In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 09-812V

Filed: August 30, 2013

FATIMA MOHAMUD, parent of KOSHIN YUSUF, a minor	*	TO BE PUBLISHED
	*	Tetanus-diptheria-pertussis vaccination ("Tdap"); Encephalopathy; Seizure Disorder
Petitioner,	*	
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald Homer (Christina Ciampolillo and Sylvia Chin-Caplan), Conway, Homer & Chin-Caplan, P.C., Boston, MA, for Petitioner

Darryl Wishard, U.S. Dep't of Justice, Washington, DC, for Respondent

DECISION DENYING ENTITLEMENT AND DISMISSING CASE[1]

This matter is before the special master for a decision on entitlement. On November 23, 2009, Petitioner, Fatima Mohamud ("Petitioner"), filed a petition on behalf of her son, Koshin Yusuf ("Petitioner's son" or "son"), pursuant to the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. § 300a-1, *et seq.*, as amended.[2] Petitioner alleges that her son

[1] Because this decision contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, § 205, 44 U.S.C. § 3501 (2006). The decisions of the special master will be made available to the public with the exception of those portions that contain trade secret or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. As provided by Vaccine Rule 18(b), each party has 14 days to file a motion requesting the redaction from this decision of any such alleged material. In the absence of a timely request, which includes a proposed redacted decision, the entire document will be made publicly available. If the special master, upon review of a timely filed motion to redact, agrees that the identified material fits within the categories listed above, the special master shall redact such material from the decision made available to the public. 42 U.S.C. § 300aa-12(d)(4); Vaccine Rule 18(b).

[2] Part 2 of the Vaccine Act establishes the National Vaccine Injury Compensation Program, 42 U.S.C. § 300a-10, *et seq.*

suffered seizures and autoimmune encephalopathy as a result of his receipt of the tetanus diphtheria acellular pertussis ("Tdap") vaccine he received on July 23, 2007, at the age of 12. Respondent asserts that Petitioner's son's injuries were not caused by the vaccine and, thus, Petitioner is not entitled to compensation.

As explained in detail below and based on the record as a whole, Petitioner has failed to satisfy her burden of establishing that the vaccine caused her son's injury. First, in light of the facts of this case, Petitioner's proposed theory that the vaccine could cause an inflammatory response that resulted in seizures and then led to prolonged inflammation which resulted in an acute encephalopathy is not plausible. Second, Petitioner has failed to provide sufficient evidence to establish a logical sequence of cause and effect, evidence that the vaccine did cause her son's injuries. There is no evidence of the occurrence of an autoimmune process, *e.g.*, there is no evidence of an inflammation. Petitioner's son's EEG, MRI and laboratory tests are all normal and the progression of his symptoms is inconsistent with the recognized progression of an autoimmune disorder. Third, there is not a medically appropriate temporal relation between the time of vaccine and initial seizure given Petitioner's medical theory. Even if the timing of the initial seizures could be considered temporally appropriate, because the next seizure was a singular isolated event that occurred months later, such a progression is inconsistent with the timing of the process that would occur if Petitioner's son was subject to an ongoing autoimmune reaction as Petitioner claims. Petitioner has failed to satisfy her burden. This action must be and hereby is **DISMISSED.**

I. PROCEDURAL BACKGROUND

Petitioner filed her claim on November 23, 2009. Shortly thereafter, Petitioner filed the pertinent medical records. On March 15, 2010, Respondent, in her Rule 4 Report, advised that her position was that Petitioner was not entitled to compensation.

Petitioner and Respondent then filed expert reports. An entitlement hearing was held on May 24, 2011 before former Chief Special Master Dee Lord.[3] At the hearing, Petitioner presented the testimony of Dr. Paul Maartens, and Respondent presented the testimony of Dr Schlomo Shinnar.

Upon review of the transcript, it was discovered that due to technical difficulties during the hearing, there were many gaps in the substantive testimonies of the experts. As a result, prior to submitting post-hearing briefs, the former special master ordered the parties to review the transcript and provide a status report that identified corrections and additions to the hearing transcript to fill in the gaps in the transcript. The parties submitted that document on September 6, 2011.

Subsequently, the parties submitted post-hearing briefs in October and November 2011. The previously-assigned special master resigned in September 2012, prior to issuing a decision. This matter was then reassigned to this special master. Status conferences were conducted in

[3] The hearing was conducted via videoconferencing with SM Lord in Washington, DC and both parties' lawyers and witnesses in Boston, MA.

October 2012 and June 2013. At those conferences, the parties confirmed that they did not wish further proceedings in light of the reassignment. The parties also confirmed that they were satisfied with the state of the transcript. Subsequently, they filed a status report stating this. The matter is now ready for decision.

II. FACTS

The facts as evidenced by the records and testimony are as follows:[4]

Petitioner's son was born on September 10, 1994. Petitioner's Exhibit ("P's Ex") 10. Petitioner's son had a history of allergic rhinitis, asthma, and recurring strep pharyngitis that began as early as 2002 when he was seven years old. P's Ex. 3 23-26. In 2002 he suffered a trauma to the head. P's Ex. 1 at 13. An x-ray did not show an obvious fracture but given only a lateral view was taken, they did not rule out skull fractures. P's Ex. 1 at 12. In the months prior to his July 23, 2007, medical examination and vaccination, he had experienced increased anger issues. P's Ex. 2 at 121. During a routine visit to his primary care physician, Dr. Haycraft, on July 23, 2007, he received a Dtap vaccine. P's Ex. 3 at 27. That evening he had a generalized headache, which dissipated by the following morning. P's Ex. 2 at 121.

The next morning, July 24, 2007, Petitioner's son collapsed on the floor, suffering a generalized seizure. P's Ex. 2 at 121. He had not had a recent fever, upper respiratory or gastrointestinal symptoms and was afebrile at the time. *Id.* He did not have a headache at the time. P's Ex. 2 at 122. The seizure was brief and when he was found he was confused and pale, but knew where he was and was oriented to time and place. P's Ex. 2 at 113, 121. Petitioner's son was taken to the hospital by EMS. P's Ex. 2 at 6; P's Ex. 4 at 3. He was afebrile with a chief complaint of seizure. P's Ex. 2 at 83. In the notes from the neurologic examination, it was noted that Petitioner's son was "initially alert and appropriately responsive." P's Ex. 2 at 84. His lab results and head CT scan results were normal. P's Ex. 2 at 148.

While being evaluated in the emergency room, Petitioner's son had two additional seizures. P's Ex. 2 at 84. The first seizure was described as "a forward flank stare and some eye fluttering" which lasted approximately 60 seconds and "no generalized tonic-clonic movements were observed." *Id.* About an hour and a half later, Petitioner's son experienced the second seizure which was described as being similar to the first. *Id.*

The neurologist who examined Petitioner's son, Dr. Lawrence Burstein, noted that Petitioner's son was stable and afebrile. P's Ex. 2 at 66. Dr. Burstein also noted that there was a history of possible seizures in a maternal aunt. P's Ex. 2 at 65. On neurologic examination, Petitioner's son's mental status was found to be intact. P's Ex. 2 at 66. His speech was fluent. *Id.* There was no right/left disorientation. *Id.* His cranial nerves were intact and fundi normal. *Id.* His motor exam revealed normal muscle strength and tone in both upper and lower extremities. *Id.* He had a normal CT, an unremarkable complete blood count, a negative drug screen and normal electrolytes. P's Ex. 2 at 122. Petitioner's son had not had a fever at home,

[4] The facts as set forth herein are derived from the medical records, with reference to the Rule 4 Report and the parties' pre-hearing and post-hearing submissions.

but he did develop and had a low-grade fever the evening he was admitted to the hospital. *Id.* The impression upon Petitioner's son's admission was of one having experienced several seizures, most likely partial complex with secondary generalization. P's Ex. 2 at 66. It was noted that Petitioner's son should be checked periodically and if he developed a headache, stiff neck or continued spikes of fever, he should be reevaluated for a spinal tap. P's Ex. 2 at 123. Upon admission, plans were made to perform a sleep deprived electroencephalogram as well as MRI studies the next morning. P's Ex. 2 at 121-22.

On July 25, 2007, a brain MRI and a sleep deprived EEG were performed. The results of the EEG and MRI were normal. P's Ex. 2 at 69-70; P's Ex. 2 at 127. Petitioner's son was discharged from the hospital on July 26, 2007 with a discharge diagnosis of partial complex seizures with secondary generalization. P's Ex. 2 at 113.

Petitioner's son's next visit to a doctor was on August 9, 2007 when he saw his primary care physician. P's Ex. 3 at 17, 20. Notes from that visit, based on the medical history provided to the doctor, indicate that Petitioner's son's seizures that led to his hospitalization were febrile. *Id.*.

On August 28, 2007, Petitioner's son had a follow up visit with the neurologist who saw him in the hospital, Dr. Burstein. P's Ex. 5 at 30. Dr. Burstein noted that Petitioner's son had not experienced any seizures since his hospitalization. P's Ex. 5 at 30. Petitioner's son was noted to be "pleasant, alert, cooperative" and "in no distress." *Id.* Although he had some occasional headaches when he first started on medication, those had resolved and Petitioner's son was not experiencing any problems with side effects or his health. *Id.* Dr. Burstein indicated that Petitioner's son's mental status was intact, he had "good fund of knowledge and memory," he had normal strength and his gait was normal. *Id.*

Petitioner's son next saw the neurologist, Dr. Burstein, nearly five months later, on January 2, 2008, for a follow-up appointment. P's Ex. 5 at 16. Petitioner's son had not experienced any seizures since his last visit in August 2007. *Id.* at 32. A complete review of symptoms revealed they were negative and Petitioner's son was otherwise in good health. *Id.* at 16.

On January 8, 2008, Petitioner's son experienced a generalized tonic clonic seizure at school. P's Ex. 6 at 9. On January 23, 2008, Petitioner's son had an appointment with his primary care physician as a result of the recent seizure activity. P's Ex. 3 at 14. His doctor updated his prescriptions and recommended a follow-up in one month. *Id.* He did not see his neurologist, Dr. Burstein, at that time.

Petitioner's son experienced seizures on March 15, 2008 and March 31, 2008. P's Ex. 2 at 37, 42; P's Ex. 3 at 8-9.[5] He had not had any symptoms of illness recently, such as fevers,

[5] Review of the medical records from Petitioner's primary care physician on April 2, 2008 indicates that Petitioner, in providing the doctor her son's medical history, had indicated that in addition to the March 15, 2008, seizure, her son had also suffered a seizure a few days before coming to the appointment. P's Ex. 3 at 8-9.

coughing or congestion. P's Ex. 2 at 42. Following these seizures, on April 2, 2008, Petitioner's son again visited his primary care physician. P's Ex. 3 at 8. On that date, for the first time since his July 2007 visit, there is a note that Petitioner's son appeared moody, tired and angry at times. *Id.*

On May 13, 2008, Petitioner's son again visited his primary care physician. P's Ex. 3 at 3-4. At that time, his doctor noted that the medication for his seizures is helping but that Petitioner's son is angry and having headaches and his grades are going down. *Id*. His doctor also noted that he had had 10 seizures since August 2007. *Id.*[6]

On June 4, 2008, Petitioner's son again experienced a seizure that lasted approximately three (3) minutes. P's Ex. 2 at 6; P's Ex. 6 at 6. It was noted that he did not have a fever and had not had vomiting or diarrhea. P's Ex. 2 at 15. His neurologist, Dr. Burstein, was consulted and at that time, Petitioner's son's medications were modified. *Id.*

On July 2, 2008, Petitioner's son was seen again by Dr. Burstein for a follow-up appointment. P's Ex. 5 at 22. Petitioner's son was noted to be "an alert and cooperative boy in no distress." *Id.* Dr. Burstein recommended a repeat EEG and continued to have Petitioner's son take his current anti-seizure medication, Keppra. *Id*. The second EEG was normal. P's Ex. 5 at 14. Petitioner's son was directed to follow-up with Dr. Burstein in three months. P's Ex. 5 at 22.

Petitioner's son did visit his primary care physician on August 1, 2008. P's Ex. 3 at 1-2. At that time, the medical history reported that Petitioner's son was experiencing depression with anxiety and having trouble in school. P's Ex. 3 at 1-2.

On September 26, 2008, Petitioner's son had an additional follow-up appointment with the neurologist, Dr Burstein. P's Ex. 5 at 4. It was reported that Petitioner's son had one additional seizure since his last visit on July 2, 2008. *Id.* He was noted as being "alert and cooperative" and "in no distress." P's Ex. 5 at 4. Petitioner's son, upon review of systems, was found to have no problems with appetite or sleep. *Id.* There were no abnormalities on review of Petitioner's son's system, and his exam was normal. P's Ex. 5 at 4.

Petitioner's son visited his neurologist again on March 4, 2009 and on July 20, 2009. P's Ex. 18 at 4, 9. He reported being seizure free at that time, his last reported seizure being sometime between July and September 2008. *Id.* The results of laboratory tests taken after the July 20, 2009 visit were normal. P's Ex. 18 at 14.

In August 2009, Petitioner applied for and had what appears to be a government funded social support plan completed for her son. P's Ex. 12 at 1-3. That plan was based on the need to assist in his safety. P's Ex. 12 at 4. The services to be provided were personal care assistance services. P's Ex. 12 at 1-4. In the report that served as the basis for the plan, Petitioner reported

[6] Review of the records do not indicate that Petitioner's son had had 10 seizures up to that point. The records show that he had three seizures when he was hospitalized in July 2007, followed by one in January 2008 and two in March 2008 for a total of six up to that point.

her son having had a mild, grand mal seizure lasting ten minutes in July 2009. *Id.* According to Dr. Burstein notes, Petitioner did not seek medical treatment for her son in connection with that seizure nor did Petitioner mention it in subsequent visits to her son's neurologist.

In November 2009, there was a consultation with the neurologist, Dr. Burstein, regarding giving Petitioner's son a H1N1 vaccine. P's Ex. 18 at 24. The reason for the consult is that Petitioner had expressed her belief that the Tdap vaccine received by her son previously had caused his seizures. *Id.* Dr. Burstein approved the administration of the vaccine. *Id.* Petitioner received that vaccine at that time. P's Ex. 16 at 10. There were no seizures reported thereafter.

Petitioner's son again saw his neurologist, Dr. Burstein, on January 4, 2010 and July 8, 2010. P's Ex. 18 at 23 and 32. At that time, the doctor reported that Petitioner's son had been seizure free since before November 2008. *Id.* Petitioner's son's lab reports were normal. There was a plan to do another EEG in conjunction with her son's next visit after July, 2010. P's Ex. 18 at 32. In November 2010, Petitioner's son visited a physician at which time he reported no dizziness, headaches and syncope. P's Ex. 16 at 6. Petitioner's third EEG, conducted on January 13, 2011, was normal. P's Ex. 21 at 1.

III. APPLICABLE LEGAL STANDARDS

The Vaccine Act provides two means of recovery: Table claims and off-Table claims.[7] In an off-Table, or causation-in-fact case, such as this one, a petitioner must prove actual causation by a preponderance of the evidence. *Moberly v. Sec'y of Health & Human Servs.,* 592 F.3d 1315, 1321 (Fed. Cir. 2010). To prove actual causation, a petitioner must "show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.' " *Moberly,* 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Human Servs.,* 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)). Causation is determined on a case-by-case basis. *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994).

A petitioner satisfies this burden if she provides: (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 proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). A petitioner must satisfy the three *Althen* prongs by preponderant evidence. *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). This preponderant-evidence standard "simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence." *Moberly,* 592 F.3d at 1322 n.2; *Althen*, 418 F.3d at 1279 (citing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572–73 (Fed. Cir. 1993)) (noting the standard requires that a petitioner demonstrate the existence of the element is "more probable than not."). Evidence used to satisfy one of the *Althen* prongs can overlap and be used to satisfy another prong. *Capizzano,* 440 F.3d at 1326.

[7] In a Table case, unlike the present case, a claimant who shows that he or she received a vaccination listed in the Vaccine Injury Table, 42 U.S.C. § 300aa–14, and suffered an injury listed in the Table within a prescribed period is afforded a presumption of causation. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1374 (Fed. Cir. 2009).

There are no "hard and fast *per se* scientific or medical rules" for finding causation under the Vaccine Act. *Knudsen,* 35 F.3d at 548. The Vaccine Act does provide that a claimant may satisfy the preponderant evidence standard by producing "medical records or a medical opinion." 42 U.S.C. § 300aa-13(a)(1). A petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case. *Moberly,* 592 F.3d at 1322. However, the explanation need only be "legally probable, not medically or scientifically certain." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345-46 (Fed. Cir. 2010); *Moberly,* 592 F.3d at 1322 (quoting *Knudsen,* 35 F.3d at 548-49). Along these lines, a special master may not require "epidemiologic studies. . .or general acceptance in the scientific or medical communities. . . ." *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009).

At the same time, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly,* 592 F.3d at 1324; *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010). In determining reliability, a special master may appropriately rely on the standards set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-94 (1993); *see Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) (finding that special masters' use of the *Daubert* factors reasonable); *Cedillo,* 617 F.3d at 1338-39 (finding no legal error in the standards applied by the special master in utilizing *Daubert).* When a party relies upon expert testimony, that testimony must have a reliable scientific basis. *Cedillo,* 617 F.3d at 1339. Although a party need not produce medical literature to establish causation, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury. *Andreu,* 569 F.3d at 1379; *Althen,* 418 F.3d at 1281; *see also Daubert,* 509 U.S. at 593-94.

In cases in which a petitioner relies upon expert testimony to prove causation, the expert testimony must rest upon an objective and reliable scientific basis and must prove causation to a degree of legal certainty, but not to a medical or scientific certainty. *See Moberly,* 592 F.3d at 1322 ("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' ") (quoting *Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs.,* 35 F.3d at 548–49)); *see also Cedillo v. Sec'y of Health & Human Servs.,* 617 F.3d at 1339; *Terran,* 195 F.3d at 1316. Although a petitioner may rely solely on expert testimony, "[a]n expert opinion is no better than the soundness of the reasons supporting it." *Perreira v. Sec'y of Health & Human Servs.*, 33 F.3d 1375, 1377 n.6 (Fed. Cir.1 994). Therefore, a Special Master does not need to credit expert opinion testimony that is connected to the existing data or methodology only by the *ipse dixit* of the expert, or where there is simply too great an analytical gap between the data and the opinion proffered. *Cedillo,* 617 F.3d at 1339.

With regard to alternative causes, the respondent bears the burden of proving by preponderant evidence that an alternative cause, or factor unrelated, was the sole cause of the injury. 42 U.S.C. § 300aa-13; *de Bazan v. Sec'y of Health & Human Servs.,* 539 F.3d 1347, 1354 (Fed. Cir. 2008); *Knudsen,* 35 F.3d at 549. But, neither 42 U.S.C. § 300aa-13 nor the decisions limit what evidence the special master may consider in deciding whether a prima facie case has been established. *Doe 11 v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010) (quoting *de Bazan,* 539 F.3d at 1353); *see also Walther v. Sec'y of Health &*

Human Servs., 85 F.3d 1146, 1151 (Fed. Cir. 2007). As a result, the government may also present and the special master may consider evidence of alternative causes on the issue of the adequacy of the petitioner's evidence regarding the petitioner's case-in-chief. *Doe 11,* 601 F.3d at 1358 (citing *de Bazan*, 539 F.3d at 1354).

In this regard, there are two particular points that the decisions make clear. First, a special master may not require the petitioner to shoulder the burden of eliminating all possible alternative causes in order to establish a *prima facie* case. *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379-80 (Fed. Cir. 2012). *S*econd, a special master may find that a factor other than a vaccine caused the injury in question only if that finding is supported by a preponderance of the evidence. *Stone*, 676 F.3d at 1379-80 (citing *Doe 11*, 601 F.3d at 1356–57); *see Walther*, 485 F.3d at 1151-52 (the petitioner does not bear the burden of eliminating alternative independent potential causes, and the respondent has the burden of proving an alternative cause as the sole, unrelated factor that caused the injury by a preponderance of evidence).

It is established that a special master is entitled to, and should, consider the record as a whole in determining causation. 42 U.S.C. § 300aa-13(a)(1)(A). In considering the record, the Vaccine Act does not contemplate full blown tort litigation. *Knudsen*, 35 F.3d at 548. A petitioner may use circumstantial evidence to prove the case, and "close calls" regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280. Indeed, "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280); *Capizzano*, 440 F.3d at 1324.

IV. PARTIES' POSITIONS

The parties' respective positions are summarized as follows:

Petitioner claims that the Tdap vaccination her son received when he was 12 years of age caused him initially to have an inflammatory response due to an initial cytokine reaction that resulted in a seizure. Tr. at 7, cited in Petitioner's Post-hearing Brief at 17.[8] Once the seizures occurred, there was an imbalance of cytokines which continued and led to prolonged inflammation. This persistent inflammation led to a delayed immune-mediated process, molecular mimicry, which resulted in an autoimmune encephalopathy. Tr. at 8 and 12. As a result of this autoimmune encephalopathy, Petitioner's son exhibited negative behavior, including having problems with anger, memory and energy, spitting and hitting others and having trouble maintaining basic hygiene and tasks of daily living. Tr. at 9-11,43, 60, 67, cited in Petitioner's Post-hearing Brief at 21. Petitioner says that it is logical to conclude that the Tdap vaccine caused his injuries because prior to receiving the vaccine, he was healthy yet following the vaccine, he exhibited symptoms of general inflammation and suffered a seizure within 24 hours. Tr. at 7, 84, cited in Petitioner's Post-hearing Brief at 25-26. As to temporal relation, Petitioner relies on the fact that seizures within 24 hours following pertussis vaccines is an appropriate timeframe for the onset of symptoms. Tr. at 15, cited in Petitioner's Post-hearing

[8]Petitioner relied on the report and testimony of Dr. Paul Maertens, the Chief of the Child Neurology Department at the University of South Alabama. Tr. at 4-5.

Brief at 30. As to the encephalopathy, Petitioner relies on the VAERs report, completed five weeks after the vaccination that notes Petitioner's son exhibited difficulties at that time and concludes that that is an appropriate time for onset. Tr. at 164-65, P's Ex. 9 at 1-2, cited in Petitioner's Post-hearing Brief at 30.

Respondent argues that Petitioner failed to show how the Tdap vaccine can cause autoimmune epilepsy, failed to show that it did cause Petitioner's son to develop an autoimmune encephalopathy and failed to show that there was a medically-appropriate temporal relation. Tr. at 116-119; Tr. at 159-162.[9] First, as to theory, Respondent contends that Petitioner's theory is not plausible or reliable because there is no evidence of inflammation, a required prerequisite to molecular mimicry occurring. Tr. at 7, 99, 121-122, cited in Respondent's Post-hearing Brief at 14. Respondent also disputes that autoimmune epilepsy is well recognized in the medical community and asserts that Petitioner's son had no markers that would indicate he had autoimmune epilepsy or an encephalopathy. Tr. at 74-76, 88. According to Respondent, Petitioner's son's clinical picture shows that he does not have a progressive encephalopathy and, thus, his seizures are not caused by an autoimmune process. Tr. at 117-119, 133. Finally, the progress of Petitioner's illness is inconsistent with the progress of an autoimmune reaction so that the temporal relationship is not medically appropriate. Tr. at 121-122, 139,147, 155.

V. DISCUSSION

As explained below, based on the record as a whole, the special master concludes that Petitioner has failed to satisfy her burden of proof. First, the medical theory upon which she relies, a persistent inflammatory response that led to molecular mimicry, is not plausible because based on the facts of the case, the theory could not have occurred. Second, Petitioner has failed to show a logical sequence of cause and effect because Petitioner's son's clinical signs indicate that no encephalopathy has occurred. Third, the progression of Petitioner's son's injuries is inconsistent with the progression of an individual subject to the autoimmune disorder Petitioner claims her son experienced, an autoimmune encephalopathy.

A. Petitioner's Medical Theory is Not Plausible So That She Fails To Satisfy *Althen's* Prong One.

The special master concludes that Petitioner has failed to show a plausible medical theory causally connecting the vaccine to the injury, the first *Althen* prong. Under the first *Althen* prong, a petitioner must demonstrate that the vaccine at issue can cause the injury alleged. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355–56 (Fed. Cir. 2006). To satisfy this prong, "a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed.Cir.2010) (quoting *Knudsen*, 35 F.3d at 548–49); *see also Moberly*, 592 F.3d at 1324.

[9] Respondent relied on the report and testimony of Dr. Schlomo Shinnar, the Director of the Comprehensive Epilepsy Management Center at Montefiore Medical Center and University Hospital at the Albert Einstein College of Medicine. Tr. at 101.

Given that Petitioner is claiming that her son's injuries consist of a seizure disorder and changes in his behavior, such as anger and lack of hygiene under *Althen's* first prong, Petitioner must present a medical theory that, in light of the circumstances of the case, could explain how the vaccine could have caused her son's injuries. For her explanation, Petitioner's expert, Dr. Maertens, testified that the Tdap vaccine can cause an inflammatory response due to the fact that the vaccine changes the cytokine balance. Tr. at 7, 92-93. This inflammation can result in seizures. Tr. at 7.

Dr. Maertens further opined that once the initial seizure(s) occurred, the pro-inflammatory cytokines, which are enhanced by the vaccine, lead to a prolonged inflammation. Tr. at 48, 81. And it is this persistent inflammation that allows for the disruption of the blood brain barrier. *Id*. Once the blood brain barrier is disrupted, an autoimmune process can occur. Tr. 48, 82. This autoimmune reaction is caused by molecular mimicry. Tr. at 12-13. This molecular mimicry-caused autoimmune process causes a persistent or fluctuating dysfunction of the brain, which Dr. Maertens called an autoimmune encephalopathy. Tr. at 7-8. This autoimmune encephalopathy can cause various disturbances to one, including emotional and behavioral problems. Tr. at 11-12.

As Petitioner's expert acknowledged, the theory upon which Petitioner is relying requires inflammation. Petitioner's expert, Dr. Maertens, agreed that with regard to the seizures, they would occur when there was an inflammatory response. Tr. at 7; 81; 97. Indeed, the literature that Dr. Maertens referenced with regard to a vaccine causing a seizure demonstrates that the seizure caused by a vaccine would be febrile not afebrile seizures. P's Ex. 14B. Similarly, Dr. Maertens acknowledged that a vaccine injury due to molecular mimicry as he described, an autoimmune encephalopathy, cannot occur without inflammation. Tr. at 97-99; *see also* Tr. at 49.

The fundamental problem with Petitioner's theory is that the facts show there is no sign of an inflammation. The contemporaneous medical records from Petitioner's son's initial hospitalization for the seizure within 24 hours of his vaccination show that he was afebrile and alert. P's Ex. 2 at 121. Petitioner's son did not have a headache. *Id.*

And, as to Petitioner's son's alleged long-term injury, an autoimmune encephalopathy, as was explained by Respondent's expert's testimony, such an injury would be evident through an abnormal EEG. Tr. at 116. The medical records show that Petitioner's son's EEGs were all normal. P's Ex. 2 at 69-70; 127; P's Ex. 5 at 14 and P's Ex. 21 at 1. Petitioner's expert acknowledged that in the reports he presented on cases of autoimmune epilepsy none of the patients had normal EEGs. Tr. at 50-51. The absence of abnormal EEGs undercuts the theory that there was a persistent inflammation. Because there is no evidence of inflammation, Petitioner's theory of an autoimmune disorder is not plausible as to this case. Tr. at 124-25.

Petitioner points to the medical history that she provided to Petitioner's son's primary care physician, recorded a month after the initial seizures, when she advised the doctor that her son had a febrile seizure as support of a sign of inflammation during her son's initial hospitalization. But, as explained in more detail under Subsection V.B, that medical history provided solely by Petitioner is contrary to the contemporaneous medical records written at the

time of her son's hospitalization by health care providers and is based entirely on Petitioner's subjective memory. The contemporaneous medical records of Petitioner's son's hospitalization are clear and consistent and provide that her son did not have a headache, fever or other signs of inflammation. Those contemporaneous medical records should be and, thus, are accorded great weight here whereas Petitioner's subjective statement made after some lapse of time is simply not reliable. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). The records relating to Petitioner's son's illness demonstrate that there was no evidence of an inflammation. Without an inflammation, as Petitioner's own expert admitted, the autoimmune process he posited could not occur. Tr. at 97.

Another reason that Petitioner's theory is not plausible is that the progression of his illness is not consistent with how an autoimmune process caused by molecular mimicry would occur. Petitioner's expert did not address the progression of this illness with any specificity other than to state that the onset of seizures within 24 hours after vaccine and pertussis has been known to occur. Tr. at 63-64. But, as explained above, with regard to the vaccine causing a seizure within 24 hours, even Petitioner's expert acknowledged that this would have to have been due to an inflammation. And, again, there was no indication of any such inflammation at the time of the seizure.

With regard to the alleged long-term effects, Petitioner's expert, relying on statements in the VAERs report, statements made by Petitioner's husband, the report's preparer, explained that the first signs occurred about five weeks after seizure. Tr. at 164. According to Petitioner's expert, it is typical for patients with autoimmune disorders to experience flairs in their symptoms. Tr. at 15-16; 61.

Petitioner's expert explained that Petitioner's son's negative changes in behavior, would be the result of this encephalopathy, not due to his seizures. Tr. at 15. Thus, the importance of this initial seizure, under Petitioner's theory, is limited to the fact that it was to have caused an initial inflammation that later led to a persistent inflammation that led to molecular mimicry. Tr. at 48-49. But, as already explained, given there is no evidence of inflammation at the outset, Petitioner's theory could not have caused Petitioner's son's injuries.

An additional reason that Petitioner's theory of molecular mimicry is not plausible is because the progression of Petitioner's son's illness is not consistent with the manner in which molecular mimicry progresses. Tr. at 11-12; 48-49. Respondent's expert explained, without objection or rebuttal, that all the molecular mimicry models produce a monophasic illness. Tr. at 122. What happens is that after a two-to-six week latency period, the patient becomes sick and then, under the models, there is an acute deterioration that occurs over the course of 20-30 days. Tr. at 159-60.

The progression of Petitioner's son's illness did not reflect this pattern. He experienced three seizures in a short period of a day or so, after which he did not experience another seizure until nearly six months later. During that period, there were no symptoms of an acute deterioration. Additionally, there were no headaches, there were no fevers, there were no abnormal EEGs, and there were no additional seizures.

Also, Petitioner's son's behavioral problems did not follow this pattern either. The

evidence shows that Petitioner's son had these behavioral, anger issues before Petitioner's son received the vaccine. P's Ex. 2 at 121. And, following the vaccine, there is no mention in the medical records of such behavioral problems until April 2008. P's Ex. 3 at 8. Although there is an isolated reference in the VAERS report made August 2007 by Petitioner, this is a statement from Petitioner which is based on memory and unsubstantiated by any medical records. As such, it is accorded little, if any, weight especially when compared to the contemporaneous medical records. *Curcuras*, 993 F.2d at 1528.

The progression of Petitioner's son's illness following the vaccine, with no symptoms until a lone seizure occurs nearly six months later, is not consistent with the progression of molecular mimicry as defined in the models of that autoimmune process. Because the progression is inconsistent with this process, it is not plausible that such mechanism could have occurred. Tr. at 147-48.

Even in an abstract sense, there is little support that Petitioner's theory could be in operation here. In discussing the theory generally, Petitioner's expert acknowledged that there were no studies that supported his hypothesis that Tdap can cause epilepsy via epileptic mimicry. Tr. at 46. He acknowledged that there were no case control studies involving the Tdap vaccine being involved in molecular mimicry and causing epilepsy. Tr. at 45. Petitioner's expert testified that he believed the medical community agreed molecular mimicry can be a mechanism that causes epilepsy but he admitted that physicians were extremely cautious. *Id*. As Petitioner's expert admitted, there was still lots of resistance in the medical community as to whether it accepts Dtap as playing a role in causing epilepsy. *Id*. The sources upon which Petitioner's expert relied were references which dealt with either whole cell pertussis toxin or whole cell pertussis vaccine, which are distinguishable from the vaccine at issue here. Tr. at 47. Based on the foregoing, the medical literature does not provide much, if any, support for Petitioner's theory.

Given there is a lack of support for Petitioner's medical theory in the medical literature and, more important, given the facts do not support that the theory propounded by Petitioner could have occurred, it is not plausible. Because it is not a plausible theory, Petitioner has failed to satisfy her burden as to *Althen's* Prong I.

B. Petitioner Has Failed To Demonstrate There Is a Logical Sequence of Cause and Effect Indicating that the Vaccine Caused her Son's Injuries.

Even if it could be determined that Petitioner's theory is plausible, Petitioner's claim still fails because Petitioner has failed to satisfy her burden as to *Althen's* Prong 2. The evidence does not show a logical sequence of cause and effect, that the vaccine did cause Petitioner's son's injuries. The reason for this is that a critical prerequisite for demonstrating that the vaccine caused Petitioner's injuries at the time of the initial seizure and then later leading to an autoimmune encephalopathy is that there is evidence of the existence of an inflammation. As explained below, because there is no indication that Petitioner's son experienced an inflammation, there is no evidence of an autoimmune cause. As such, there is no evidence the vaccine caused the injuries.

First, as previously alluded to, *see supra* V.A., at the time of Petitioner's son's initial

seizure, there is no evidence of an inflammation. The contemporaneous medical records, which are clear and consistent, show no evidence of an inflammation. Petitioner's son was afebrile during his initial seizures in July 2007. Although he had had a headache the day before, that headache had dissipated by the time of the seizure. Petitioner's son's MRI and EEG were normal. Petitioner's son was alert and responsive. These records, created contemporaneously with the events that they describe, are presumed to be accurate. It is recognized that individuals seeking treatment will report the circumstances relating to their symptoms and history accurately to ensure the doctors have all information necessary to treat their ailments. *Curcuras* 993 F.2d at 1527-28; *see also Capizzano*, 440 F.3d at 1326 (particular attention should be paid to contemporaneous medical records). Here, the contemporaneous medical records created at the time of Petitioner's son's initial seizure and related hospitalization in July 2007 indicate that there were no signs of any inflammation at the time of the initial seizures. P's Ex. 2 at 84-85, 121; P's Ex. 2 at 129-130. Significantly, there does not appear to be disagreement between the parties on this as both experts agreed that Petitioner's son's seizures were afebrile. Tr. at 25; 109.

Similarly, there are no signs of an autoimmune encephalopathy which Petitioner claims her son experienced that led to his behavioral changes. Again, Petitioner's expert admits that there would have to be inflammation for this to occur. But, the records show no clinical evidence of such an inflammation. As Respondent's expert explained, autoimmune encephalopathy requires an encephalopathy and evidence of autoimmune processes. Tr. at 115. Not only does there need to be evidence of antibodies, there needs to be evidence of neurological symptoms attributed to antibodies and an EEG that indicates an encephalopathy. Tr. at 116. Here the evidence was unequivocal that every one of Petitioner's son's EEGs were normal. As such, there was no evidence of an autoimmune process. Because there was no evidence of an autoimmune process, Petitioner's son's illnesses could not have been caused by the vaccine.

Significantly, Petitioner's expert did not dispute that the existence of antibodies and abnormal EEGs were indicators of an autoimmune encephalopathy. When questioned regarding these clinical signs during his testimony, Petitioner's expert admitted that Petitioner's son was never tested for the antigen-1 antibody, which would indicate the existence of an autoimmune disorder. Tr. at 47.

More important, Petitioner's expert admitted that in the patients he had observed with autoimmune encephalopathy, all had abnormal EEGs, unlike Petitioner's son's EEGs, which were all normal. Tr. at 50-51. The seizures in the patients Petitioner's expert had observed were severe in comparison to those of Petitioner's son. Tr. at 51. Unlike those cases, following the initial group of three seizures in July 2007, Petitioner's son's next seizure was not until January 2008. P's Ex. 6 at 9. That seizure did not require hospitalization *Id.* The next two seizures were not for another few months. P's Ex. 2 at 37, 42.

With regard to Petitioner's son's behavioral changes, there is no evidence linking these changes to the vaccine. First and foremost, both experts agreed that Petitioner's son was already evidencing behavioral problems, *i.e.,* anger prior to his first seizure in July 2007. P's Ex. 2 at 121. Following the vaccine, there was no report in any doctor's records of any problems until nearly nine months later, in April 2008. P's Ex. 3 at 8. And, the evidence also shows that

following a period of time, Petitioner's son's grades improved and that he was primarily receiving A's and B's. P's Ex. 18 at 9. Thus, this pattern of behavioral changes does not show any evidence of a link with the vaccine. Instead it is merely coincidental with Petitioner's son's receipt of the vaccine.

To support his claim that the vaccine caused her son's injuries, Petitioner relies on the opinions of treating physicians, on Dr. Maerten's opinion, the supporting scientific literature and her claim of a medically appropriate temporal relation. P's Post-hearing Brief at 29. A review of each of these categories of information shows that Petitioner has failed to show any evidence of inflammation or an autoimmune encephalopathy and, thus, a logical sequence of cause and effect.

First, to support her claim that treating physicians opined that the vaccine caused the injuries, Petitioner cites to excerpts from two doctors' records, a Dr. Krishnan and Dr. Haycraft. With regard to "Dr. Krishnan," Petitioner refers to records at the time of Petitioner's son's hospitalization. P's Ex. 13 at 5. Those notes, recorded on the date of admission, July 24, 2007, refer to a vaccine reaction as part of a differential diagnosis apparently to imply that a treating physician gave that as a possible diagnosis. P's Ex. 2 at 125-126. But, in actuality, rather than a treating physician, those notes were written by Brian Kirshnan, then a third-year medical student. P's Ex. 13 at 5; P's Ex. 2 at 116-120, 125-126. As a medical student, his role was different than that of a physician, and he would have been encouraged to written down a broad range of differential diagnoses. Resp. Ex. D at 2-3; Tr. at 64, 110. Although this medical student noted Tdap vaccine reaction as one of the possibilities in his notes on differential diagnoses, significantly, none of the treating physicians during the July 2007 admission did.

Moreover, even student Kirshnan's notes are inconsistent. Although he included the vaccine as part of the differential diagnosis initially, he also clearly noted that Petitioner's son was afebrile. P's Ex. 2 at 116-120, 125-126. He further noted that one of the symptoms that would occur with a vaccine reaction would be fevers. He then notes that the staff would need to monitor fevers to decide whether the reaction should remain in the differential. P's Ex. 13 at 5. Interestingly, by the time of discharge, third year medical student Krishnan did not list the vaccine reaction as part of the differential diagnosis. P's Ex. 2 a 128. Instead, he had narrowed his differential diagnosis to primary seizure disorder, another possibility he had originally listed but one which was not associated with fevers. P's Ex. 13 at 5; P's Ex. 2 at 128. More important, the actual treating physicians' diagnosis, listed on the discharge summary, was partial complex seizures with secondary generalization. P's Ex. 2 at 113.

As to Dr. Haycraft, Petitioner's son's primary care physician, although it is true that in notes from a follow up visit in August 2007, Dr. Haycraft, described the seizures in the hospital as febrile, those notes are not reliable when compared to the contemporaneous medical records. P's Ex. 3 at 17, 20. Those notes are based on the medical history provided by Petitioner and not on actual medical personnel's observations at the time of the event. In fact, even the medical records provided to Dr Haycraft from the July 2007 hospitalization reflected that Petitioner's son was afebrile at the time of the seizure. P's Ex. 2 at 66. The report from the neurological consult done during the hospitalization, a copy of which was provided to Dr. Haycraft, clearly states that Petitioner's son was afebrile. *Id*. Having weighed the evidence, the special master accords

greater weight to the contemporaneous medical records and finds that Petitioner's son was afebrile at the time of the initial seizure(s) in July 2007.[10]

Second, with regard to Dr. Maerten's opinion, Petitioner's primary reference is to his opinion that the vaccine caused the initial seizures and then later caused an encephalopathy that resulted in his developing a "regression in the sense that the child was never the same." Tr. at 8. The apparent source for Dr. Maerten's statements regarding Petitioner's son's behavior regressions is an application for a service plan for a personal care assistant that Petitioner completed during the summer of 2009. P's Post-hearing Brief at 12, citing P's Ex. 12, at 1-3. This is apparently a government service provided when there is evidence of a need for safety reasons, that an individual may cause harm to themselves or others. P's Ex. 12 at 5. The excerpt is from the portion of the application for the service plan completed based on Petitioner's statements, not on medical records.[11] Given this is Petitioner's statement alone, unsubstantiated by the medical records, it cannot be the basis for an award of entitlement. See 42 U.S.C. 300aa-13. Absent some substantiation, this statement cannot be a basis for a ruling in favor of entitlement. The references in this document, upon which Dr. Maertens is basing his conclusions regarding the changes in Petitioner's son, are not reliable. As such, Dr. Maertens' conclusions based on them are similarly not reliable.

Third, as to medical literature, Petitioner appears to suggest that following the initial seizures her son suffers from some form of autoimmune epilepsy as evidenced by her providing medical literature regarding that. P's Exs. 14A – 14G. But, as previously discussed, the situations discussed in the medical literature are distinguishable. As to the case reports on autoimmune encephalopathy, Petitioner's expert himself acknowledged the patients in those cases, unlike Petitioner's son, had abnormal EEGs and severe seizures. The medical literature

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[10] Petitioner also cites to other portions of Dr. Haycraft's recorded medical history and relies on them as statements that are alleged to be a treating physician's opinion that the vaccine caused her son's injury. In particular, Petitioner cites to Dr. Haycraft's medical history that describes that it was Petitioner who was the source of Dr. Haycraft's information regarding Dr. Burstein. Petitioner is the one who advised Dr. Haycraft that Dr. Burstein might have concluded that the vaccine might have caused the seizures. P's Ex. 3 at 14-15. Those statements are part of the medical history given by Petitioner to Dr. Haycraft and are entirely secondhand. Petitioner does not cite to any of Dr. Burstein's actual records that reflect his opinion that the vaccine might have caused the injury, and a review of those records do not indicate that he made those statements. As a result, based on this, the special master finds that the second hand statements in Dr. Haycraft's records regarding Dr. Burstein's possible opinions are not reliable and cannot be considered a treating physician's opinion as to vaccine causation.

[11] . Petitioner apparently stated in this document that her son had a seizure in July 2009. P's Ex. 12 at 1-3. It is uncertain the reason for the focus on this statement. To the extent it is being provided as evidence of a seizure in July 2009, given it is described as a grand mal seizure with a 10 minute duration, a somewhat significant event, it is uncertain why Petitioner would not have sought immediate medical attention when such event occurred or failed to mention it to her son's neurologist at their next appointment. The absence of any contemporaneous medical record regarding treatment of such a significant event calls into question whether the event occurred or, if so, whether it was as severe as described.

regarding pertussis caused seizures generally were cases where the agent was whole cell not acellular pertussis. *See* P's Ex. 14A. When asked whether some autoimmune process would more likely than not have caused Petitioner's son's epilepsy due to the vaccine or that it could be coincidental to the onset of the seizure, Petitioner's expert only replied "It's possible." Tr. at 49. However, that something is possible is not sufficient to satisfy Petitioner's burden of proof. *See Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548–49 (Fed. Cir. 1994)(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).

Fourth and finally, Petitioner refers to the temporal relation between the vaccine and the onset of seizures and the lack of their being another cause. Tr. at 15-16, 55. However, mere temporal relation and the lack of any other explanation is insufficient to establish a logical sequence of cause and effect. *See Grant v. Sec'y of Dep't of Health & Human Servs.*, 956 F.2d 1144, 1147-49 (Fed. Cir. 1992) (discussing how a proximate temporal association alone nor the absence of alternative causest suffice to show a causal link between the vaccination and the injury). And, as explained *infra*¸ V.C., the temporal relation is wrong here. Briefly, while it is clear that Petitioner's son suffered seizures within 24 hours of receipt of the vaccine, there was no indication of an inflammation associated with them. Thus, they do not indicate that the vaccine caused the injuries. Although a medically-appropriate temporal relationship in combination with other evidence can be sufficient to satisfy Petitioner's burden as to *Althen's* Prong 2, in this case, there is no other evidence to support a vaccine cause of Petitioner's son's initial seizures or his subsequent condition—his memory loss, anxiety, depression and behavioral problems.

Petitioner's evidence is insufficient to show that the vaccine caused her son's injuries. She has failed to satisfy *Althen's* Prong 2.

C. Petitioner Has Failed to Demonstrate an Appropriate Temporal Relationship Between the Vaccine and Her Son's Injuries.

With regard to a medically appropriate temporal relation, *Althen's* Prong 3, Petitioner's conclusions regarding the timing do not support her theory and are unsupported by the evidence. In support of her argument regarding timing, Petitioner makes two claims. First, Petitioner claims that there is an appropriate temporal relation between the vaccine and her son's seizures because the seizures occurred within 24 hours of the vaccine. Petitioner makes a separate claim that there is a temporal relation between the vaccine and her son's other problems, *e.g.*, his memory loss, because her son experienced the onset of symptoms of his alleged autoimmune encephalopathy within an appropriate time frame. Petitioner's Post-hearing Brief at 30.

With regard to the first allegation regarding the temporal relation between timing and a seizure, that Petitioner's son had a vaccine within 24 hours of a vaccine does not address the central issue in this case. The Vaccine Act provides for compensation for injuries the residual effects of which have lasted for more than six months. 42 U.S.C. § 300aa-11(c)(1)(D)(i). Because compensation is not awarded unless injuries have occurred for longer than six months, that a seizure occurred within 24 hours or a day of receipt of the vaccine, is not controlling. Thus, that Petitioner suffered a seizure or seizures within 24 hours of receipt of the vaccine does

not, in and of itself, establish an appropriate temporal relationship.

Petitioner's expert implicitly acknowledged that there was no correlation between Petitioner's son's behavior and his memory and symptoms of the encephalopathy and the seizure. Tr. at 15. Dr. Maertens stated that the symptoms of the encephalopathy are not related directly to the seizure. Tr. at 16. Because they are not related directly to the seizure, the timing of the initial seizures in relation to the vaccine is irrelevant to whether the vaccine caused these other symptoms.

With regard to symptoms of an encephalopathy, the materials upon which Petitioner is basing his claim that an appropriate time frame exists, are not reliable. Petitioner's expert stated that an appropriate time frame for onset when it is an immune mediated mechanism could be days after the vaccine up to six weeks. Tr. at 16. And, Petitioner claims that the onset of the encephalopathy began approximately four weeks after the vaccination and that that is within the appropriate time frame. Tr. at 16. To support her claim that the onset occurred within four weeks of the vaccine, Petitioner relies on two documents, her statements in the VAERs report completed in August 2007 and the boxes she checked on the intake sheet at the initial follow-up with the neurologist that ask generally for the identification of symptoms of concern. Tr. at 16.

Neither of those documents is a reliable source for determining the timing of the onset of symptoms. First, as to the VAERs form, it is generally recognized as subjective and not a source upon which to rely to make conclusions. The Court uniformly has upheld concerns about the reliability of VAERS data. *See Analla v. Sec'y of Health & Human Servs.*, 70 Fed. Cl. 552, 558 (Fed. Cl. 2006); *see also Capizzano v. Sec'y of Health & Human Servs.*, 63 Fed.Cl. at 231 (VAERS data has limited value due to the manner in which it is collected, the lack of confirmation of the reported information, and the lack of any systemic analysis).

Second, the other document is another form completed by Petitioner at the time of the initial follow-up visit to the neurologist, Dr. Burstein, after her son's hospitalization. This form simply asked Petitioner to check off symptoms that are of concern to her. P's Ex. 5 at 50-51. Under neurologic, she checked off memory loss, seizures, trouble walking. P' Ex. 5 at 51. And, under respiratory, she checked off wheezing. *Id.* Nowhere was Petitioner asked nor did she identify the timing of the onset of those symptoms. And, in fact, at least some of the symptoms she checked had occurred before her son received the vaccine. *See* P's Ex. 2 at 121.

At the same time, the contemporaneous medical records written on that day by the neurologist that reflect the results of his independent, professional and diagnostic examinations indicate that no such symptoms even existed on that date. In his report of examination, Dr. Burstein indicated that he found Petitioner's son to be alert and in no distress. P's Ex. 5 at 30. The neurologist indicated that Petitioner's son's mental status was intact with normal speech and language. *Id.* The doctor further indicated that Petitioner's son had a "good fund of knowledge and memory" and that his cranial nerves were intact. *Id.* A motor examination showed normal strength and tone in both upper and lower extremities. *Id.* Petitioner's son's reflexes were 2+ and symmetric and he had no dysmetria. *Id.* Finally, his gait was normal, and the Romberg test was negative. *Id.*

Given the neurologist's notes are the contemporaneous medical records recorded for purposes of treatment, they are accorded substantial weight especially as compared to Petitioner's reported medical history, including the history recorded following her own conclusion regarding causation as reflected in the VAERs report. *See Manville v. Sec'y of Dep't of Health & Human Servs.*, 63 Fed. Cl. 482, 494 (Fed. Cl. 2004) (VAERS reports can be filed by anyone, thus raising questions about the quantity and quality of the information gathered); *Ryman v. Sec'y of Dep't of Health & Human Servs.*, 65 Fed. Cl. 35, 40 (Fed. Cl. 2005) (VAERS reports may be biased toward pre-existing notions of adverse events). Those notes recorded by the doctor reporting the symptoms that existed on that date do not indicate any of the symptoms Petitioner claims to have existed at that time.

Subsequent contemporaneous medical records are consistent with the physician's notes of August 2007. In reports from subsequent examinations in January 2008 by the neurologist and primary care physician, there is no indication that Petitioner's son is experiencing any of the symptoms Petitioner now describes. Ex. 5 at 16; Ex. 3 at 14. It is not until April 2008 when Petitioner's son visits his primary care physician after experiencing one or two seizures in March 2008, that there is any indication that Petitioner's son is evidencing moodiness or other such behavioral changes. P's Ex. 3 at 8.

Because this was merely a subjective checklist of symptoms by Petitioner, the reliance on this form as a basis for onset of symptoms is not reliable when compared with the physician's examination notes from that date, which are the result of his application of professional medical examination and diagnostic techniques revealed no such symptoms. P's Ex. 5 at 30.

Additionally, there is no temporal relation between the vaccine and these alleged behavioral problems in that the evidence is that those problems began before the vaccine. In the contemporaneous medical records dictated at the time of Petitioner's son's initial hospitalization, the records indicate that Petitioner's son was already having anger issues for at least a few months before the vaccine. P's Ex. 2 at 121. Given these issues were already evident before the vaccine, there is not a medically appropriate temporal relationship between the vaccine and their onset.[12]

An examination of the normal progression of an autoimmune response made through the mechanism Petitioner proffers, *i.e.*, molecular mimicry, reveals that the timing is incorrect for any theory based on vaccine-induced seizure. To the extent that Petitioner is alleging that the seizure that occurred within 24 hours of vaccine led to her son's seizure disorder because Petitioner's theory is that there was some sort of cytokine reaction followed by molecular mimicry that was the cause, the timing is too short. Tr. at 121. Petitioner does not cite to any literature or assert that such a cytokine reaction and molecular mimicry process could occur within 24 hours. Significantly, Respondent's expert, Dr. Shinnar, stated that such a process would take longer than 24 hours so that the 24 hours between vaccine and seizure is too short a time frame. Tr. at 122, 139, 147, 155-56.

[12] Petitioner has not made a significant aggravation claim so that there is no basis upon which to make an analysis under that theory.

To the extent that Petitioner is claiming that some autoimmune process began through molecular mimicry which resulted in this alleged autoimmune disorder, again the timing is wrong. If that were to occur you would see an acute deterioration clinically during that two-to-six week period. Tr. at 159-160. Here following the initial seizures within the first 24 hours, there was no evidence of any clinical symptoms in the next approximately 30 days. Tr. at 160. Petitioner's son had a normal EEG, and he was doing perfectly fine. Tr. at 160. There is nothing in the evidence that indicates an autoimmune process was occurring as a result of molecular mimicry. Tr. at 161. There was no indication of any deterioration, much less a massive deterioration occurring within two and six weeks as would be the typical progression were this to be due to an autoimmune process caused by molecular mimicry. Tr. at 161.

Based on the foregoing, Petitioner has failed to satisfy her burden of establishing an appropriate medically acceptable temporal relation based on the theory upon which she is relying.

CONCLUSION

Having considered the record as a whole and weighing the parties' respective positions carefully, the special master concludes that Petitioner has failed to satisfy her burden of proof. Petitioner's claim is hereby **DISMISSED.**

IT IS SO ORDERED.

s/ Daria J. Zane
Daria J. Zane
Special Master