. A showing of significant aggravation requires demonstration of the following elements 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.

Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 144 (Fed. Cl. 2009). Judge Lettow's analysis in arriving at that test is persuasive. He derived this six-element test from the Federal Circuit's test for on-Table significant aggravation claims set forth in *Whitecotton v. Sec'y of Health & Human Servs.*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), *on remand from Shalala v. Whitecotton*, 514 U.S. 268 (1995). The first three elements of the *Loving* test are identical to the *Whitecotton* test, and the final element of the *Whitecotton* test is modified to account for off-Table injuries.

In following the *Loving* test, the Court notes that the final three elements are derived directly from *Althen*. As described above, the Special Master found that there was no "logical sequence of cause and effect" (*Althen* prong II) between the December 1 vaccinations and the

events on December 28 and after. *See* Decision at 32-33. This finding was based upon the Special Master’s conclusions (1) that the December 2 event was not a seizure, and (2) that AVMs do not present in a manner consistent with Petitioner’s theory. *See* Decision at 18-32. Without a logical sequence leading from A.H.’s vaccinations to the December 28 event, Petitioner cannot show that the vaccination was the significant aggravating factor of her pre-existing condition.

Put another way, there was no need for the Special Master to rule separately on Petitioner’s significant aggravation claim in this case because the vaccine injury (upon which the Master ruled) and the alleged aggravation are one in the same. That is, the experts agreed in this case that the “new” injury upon which the Special Master ruled actually occurred *because of* A.H.’s pre-existing condition, the AVM. Decision at 17 (noting that the experts agree that A.H. had an AVM, which was unrelated to the immunizations). Hence, this case presents a factual situation where the Special Master’s finding that Petitioner failed to make out a case under an injury theory is also dispositive on any significant aggravation theory.

IV. Conclusion

It is clear to the Court that the Special Master “has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.” *Porter*, 663 F.3d at 1253-54. To the extent that the Special Master failed to make the express rulings about which Petitioner complains, those rulings are inconsequential because the rulings expressly made by the Special Master are dispositive in this matter. Hence, Petitioner’s Motion for Review is denied, the Special Master’s decision is affirmed, and the Clerk is directed to enter judgment accordingly.

/s Edward J. Damich
EDWARD J. DAMICH
Judge