

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 01-0198V

Filed: November 14, 2013

Not to be Published

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SEBASTIAN VIG, a minor,  
by his mother and natural guardian,  
EDITH VIG,

Petitioner,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES

Respondent.

Autism; Failure to Prosecute; Failure  
to Follow Court Orders; Dismissal

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Edith Vig, Charlottesville, V.A., pro se petitioner.

Traci R. Patton, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

**DECISION**<sup>1</sup>

**Vowell**, Chief Special Master:

On April 4, 2001, Edith Vig [“petitioner” or “Ms. Vig”] filed a Petition for Vaccine Compensation in the National Vaccine Injury Compensation Program [“the Vaccine Act”],<sup>2</sup> alleging that Sebastian was injured by a vaccine or vaccines listed on the Vaccine Injury Table. See § 14. Petitioner filed amended petitions on July 25, 2002

<sup>1</sup> Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 (2006)). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

<sup>2</sup> The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 et. seq. (2006). All citations to the Vaccine Act in the decision will be to 42 U.S.C. § 300aa.

and October 21, 2002. In the amended petition filed on October 21, 2002, petitioner alleges that her son, Sebastian, suffered a “Table”<sup>3</sup> encephalopathy after receiving the diphtheria-tetanus acellular pertussis [“DTaP”] vaccine on April 14, 1998 or, in the alternative, that the vaccines Sebastian received actually caused his autism.

### I. Procedural History.

On January 23, 2004, Special Master Edwards conducted a hearing to determine if Sebastian suffered a Table encephalopathy. After examining the evidence and hearing expert and lay testimony, he concluded that Sebastian had not suffered a Table injury.<sup>4</sup> Following this ruling, the case was included in the Omnibus Autism Proceeding [“OAP”]<sup>5</sup> and stayed, pending resolution of the general causation issues being addressed in the test cases. Notice, filed Feb. 12, 2004, at 1-2.

The case was reassigned to me on February 8, 2007. During the period between the test case hearings<sup>6</sup> and the final appellate action on the test case decisions, I ordered petitioner to file the medical records necessary to establish that the petition was timely filed. Order, issued Jan. 15, 2008, at 7. Following the resolution of the OAP test cases,<sup>7</sup> I ordered petitioner to file an amended petition. Order, issued Mar. 23, 2011, at 1. After informal discussions with the parties, I cancelled the deadline for filing an amended petition and allowed petitioner additional time to explore alternative theories of causation. See Order, issued Apr. 8, 2011, at 1.

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<sup>3</sup> A “Table” injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified. To qualify as a Table injury, Sebastian must have suffered an encephalopathy as defined in Table within 72 hours of receiving the DTaP vaccine. See 42 C.F.R. § 100.3(b)(2) (the Vaccine Table’s definition of encephalopathy).

<sup>4</sup> Special Master Edwards ruled from the bench that petitioner was not entitled to a presumption of causation as she had not shown that Sebastian suffered an encephalopathy as described in the Vaccine Table. Transcript [“Tr.”] at 98-101.

<sup>5</sup> A detailed discussion of the OAP can be found at *Dwyer v. Sec’y, HHS*, No. 03-1202V, 2010 WL 892250, at \*3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

<sup>6</sup> The Petitioners’ Steering Committee [“PSC”], an organization formed by attorneys representing petitioners in the OAP, litigated six test cases presenting two different theories of vaccine causation of autism spectrum disorder [“ASD”] in 2007-08.

<sup>7</sup> Decisions in each of the three test cases pertaining to the PSC’s first theory rejected the petitioners’ causation theories. *Cedillo v. Sec’y HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff’d*, 89 Fed. Cl. 158 (2009), *aff’d*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec’y HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff’d*, 88 Fed. Cl. 473 (2009), *aff’d*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec’y HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff’d*, 88 Fed. Cl. 706 (2009). Decisions in each of the three “test cases” pertaining to the PSC’s second theory also rejected the petitioners’ causation theories, and petitioners in each of the three cases chose not to appeal. *Dwyer*, 2010 WL 892250; *King v. Sec’y HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec’y HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

On May 18, 2011, petitioner's counsel<sup>8</sup> filed a motion to withdraw as attorney of record. I granted the motion and held a telephonic status conference with Ms. Vig and respondent's counsel on June 8, 2011, to discuss how Ms. Vig intended to proceed. During the call, petitioner clarified that she wished to proceed on the theory that the pertussis-containing vaccine Sebastian received on April 14, 1998, caused his current condition, which she described as an encephalopathy.<sup>9</sup> See Order, issued Jun. 8, 2011, at 2. She also indicated that she had expert reports on causation that she wanted me to consider, but that had not yet been filed. *Id.* I ordered her to file those expert reports. *Id.* I also encouraged petitioner to identify, by exhibit and page number, the medical records she felt "were not brought to the special master's attention in 2004 as supportive of her case." *Id.* at 3.

On June 23, 2011, petitioner filed a letter that highlighted excerpts from medical records already filed and several newly filed documents.<sup>10</sup> Because petitioner referenced videotapes of Sebastian, I ordered her to file all video records of Sebastian from birth to two years of age. Order, issued Jun. 28, 2011, at 1. Petitioner complied on August 10, 2011. See Petitioner's Exhibit ["Pet. Ex."] 29.<sup>11</sup>

Noting that petitioner had not filed the expert reports on causation she referenced during the June 8, 2011 status conference, I ordered her to file an updated exhibit list and any additional expert reports she would like me to consider. Order, issued Aug. 24, 2011, at 1-3. I cautioned petitioner that "I [did] not intend to revisit Special Master Edwards's ruling" that Sebastian had not suffered a Table encephalopathy.<sup>12</sup> *Id.* at 2. I ordered respondent to file a supplemental Rule 4(c) report and encouraged her to file an expert report as well. *Id.* Petitioner filed an updated exhibit list on September 9, 2011.

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<sup>8</sup> At this time, petitioner's counsel was Thomas Gallagher. Petitioner's original attorney was Clifford Shoemaker. He represented petitioner until August 10, 2001, when Mr. Gallagher became attorney of record.

<sup>9</sup> The term "encephalopathy" is defined as "any degenerative disease of the brain." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ["DORLAND'S"] at 614 (32<sup>th</sup> ed. 2012). The term is used to describe a wide variety of injuries, ranging from a temporary, mild impairment to severe, progressive, and fatal conditions. See *id.* at 614-15 (describing various types of encephalopathies).

<sup>10</sup> Petitioner filed each document, whether previously or newly filed, using exhibit numbers 24-42. Since this arrangement meant that the newly filed material did not have consecutive exhibit numbers, I ordered petitioner to file an updated exhibit list, assigning only the newly filed material a separate exhibit number. Order, issued Aug. 24, 2011, at 1-2.

<sup>11</sup> Petitioner originally did not assign an exhibit number to the video of Sebastian, but later listed the video as Exhibit 29. See Notice, filed Sept. 9, 2011, at 4 (Updated Exhibit List).

<sup>12</sup> Petitioner's Exhibit 29, the video recordings filed on August 10, 2011, thoroughly refutes petitioner's claim that Sebastian suffered a Table encephalopathy. Although Sebastian displays some behaviors associated with autism, he clearly was aware of and responsive to his environment.

On September 16, 2011, Richard Gage filed a motion to be substituted as attorney of record. I thereafter ordered petitioner to file an expert report and suspended respondent's deadline to file a supplemental Rule 4 (c) report. Order, issued Oct. 6, 2011, at 1. Over the next eight months, petitioner filed only a status report, indicating again that she was proceeding under a theory of "non-Table" or "off-Table" encephalopathy. See Status Report, filed Apr. 16, 2012, at 1. She failed to produce amended pleadings or an expert report.

On June 22, 2012, Mr. Gage filed a motion to withdraw as attorney of record.<sup>13</sup> I granted Mr. Gage's motion to withdraw on September 24, 2012. Edward Kraus, petitioner's fourth attorney, became her attorney of record on November 26, 2012.

On December 7, 2012, I held a telephonic status conference with the parties. Affording Mr. Kraus an opportunity to familiarize himself with the record, I gave petitioner two months to file a status report indicating how she wished to proceed. On February 11, 2013, petitioner filed a status report, indicating Mr. Kraus would be filing a motion to withdraw as attorney of record and that she would be proceeding as a *pro se* petitioner. Status Report at 1. I granted Mr. Kraus's motion to withdraw.

In view of the length of time previously afforded petitioner to explore alternative theories and to produce evidence supportive of those theories, I gave petitioner 60 days to file an expert report supporting her off-Table claim. Order, issued Mar. 1, 2013, at 1-2. When petitioner failed to comply, I ordered her to file an expert report, addressing her off-Table injury claim, or show cause why this case should not be dismissed for failure to prosecute. Order to Show Cause, issued May 7, 2013, at 1-2.

In response, petitioner filed a motion to stay this case until she could find "new resources to defend and represent Sebastian." Motion, filed May 24, 2013, at 1. In her motion, petitioner argued that she has "already provided the court with multiple expert reports, tests and video supporting Sebastian's case." *Id.*

I denied petitioner's request<sup>14</sup> and again ordered her to file an expert report addressing her off-Table injury claim or show cause why this case should not be dismissed for failure to prosecute. Order to Show Cause, issued June 18, 2013, at 2. Petitioner has failed to respond.

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<sup>13</sup> On June 22, 2012, Mr. Gage also filed a motion for interim attorneys' fees and costs for his services and on July 2, 2012, filed a similar motion for Mr. Gallagher's services. I awarded the interim attorneys' fees and costs on August 21, 2012 and September 11, 2012.

<sup>14</sup> In effect, she has requested an indefinite stay of Sebastian's case. Although Vaccine Rule 9 allows a special master to suspend proceedings for up to 180 days for good cause, petitioner's case has been pending for more than twelve years and was stayed for far longer than 180 days during the OAP litigation. See Vaccine Rule 9; Notice, filed Feb. 12, 2004, at 1-2. Petitioner has had more than 30 months to produce evidence supporting an alternate causation theory. See Order, issued Mar. 23, 2011. Thus, she has had ample time to prove vaccine causation.

This case now has been pending for more than twelve years. During that time, petitioner has attempted to prove her claim as a *pro se* petitioner and while being assisted by four different attorneys. Special Master Edwards determined that Sebastian had not suffered from a Table encephalopathy. Petitioner has been unable to produce an expert report to demonstrate actual causation by the vaccines Sebastian received. Thus, I dismiss the petition for lack of evidence as well as the failure to comply with my orders to produce an expert report supporting her claims.

## II. Medical History.<sup>15</sup>

### A. Early Medical Care.

Sebastian was born on September 2, 1997 after an unremarkable pregnancy. Pet. Ex. 1, p. 22. His Apgar scores<sup>16</sup> were 9 at both one and five minutes. *Id.* Eleven days after birth, he was seen by his pediatrician for a mildly swollen eye with some discharge and diagnosed with injected conjunctiva. Pet. Ex. 2, p. 42.

During Sebastian's first well child visit on September 18, 1997, his pediatrician noticed a cardiac abnormality. Pet. Ex. 2, p. 38. After discussing the matter with specialists at the Pediatric Cardiology Clinic at Walter Reed Army Medical Center ["WRAMC"], Sebastian's pediatrician referred him to Inova Fairfax Hospital. *Id.* Sebastian was discharged from the hospital on September 20, 1997, after being placed on two medications to treat his cardiac condition. *Id.*, p. 25. He had a follow up appointment on September 25, 1997, with Dr. Susan des Jardin from WRAMC who noted that Sebastian's echocardiogram at Inova Fairfax Hospital was reportedly normal and his atrial flutter appeared to be resolved on medication. *Id.*, p. 37. Approximately eighteen months later, Sebastian was off all medication and had not experienced a recurrence of his atrial flutter. *Id.*, p. 14.<sup>17</sup>

In the six months following Sebastian's initial well child visit on September 18, 1997, Sebastian visited his pediatrician for well child assessments and minor illnesses. See e.g., Pet. Ex. 2, pp. 5 (four month well child visit on January 16, 1998), 7 (visit for a cold and rash diagnosed as eczema on February 23, 1998). On March 30, 1998, Sebastian saw his pediatrician because he had suffered from a 103° fever for three days. Pet. Ex. 2, p. 7. Sebastian's temperature at the time of his visit was 98° and he was diagnosed with a viral illness. *Id.*

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<sup>15</sup> Petitioner originally filed medical records on November 8, 2001 and several times thereafter. Unless I specify otherwise, I am referring to the version of medical records filed on March 6, 2008 and thereafter.

<sup>16</sup> An Apgar score is a numerical assessment of a newborn's condition (with lower numbers indicating problems), usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle ton, reflex irritability, and color, with from zero to two points awarded in each of the five categories. DORLAND'S at 1682.

<sup>17</sup> This medical record was also filed at Pet. Ex. 13, p. 3.

## B. The Allegedly Causal Vaccines and Subsequent Illness.

On April 14, 1998, Sebastian visited his pediatrician for his six month well child assessment. Pet. Ex. 2, pp. 4, 7. The medical record from that visit indicates he was able to laugh, play, babble, roll for mobility, support his head and chest, hold his bottle, and sit. *Id.*, p. 4. Sebastian had been ill recently, experiencing a fever and not eating or sleeping, but his temperature was not elevated at the time of the visit. *Id.*, pp. 4, 7. He was administered his third DTaP and haemophilus influenzae type b [“Hib”] vaccines.<sup>18</sup> *Id.*, p. 4; see also Pet. Ex. 2, p. 24 (record of Sebastian’s vaccinations). Petitioner believes that this DTaP vaccination caused Sebastian’s encephalopathy or autism.

Sebastian saw his pediatrician the next morning (April 15, 1998) because he had developed a fever shortly after midnight. Pet. Ex. 2, pp. 7-8. According to the intake notes, Sebastian experienced a fever of 106° between 1 and 2 AM and currently had a temperature of 99.2°. *Id.*, p. 7. Later notes, presumably from the pediatrician, indicate Sebastian’s temperature was as high as 104° between 1 and 2 AM and was 101° at the time of the physician’s examination. *Id.*, pp. 7-8. The chart reflected that Sebastian was not vomiting or coughing, had received vaccinations the previous day, had been given Tylenol at the time of his shots, had drunk tea that morning, and was smiling at the time of the examination. *Id.*, p. 7. There was a notation of “NAD,” meaning no apparent distress. *Id.* At the end of the notes from this visit, there was a notation that Ms. Vig would call the next morning with an update and to follow-up with blood tests. *Id.*, p. 8. The doctor added “[c]ould this be rxn from DTAP ? Perhaps -> need to watch . . . fever and reassess.” *Id.*

In the evening of April 15, 1998, Sebastian was taken to the emergency room at Potomac Hospital. Pet. Ex. 4, pp. 3-4. At 11 PM, his temperature was recorded as 38.3° Celsius (100.9° Fahrenheit). *Id.*, p. 4. Blood tests were performed. *Id.*, p. 10. He was discharged at approximately 1 AM the following morning, April 16, 1998. The notes regarding his discharge indicate Sebastian was stable. *Id.*, p. 4.

Ms. Vig called Sebastian’s pediatrician on the afternoon of April 16, 1998 because he still was experiencing a fever. Pet. Ex. 2, p. 8. It appears that the pediatrician checked on Sebastian’s lab results, as approximately 10 minutes later, he informed Ms. Vig that the results were normal. *Id.* Sebastian’s pediatrician noted that the fever could be a reaction to the DTaP vaccination and that Sebastian should be watched and reassessed. *Id.*

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<sup>18</sup> Prior to this visit, Sebastian had received his first hepatitis B vaccination on September 3, 1997; his second hepatitis B vaccination on September 29, 1997; his initial DTaP, Hib, and inactivated polio vaccinations [“IPV”] on October 23, 1997; and his second DTaP, Hib, and IPV vaccinations on January 16, 1998. Pet. Ex. 2, p. 24.

Sebastian returned to the emergency room at Potomac Hospital just before midnight on April 16, 1998. Pet. Ex. 4, p. 9. His temperature was 39.4° Celsius (102.9° Fahrenheit), measured rectally, and he was administered Motrin. *Id.*, p. 7. Additional lab work was performed and he was discharged. *Id.*, pp. 11-13.

As follow-up to Sebastian's visits to the emergency room, Sebastian saw his pediatrician on April 17, 1998. Pet. Ex. 2, pp. 8-9. His temperature was recorded as 99.6°. *Id.*, p. 8. Sebastian had been sleeping and eating well the prior day, April 16, 1998. *Id.*, p. 9.

Sebastian was seen again by his pediatrician on April 19, 1998. Pet. Ex. 2, p. 10. He was afebrile but he was fussy, not sleeping, had decreased appetite, and suffered from diarrhea. *Id.* Later that day, Sebastian's pediatrician learned that the blood drawn at Potomac Hospital on April 16, 1998 had tested positive for gram positive cocci.<sup>19</sup> Pet. Ex. 2, p. 10. Sebastian was admitted to Inova Fairfax Hospital for further treatment. Pet. Ex. 3, p. 4.

The doctors treating Sebastian at Inova Fairfax Hospital noted that he was "clinically improving" but questioned if he had meningitis. Pet. Ex. 3, p. 7. After discussing the possibility of a spinal tap procedure with Sebastian's parents, the blood cultures were repeated and antibiotics administered. *Id.*, pp. 9, 11. That evening he was described as intermittently irritable but "smiling" and afebrile. *Id.*, p. 11. The next day Sebastian's blood cultures were negative and, he was described as "alert" and "playful" and was discharged. *Id.*, pp. 11-12. Five days later, the most recent blood cultures still showed no growth. *Id.*, p. 16.

### C. Medical Treatment Following the April 1998 Illness.

Sebastian was seen for a fall and wrist injury on May 22, 1998. Pet. Ex. 2, p. 10. Videotapes of Sebastian dated August 25, 1998 through October 12, 1998 show him playing with toys, smiling, vocalizing, and playing with his older sister. See Pet. Ex. 29.

At Sebastian's 12 month<sup>20</sup> well child visit on November 2, 1998, he was described as meeting all his developmental milestones, having "a lot of single words," being active, and climbing. Pet. Ex. 2, p. 3. He was noted to concentrate for long periods of time but no additional details regarding this behavior were provided. *Id.* He received his first measles, mumps, and rubella ["MMR"] vaccine and his third hepatitis B vaccine. Pet. Ex. 2, pp. 3, 24.

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<sup>19</sup> Blood cultures taken during Sebastian's second visit to the emergency room at Potomac Hospital on April 16, 1998 were reported on April 19, 2013 to contain gram positive cocci. Pet. Ex. 4, p. 13. In her affidavit filed prior to the hearing and her testimony at the hearing conducted by Special Master Edwards, petitioner asserted that this result later was determined to have been a mistake due to human error. Affidavit, filed July 25, 2002, at 2-3; Tr. at 29. Given that the subsequent cultures were negative, I accept Ms. Vig's testimony and affidavit on this point.

<sup>20</sup> Sebastian was 14 months old at the time of this visit.

Sebastian next saw his pediatrician on January 13, 1999, because he had experienced a fever for the prior three days and was cranky, fussy, and irritable. Pet. Ex. 2, p. 11. His temperature at that visit was 99.7°. He was diagnosed with pharyngitis and otitis media and prescribed amoxicillin. *Id.* A few days after this visit, Ms. Vig called Sebastian's pediatrician because he had a rash on his neck and behind his ears. Petitioner was told to discontinue the amoxicillin if the rash increased or spread. *Id.*, p. 12.

At Sebastian's 18 month<sup>21</sup> well child visit on April 13, 1999, his development was described as normal except for an issue with his speech. Pet. Ex. 2, p. 6. "[w]ords" was written under the Abnormalities Section. *Id.* Sebastian was described as temperamental and non-compliant with "time outs." *Id.* He received the diphtheria-tetanus ["DT"], oral polio ["OPV"], and varicella vaccines at this visit.<sup>22</sup> It was noted that Sebastian was moving to Japan. Pet. Ex. 2, p. 6.

While in Japan, Sebastian received care at the Yokosuka Naval Hospital. See Pet. Ex. 5. From June through October 1999, he was seen on several instances for a fever and cough. *E.g.*, Pet. Ex. 5, p. 7. On September 1, 1999, he visited the hospital due to a fever which had lasted two days, decreased appetite, and irritability. *Id.* at 10. His sister had been ill earlier in the week. *Id.* Sebastian was diagnosed with viral pharyngitis and possible coxsackievirus. *Id.* No concerns about Sebastian's development were recorded at any of these visits. See *id.*, pp. 2, 5-10.

#### D. Autism Diagnosis and Subsequent Evaluations.

On June 1, 2000, Sebastian was seen by Dr. Christopher Westbrook at the Pediatric Clinic because Ms. Vig was concerned about his behavior and loss of language. Pet. Ex. 5, p. 1. She explained that Sebastian seemed to ignore people and would watch television for hours. *Id.* Doctor Westbrook diagnosed Sebastian with autism and referred him for further evaluation. *Id.*

Sebastian saw Dr. Robert Buckley, a developmental pediatrician, two weeks later. See Pet. Ex. 5, pp. 19-23 (Dr. Buckley's report). Although Dr. Buckley determined that Sebastian did not meet "the criteria for classic autism" because he did not exhibit restrictive or repetitive behaviors or interests, he diagnosed him with Pervasive Developmental Disorder Not Otherwise Specified ["PDD-NOS"].<sup>23</sup> Pet. Ex. 5,

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<sup>21</sup> Sebastian was 19 months old at the time of this visit.

<sup>22</sup> Pet. Ex. 2, pp. 6, 24. The medical records filed show no further vaccinations.

<sup>23</sup> "PDD-NOS" is a specific diagnosis listed in the same category as autism and Asperger's disorder in the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 4th ed. text revision 2000) ["DSM-IV-TR"] at 69-70. This specific diagnosis can be confused with Pervasive Developmental Disorder ["PDD"], the umbrella term for ASD used in the DSM-IV-TR at 69. The DSM-IV-TR has since been replaced by the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 5th ed. 2013) ["DSM-V"] which uses a single umbrella diagnosis of ASD.

p. 18. He indicated that Ms. Vig and Sebastian would be returning to the United States “to pursue early intervention services and receive support from her family.” *Id.* Although petitioner communicated to Dr. Buckley her belief that the vaccines Sebastian received at nine months of age may have caused his condition, Dr. Buckley told her that “[t]hus far, no studies have shown a cause or link between immunization and autism.” *Id.*, p. 22. I discuss Dr. Buckley’s report in greater detail in Section III.B.4.

Between August and November 2000, Sebastian was evaluated by Dr. Cecelia McCarton at the Albert Einstein College of Medicine, Dr. William H. Trescher at the Kennedy Krieger Children’s Hospital, and two different speech and language pathologists. See Pet. Exs. 6, 7, 9, 10, 17. Beginning in October 2000, Sebastian received pediatric care from Plaza Family Care. See Pet. Ex. 20. Sebastian began therapy sessions at Kid Therapy on February 20, 2001. Pet. Ex. 12, p. 1. Although additional medical records were filed, they do not appear to be relevant to the issue of vaccine causation of Sebastian’s condition.

### **III. Evaluating Petitioner’s Claim.**

Under the Vaccine Act, Ms. Vig may prevail on her claim by proving a Table injury, in which causation is presumed or, alternatively, by proving an off-Table injury, in which she establishes a causal link between a vaccine and the injury alleged. Because Special Master Edwards ruled in 2004 that Sebastian did not suffer a Table injury, Ms. Vig must prove that a covered vaccine caused Sebastian’s condition, whether it is characterized as autism or encephalopathy.<sup>24</sup> I will briefly discuss the Table injury claim in order to provide a complete analysis of the causation claims presented, but focus the majority of the discussion below on petitioner’s off-Table claim.

#### **A. Applicable Legal Standards.**

##### **1. Table Injury.**

Under the Vaccine Act, a petitioner may prove entitlement to compensation if the vaccinee has “sustained, or had significantly aggravated any illness, disability, injury, or condition set forth in the Vaccine Injury Table.” § 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Vaccine Act, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). If a petitioner establishes that the vaccinee has suffered a Table injury, causation is presumed.

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<sup>24</sup> Petitioner has characterized Sebastian’s autism as an encephalopathy. See, e.g., Order, issued Jun. 8, 2011, at 2; see *supra* note 9 (for the definition of “encephalopathy”).

## 2. Off-Table or Actual Causation Claim.

If the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, a petitioner must prove that the administered vaccine caused injury to receive compensation on behalf of the vaccinee. § 11(c)(1)(C)(ii). In such circumstances, a petitioner is said to assert an off-Table claim. To prevail, the petitioner must prove her claim by preponderant evidence. § 13(a)(1)(A).

This standard is “one of . . . simple preponderance, of ‘more probable than not’ causation.” *Althen v. Sec’y, HHS*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec’y, HHS*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the injury, only that the vaccination was a “substantial factor” and a “but for” cause. *Shyface v. Sec’y, HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999); see also *Pafford v. Sec’y, HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (a petitioner must establish that a vaccination was a substantial factor and that the harm would not have occurred in the absence of the vaccination).

The Federal Circuit has set forth three factors petitioners must establish to prove causation in off-Table cases. See *Althen*, 418 F.3d at 1278. *Althen* requires petitioners to provide: “(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.” *Id.* All three prongs of the *Althen* test must be satisfied by preponderant evidence. *de Bazan v. Sec’y, HHS*, 539 F.3d 1347, 1351-52 (Fed. Cir. 2008); *Caves v. Sec’y, HHS*, 100 Fed. Cl. 119, 132 (2011), *aff’d per curiam*, 463 Fed. Appx. 932, 2012 WL 858402 (Fed. Cir. 2012) (finding that “[w]hen a petitioner seeks to demonstrate causation in fact by meeting the three *Althen* requirements, each of those requirements must be proven by a preponderance of the evidence”).

Petitioners may satisfy this evidentiary burden by relying either on “medical records or medical opinion.” *Althen*, 418 F.3d at 1279 (emphasis in original). A special master cannot find a petitioner has proven her case by a preponderance of the evidence based upon “the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 13(a).

Expert evidence must be scientifically reliable and may be analyzed using the framework provided by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993). *Terran v. Sec’y, HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) (approving the special master’s use of *Daubert* as a framework for weighing medical expert opinions). The Federal Circuit has stated that a “special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” *Moberly v. Sec’y, HHS*, 592 F.3d 1315, 1324 (Fed. Cir. 2010).

Causation is determined on a case by case basis, with “no hard and fast *per se* scientific or medical rules.” *Knudsen v. Sec’y, HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994). Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280. *But see Knudsen*, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof fails to meet that burden).

## B. Petitioner’s Claims.

Petitioner has indicated she is proceeding under a theory of an off-Table encephalopathy. See, e.g., Status Report, filed Apr. 16, 2012, at 1. Thus, she must prove vaccine causation<sup>25</sup> by satisfying the *Althen* test. Relying on excerpts from Sebastian’s medical records, Vaccine Adverse Event Reporting System [“VAERS”] reports concerning the DTaP vaccine, and statements from medical professionals, petitioner claims she has proven the DTaP vaccine Sebastian received on April 14, 1998 more likely than not caused “permanent brain injury due to acute and chronic encephalopathy.” Pet. Letter, filed June 23, 2011, at 12. Petitioner relies on the temporal connection between Sebastian’s April 14, 1998 vaccinations and what she describes as the onset of his symptoms; statements in the medical histories she provided to treating physicians years after the events in question; and out of context statements in physicians’ letters and reports to support her claim of vaccine causation of Sebastian’s condition. I discuss petitioner’s claims and evidence in the subsections below, but in summary, the evidence fails to satisfy any of the *Althen* factors.

### 1. Temporal Relationship.

Ms. Vig claims that the temporal relationship between the April 14, 1998 DTaP vaccine and onset of Sebastian’s autism symptoms demonstrates a causal relationship. Her assertions regarding onset are not supported by the evidence.

In her June 23, 2011 letter, petitioner argued that vaccine causation is evident because Sebastian was developing normally prior to his April 14, 1998 DTaP vaccination and was “never the same afterwards.” Pet. Letter at 2. Petitioner claimed that after receiving the DTaP vaccine Sebastian began to slowly regress, exhibiting behaviors such as “head banging, throwing himself on the floor, hitting, screaming, not sleeping, staring for long periods of time in space, not looking at [her], not responding to [her] when [she] spoke to him, as if he did not hear [her].” *Id.* at 1. But, by petitioner’s own account, she did not report any difference in Sebastian’s behavior until more than six months later at his 12 month well child visit. *Id.* at 5. Although petitioner maintains

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<sup>25</sup> Although petitioner appears to understand she must prove her claim by preponderant evidence, showing that the DTaP vaccine administered on April 14, 1998 more likely than not caused Sebastian’s injuries, on several occasions, she mentions the fact that causation is presumed for Table injuries. Petitioner’s Letter [“Pet. Letter”], filed June 23, 2011, at 8, 12. I have informed petitioner that I will not revisit Special Master Edward’s ruling that Sebastian did not have a Table encephalopathy. See Order, issued Aug. 24, 2011, at 2. At the hearing, her expert essentially conceded that Sebastian’s condition after the April 14, 1998 vaccinations did not meet the statutory definition of a Table encephalopathy. Tr. at 68-70.

that she informed Sebastian's pediatrician of these behaviors, the medical records from that visit indicate only that she reported that Sebastian concentrated for long periods of time. *Compare* Pet. Letter at 5 *with* Pet. Ex. 2, p. 3 (record of Sebastian's 12 month well child visit). Videotapes of Sebastian taken during the six month period following vaccination show him to be smiling, vocalizing, and playing with toys alone and with his sister. See Pet. Ex. 29 (videotapes dated from August 25, 1998 to October 21, 1998).

It was not until a year after receiving the April 1998 DTaP vaccine that Sebastian was noted to have any developmental difficulties. See Pet. Ex. 2, p. 6 ("words" was recorded under the "Abnormalities" section of the medical record). At this April 1999 visit, Ms. Vig described Sebastian as temperamental and non-compliant with "time outs," but there is no record indicating that he was "head banging," insensitive to pain, lacked eye contact, and displayed decreased responsiveness. See *id.*

Petitioner did not mention decreased responsiveness until June 1, 2000, when she explained that Sebastian seemed to ignore people and would watch television for hours. Pet. Ex. 5, p. 1. Sebastian was diagnosed with autism at that visit, which occurred more than two years after the vaccination petitioner maintains caused his injury. *Id.*

Thus, even if a temporal relationship constitutes some evidence of a causal one, petitioner has not established that Sebastian demonstrated autism symptoms before 14 months of age, at the very earliest.

## 2. "Allergy" to Pertussis.

Ms. Vig claims that Sebastian has a pertussis "allergy" but this claim is not supported by any allergy testing or evidence of an allergic reaction to the administration of the pertussis vaccine. Even if Sebastian is deemed to have a pertussis allergy on the basis of his febrile illness following the administration of his third DTaP vaccination, there is no evidence that an allergy can cause either an encephalopathy or autism.

Sebastian's contemporaneous medical records do not reflect any reactions to the DTaP vaccinations administered on October 23, 1997 and January 16, 1998. Although he developed a fever after receiving his third DTaP vaccination on April 14, 1998, medical records from the six months after this vaccination do not reflect any pertussis allergy being diagnosed.

On January 13, 1999, when receiving pediatric care from his initial pediatricians at Wineland, Wilmot & May, Sebastian was seen for an ear infection and rash. Pet. Ex. 2, pp. 11-12. The notes from that visit reflect an allergy to pertussis but the reason for this notation was not given.<sup>26</sup> *Id.*, p. 11. Sebastian was administered only the DT

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<sup>26</sup> I note that none of Sebastian's previous records reflected such an allergy, and none reflect any concern about an encephalopathy.

vaccine, in lieu of the DTaP vaccine, at his next well child visit on April 13, 1999. *Id.*, p. 6.

### 3. Support from Patrick A. Caruso, M.D.

Ms. Vig claims that Dr. Caruso's records support her causation claim. Although Dr. Caruso made two notations in Sebastian's medical records regarding vaccine reactions causing an encephalopathy, the records do not reflect any basis for these assertions.

On December 4, 2001, Dr. Caruso wrote a note indicating that Sebastian presumably<sup>27</sup> had a reaction to his third DTaP vaccination at nine months of age and "[would] not be getting further Pertussis vaccines." Pet. Ex. 20, p. 4. The following year, Dr. Caruso wrote a second note, indicating an exemption for Sebastian from "any further vaccinations due to previous reactions causing encephalopathy." Pet. Ex. 26, p. 1.<sup>28</sup>

However, Dr. Caruso was not Sebastian's physician during the period following the April 14, 1998 DTaP vaccination. He did not begin caring for Sebastian until October 2000 after he returned from Japan. See Pet. Ex. 20 (medical records from Plaza Family Care in New Jersey). Thus, Sebastian already was diagnosed with PDD-NOS when he began seeing Dr. Caruso. Moreover, as Dr. Caruso does not indicate what he relied upon in making this causation determination, his assertions lack any indicia of reliability.

### 4. Statements from Robert H. Buckley, M.D.

Ms. Vig contends that Dr. Buckley, who diagnosed Sebastian with PDD-NOS, has opined that the April 14, 1998 DTaP vaccination caused his condition. In so asserting, she relies on statements taken out of context.

As proof of her claim that Dr. Buckley believed Sebastian's injuries to be vaccine caused, petitioner referred to statements from Dr. Buckley's August 8, 2000 letter to petitioner's insurance company (Pet. Ex. 25) and excerpts from Dr. Buckley's June 15, 2000 assessment of Sebastian's condition (Pet. Ex. 5, pp. 19-23). In the August 8, 2000 letter, Dr. Buckley stressed the importance of finding "a cause or etiology" for Sebastian's autism, indicating that his reaction to the DTaP vaccine he received when nine months old "may be a contributing factor." Pet. Ex. 25 at 1. Petitioner also

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<sup>27</sup> Although petitioner believes Sebastian's pediatrician wrote that he "had a reaction projectibly to his 3<sup>rd</sup> Pertussis vaccine," it is clear that the word "projectibly" is not what is written in this medical record. Compare Pet. Letter, filed June 23, 2011, at 7 with Pet. Ex. 20, p. 4. Rather, the word appears to be "presumably." See Pet. Ex. 20, p. 4.

<sup>28</sup> This note was not filed with the medical records from Plaza Family Care, P.C. but filed only with petitioner's June 23, 2011 letter. When filing her updated exhibit list on September 9, 2011, petitioner labeled the note as Pet. Ex. 26.

emphasized several sentences found in Dr. Buckley's assessment, discussing Sebastian's "central nervous system dysfunction" and "significant change in Sebastian's social interactions from a year of age to his present age." Pet. Ex. 5, pp. 21-22 (filed with portions highlighted on June 23, 2011). Sebastian was 33 months old when Dr. Buckley wrote this assessment.

None of these statements establish that Dr. Buckley believes the DTaP vaccine caused Sebastian's injuries. In his assessment, Dr. Buckley clearly indicated that "[t]he etiology for Sebastian's developmental difficulties is not determined at this time." Pet. Ex. 5, p. 23.

Doctor Buckley noted that generally 30% of children with ASDs experience a regression in development between 18 and 24 months of age and that the reason for this regression is unknown. Pet. Ex. 5, p. 23. When he discussed Ms. Vig's belief that what she characterized as Sebastian's regression was caused by the DTaP vaccine, Dr. Buckley explained that "no studies have shown a cause or link between immunization and autism." *Id.* While accepting that Sebastian had a significant reaction to DTaP vaccine when nine months of age, Dr. Buckley indicated that videos of Sebastian at eleven months of age showed that he had "normal social interactions and language development for a child of his age." *Id.* Reading Dr. Buckley's report *in pari materia*, he does not assert that the DTaP vaccine caused Sebastian's injuries, merely that the reaction could be a contributing factor, but an unlikely one, in view of apparently normal development two months after the vaccinations.

##### 5. Statements from Cecelia McCarton, M.D.

Ms. Vig also relies on a letter written by Dr. McCarton. The letter provides little support for petitioner's claims.

Doctor McCarton is a Clinical Professor of Pediatrics at the Albert Einstein College of Medicine who evaluated Sebastian on August 9 and 16, 2000 "in order to determine his current developmental status and . . . better define his educational and therapeutic needs." Pet. Ex. 6, p. 1. Prior to the hearing conducted by Special Master Edwards, petitioner filed a July 8, 2002 letter from Dr. McCarton as an expert report.<sup>29</sup> In the letter, Dr. McCarton concluded that because of Sebastian's reaction to the DTaP vaccine, his normal development prior to receiving the vaccine, and his subsequent developmental delay, "one must **consider** a connection or association between [Sebastian's] current developmental status and his DPT vaccination." Pet. Ex. E, p. 13 (emphasis added).

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<sup>29</sup> When filing this letter on July 25, 2002 as an expert report, petitioner labeled it as Pet. Ex. E, p. 13. Petitioner filed this letter again on June 23, 2011 using a confusing numbering system which I ordered her to correct. See Order, issued Aug. 24, 2011. When filing her updated exhibit list on September 9, 2011, petitioner did not include this letter. I will refer to this letter as Pet. Ex. E, p. 13.

## 6. Statements from William H. Trescher, M.D.

Doctor Trescher was petitioner's expert at the hearing before Special Master Edwards. His reports thus focused on the Table encephalopathy claim. To the extent that any of his three reports opine in favor of vaccine causation, they rely on petitioner's accounts of symptoms consistent with an acute encephalopathy after the April 14, 1998 DTaP vaccination, followed by rapid onset of symptoms of autism sufficiently severe so as to constitute a chronic encephalopathy. Not only do these reports fail to address petitioner's causation in fact claim, Dr. Trescher's reports and testimony were rejected by Special Master Edwards because the factual predicate, *i.e.*, the presence of symptoms of a Table encephalopathy, was lacking.

Sebastian was evaluated by Dr. Trescher at the Kennedy Krieger Institute on November 1, 2000. Pet. Ex. 9, p. 3. Doctor Trescher diagnosed Sebastian with autism, concluding that "[t]he precise underlying reason for his condition is **not clear**." *Id.*, p. 7 (emphasis added). He ordered an overnight electroencephalogram ["EEG"],<sup>30</sup> the results of which were normal. *Id.*, pp. 7-8.

Prior to the hearing addressing petitioner's Table encephalopathy claim, Dr. Trescher provided petitioner with three letters which were filed as expert reports.<sup>31</sup> Although these letters address only the Table encephalopathy claim, petitioner filed Dr. Trescher's first and second letters again on June 23, 2011 and cited to them as proof of vaccine causation in her June 23, 2011 letter. Pet. Letter at 7-8.

In his first letter, Dr. Trescher opined only that there "**may** be an association between acute encephalopathy after the vaccination and [Sebastian's] current condition." Pet. Ex. F, p. 14<sup>32</sup> (emphasis added). In his second letter, Dr. Trescher opined that Sebastian's "mental status [was] consistent with an encephalopathic process" because his physicians considered performing a lumbar puncture. Pet. Ex. 27,

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<sup>30</sup> "The EEG is a graphic recording of the electrical activity of the brain." MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS 573 (4th ed. 2010).

<sup>31</sup> Petitioner filed Dr. Trescher's first letter, dated June 7, 2002, with her first amended petition on July 25, 2002. After petitioner filed her second amended petition, Special Master Edwards ordered her to file an expert report establishing her Table claim. See Order, issued Oct. 24, 2002. In response, petitioner filed Dr. Trescher's second letter, dated January 26, 2003, on February 3, 2003. Respondent filed the expert report of Dr. Shafrir. After conducting a Rule 5 conference to discuss the expert reports submitted and his substantive concerns regarding petitioner's Table claim, Special Master Edwards allowed petitioner the opportunity to submit a supplemental report from Dr. Trescher. See Order, issued Apr. 17, 2003. Petitioner filed Dr. Trescher's third letter, dated June 27, 2003, as a supplemental expert report on July 2, 2003.

<sup>32</sup> When filing this letter on July 25, 2002 as an expert report, petitioner labeled it as Pet. Ex. F, p. 14. Petitioner filed this letter again on June 23, 2011 using a confusing numbering system which I ordered her to correct. See Order, issued Aug. 24, 2011. When filing her updated exhibit list on September 9, 2011, petitioner did not include this letter. I will refer to the letter as Pet. Ex. F, p. 14.

p. 3.<sup>33</sup> Doctor Trescher maintained that in addition to this “acute encephalopathy,” there is “evidence of a chronic encephalopathy of at least 6 months duration as documented in [his] note of 11/2/2000.” *Id.* I assume Dr. Trescher is referring to the report of his November 1, 2000 evaluation of Sebastian which he dictated on November 2, 2000. See Pet. Ex. 9, pp. 3-7 (corrections at Pet. Ex. 9, p. 2). In that report, Dr. Trescher described Sebastian’s condition, diagnosed him with autism, and stated “[t]he precise underlying reason for [Sebastian’s] condition [was] not clear.” Pet. Ex. 9, p. 7.

In his third letter, it is clear that Dr. Trescher opined that Sebastian suffered a Table encephalopathy “if Sebastian had the diminished level of responsiveness described by [petitioner].” Dr. Trescher’s Supplemental Report at 1.<sup>34</sup> Doctor Trescher acknowledged that the description given by Sebastian’s pediatrician that he was “smiling” during his April 15, 1998 visit contradicted petitioner’s claims. *Id.*; see also Pet. Ex. 2, p. 7. Furthermore, after being asked about the differences between petitioner’s accounts and the information found in Sebastian’s medical records and considering the definitions of acute and chronic encephalopathy found in the Qualifications and Aids to Interpretation [“QAI”] section of the Vaccine Injury Table, Dr. Trescher admitted that he could not opine that Sebastian suffered either an acute or chronic encephalopathy. See *infra* Section III.C.1.b.

#### 7. Report from Charles Parker, D.O.

Sebastian was evaluated by Dr. Charles Parker at Amen Clinics, Inc. on June 21, 2006. When discussing the results of a brain scan he performed on Sebastian, Dr. Parker concluded that the “mild scalloping” he saw “is often associated with toxic exposure (such as to drugs or an adverse reactions to vaccinations), infection or oxygen deprivation at some point in the past.” Dr. Parker’s Report<sup>35</sup> at 8. However, he did not specify which event he believed caused the mild scalloping seen in Sebastian’s scan or when this change occurred. Furthermore, he did not explain how or why he reached this conclusion or provide the mechanism by which the scalloping occurs.

Doctor Parker’s report is merely descriptive of findings on a brain scan. Although Dr. Parker twice mentioned the belief of Sebastian’s parents that his injuries were caused by childhood vaccines, he does not attribute the findings to a specific cause. See Dr. Parker’s Report at 1-2, 4.

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<sup>33</sup> Petitioner did not assign an exhibit number to this letter when originally filed and used an inaccurate exhibit number when filing it on June 23, 2011. When updating her exhibit list on September 9, 2011, petitioner labeled this letter Pet. Ex. 27.

<sup>34</sup> Petitioner labeled this letter which she terms Dr. Trescher’s supplemental report as Pet. Ex. A. Because petitioner used Pet. Ex. A for several earlier filed exhibits including her affidavit filed on July 25, 2002, I will refer to this exhibit as Dr. Trescher’s supplemental report.

<sup>35</sup> Petitioner originally filed Dr. Parker’s report with her June 23, 2011 letter. When she updated her exhibit list on September 9, 2011, she labeled both Dr. Parker’s report and the VAERS reports she filed as Pet. Ex. 28. I will refer to this exhibit as Dr. Parker’s report.

## 8. VAERS<sup>36</sup> Reports.

Along with her June 23, 2011 letter, petitioner also filed copies of 29 VAERS reports involving the same lot number of DTaP vaccine that Sebastian received on April 14, 1998.<sup>37</sup> These VAERS reports involved such conditions as hives, spots, fever and agitation, injection site redness and pain, vomiting, hiccups, and screaming, as well as more serious reactions, such as seizures, trance-like episodes, twitching, and opisthotonos.<sup>38</sup> One death, attributed to sudden infant death syndrome, was reported. VAERS Reports<sup>39</sup> at 24. One other case of autism (in a five year old) was reflected in these VAERS reports. *Id.* at 28. Two of the 29 reports appear to involve Sebastian's own case.<sup>40</sup>

### C. Analysis of Petitioner's Case.

I set forth the salient portions of Special Master Edwards's bench ruling below (which I have adopted as my own), followed by my own analysis of petitioner's actual causation claim.

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<sup>36</sup> The Vaccine Adverse Event Reporting System (VAERS) is program used to track and analyze adverse events following immunization. See <http://vaers.hhs.gov/index/about/index> (for more information about this program). Reports may be submitted on line or by paper by anyone. Reports often are submitted by vaccine manufacturers, medical care providers, state immunization programs, and vaccine recipients. [http://vaers.hhs.gov/about/faqs#who\\_reports](http://vaers.hhs.gov/about/faqs#who_reports).

<sup>37</sup> These reports appear to have been obtained from the U.S. Food and Drug Administration (FDA) under the Freedom of Information Act on February 13, 2004.

<sup>38</sup> Opisthotonos is "a form of spasm consisting of extreme hyperextension of the body; the head and the heels are bent backward and the body bowed forward." DORLAND'S at 1351.

<sup>39</sup> When updating her exhibit list on September 9, 2011, petitioner labeled both these VAERS reports and Dr. Parker's report as Pet. Ex. 28. I will refer to these reports as simply VAERS reports. Additionally, petitioner did not file these reports in the order they were provided to her. Thus, the page number on the report does not match the page number on the electronic Bates stamp. I will refer to these reports in the order they were filed, using the page number on the electronic Bates stamp.

<sup>40</sup> Although petitioner only identified the report at page 29 as involving Sebastian, the reports have corresponding VAERS identification numbers, 159165-1 and 159165-2 and, each report lists the other as a "related report." VAERS Reports at 8, 29. Additionally, both reports reflect the same vaccination date, and the same two vaccines (DTaP and Hib) and lot numbers, as well as the previous diagnosis of atrial flutter and other medications being identical in both reports. Both cases are reported as occurring in Virginia. Although the "onset dates" in the cases are different, with one reflecting onset on the date of vaccination and one a date more than two years later, the reports both appear to describe Sebastian's hospitalization and diagnosis following his April 14, 1998 vaccination.

## 1. Table Injury.

Prior to the hearing on January 23, 2004, Ms. Vig filed Sebastian's medical records, affidavits from herself and several family members,<sup>41</sup> and letters which were filed as expert reports from Drs. McCarton and Trescher.<sup>42</sup> Along with her Rule 4(c) report, respondent filed an expert report from and curriculum vitae of Dr. Yuval Shafir. Respondent's Exhibits ["Res. Exs."] A-B. At the hearing, Ms. Vig, Dr. Trescher, and Dr. Shafir testified.

### a. Ms. Vig's Testimony.

During her testimony, Ms. Vig described Sebastian's condition after receiving his April 14, 1998 vaccinations. As in her affidavit filed on July 25, 2002, she indicated that Sebastian initially screamed and cried and "passed out asleep" after two to three hours. Tr. at 13; *accord.* Pet. Ex. A at 3. She claimed that Sebastian was moaning and tossing in his sleep when she checked on him around 7 PM, but added to the assertions in her affidavit by indicating that "[h]is whole body was shaking" and "he was just staring to [sic] the wall," not making eye contact. *Compare* Tr. at 13-15 *with* Pet. Ex. A at 3.

She described taking Sebastian to the pediatrician the next morning. She contradicted the statements in the medical records which reflected that he was smiling and in no apparent distress. *Compare* Tr. at 18-20 *with* Pet. Ex. 2, p. 7. She claimed instead that Sebastian was not responsive and was comatose. Tr. at 19-20. She also testified that since Sebastian would not suck on his bottle, she attempted to keep him hydrated by squirting water into his cheeks with a syringe. Tr. at 21-22.

With regard to Sebastian's first visit to the emergency room on the evening of April 15, 1998, Ms. Vig testified that he did not even react to having his blood drawn. Tr. at 23-24. However, in her July 25, 2002 affidavit, Ms. Vig described Sebastian as traumatized by the tests performed, presumably including the blood draw. Pet. Ex. A at 3.

Consistent with her July 25, 2002 affidavit, Ms. Vig explained that Sebastian's visit to Inova Fairfax Hospital on April 19, 1998, was due to erroneous test results following the contamination of blood drawn during Sebastian's second visit to the emergency room at Potomac Hospital. Tr. at 29; see Pet. Ex. A at 3-4. Despite a

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<sup>41</sup> In addition to her affidavit (Pet. Ex. A), petitioner filed affidavits from Sebastian's father, Bryan R. Vig (Pet. Ex. B); Sebastian's grandparents, Henry and Aleksandra Kucinski (Pet. Ex. C); and Sebastian's uncle, Victor Kucinski (Pet. Ex. D) on July 25, 2002. Despite the fact that petitioner erroneously used letters instead of numbers and filed several exhibits using these same letters, I will refer to these exhibits as filed, giving additional information to identify them and will use the page number found at the bottom right corner of each page.

<sup>42</sup> Petitioner filed one letter from Dr. McCarton and three letters from Dr. Trescher. She filed Dr. McCarton's letter and two of Dr. Trescher's letters a second time on June 23, 2011 as proof of vaccine causation. See *supra* Section III.B.5 and 6.

notation that Sebastian was smiling, Ms. Vig still maintained that he continued to be unresponsive, not even noticing when his blood was being drawn. Tr. at 30-31. Additionally, she referred to an episode when Sebastian was one year old when he was banging his head against the wall. Tr. at 35. She claimed that the incident made her think about how he appeared to not feel pain when having his blood drawn in April 1998. However, Ms. Vig did not mention this incident of head banging at Sebastian's 12 month well child visit on November 2, 1998. See Pet. Ex. 2, p. 3.

Ms. Vig made two somewhat contradictory claims. She described an abrupt change, claiming that Sebastian was never "the same child." She also testified that she noticed a difference in him occurring over time. Tr. at 33-34.

After Drs. Trescher and Shafrir testified, Ms. Vig took the stand to clarify that she used the word "comatose" to mean only that Sebastian was not responding to her. Tr. at 95.

b. Dr. Trescher's Testimony.

Doctor Trescher testified that terms like "smiling" and "NAD" were "pretty standard phrase[s]" that do not constitute a neurological examination. Tr. at 41, 44. He complained that the medical records were "pretty silent overall on a precise description of [Sebastian's] neurological condition." Tr. at 44. Despite evidence that the motivating factor in the request to perform a lumbar puncture was the lab results showing a positive blood culture, Dr. Trescher believed the lumbar puncture discussion demonstrated that Sebastian's doctors were concerned about his neurological status. Tr. at 45-47. With regard to the discrepancies between Ms. Vig's testimony and the medical records, he argued that medical records could be wrong and that doctors always should consider the observations of the family. Tr. at 47-49. Doctor Trescher concluded his testimony during direct examination opining, as he did in his supplemental expert report, that if Sebastian had the decreased level of responsiveness described by Ms. Vig, he suffered an acute encephalopathy. Tr. at 50; see Dr. Trescher's Supplemental Report, filed July 2, 2003, at 1.

During cross examination, respondent's counsel questioned Dr. Trescher regarding several entries in Sebastian's medical records. Doctor Trescher agreed that there were entries describing Sebastian as "alert," "smiling," and in no apparent distress and that the lumbar puncture was considered primarily due to Sebastian's positive blood culture. Tr. at 54-59. He admitted he could find nothing in the medical records indicating Sebastian responded only to loud noises or painful stimuli or that he lacked eye contact. Tr. at 51-52.

Special Master Edwards then questioned Dr. Trescher. After reading the definition of acute and chronic encephalopathy required for a Vaccine Injury Table<sup>43</sup> provided to him by Special Master Edwards, Dr. Trescher admitted that he could not opine that Sebastian suffered an acute encephalopathy as defined in the Vaccine Injury Table and there was nothing in the descriptions of Sebastian provided by multiple treaters to indicate they believed he suffered such an encephalopathy. Tr. at 68-70. Doctor Trescher also admitted that if Sebastian was comatose as Ms. Vig described, he would not have been sent home with only instructions to administer Tylenol. Tr. at 71-72. He further agreed that he could not point to any evidence in the medical records that Sebastian suffered from a chronic encephalopathy as defined in the Vaccine Injury Table. Tr. at 72.

c. Dr. Shafrir's Testimony.

During his testimony, Dr. Shafrir pointed to references by at least five different pediatricians that countered petitioner's claim that Sebastian was encephalopathic. Tr. at 78-79. With regard to Ms. Vig's claims that Sebastian was shaking and comatose, Dr. Shafrir noted that she had not mentioned these observations before and had specifically informed Dr. Buckley when he evaluated Sebastian in 2000 that Sebastian had experienced no seizures. Tr. at 79. Doctor Shafrir highlighted Dr. Buckley's observation that Sebastian appeared normal in videotapes taken when he was 14 months old and the notation that Sebastian was meeting his developmental milestones when 15 months old. Tr. at 79-80.

d. Special Master Edwards's Ruling.

After hearing the testimony, Special Master Edwards indicated he would take the unusual step of offering comments from the bench regarding his "assessment of the case." Tr. at 98-99. He found that Sebastian had exhibited severe symptoms following

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<sup>43</sup> The QAI section of the Vaccine Injury Table requires that a vaccinee has suffered an acute encephalopathy and a chronic encephalopathy persisting for more than 6 months. 42 C.F.R. § 100.3(b)(2). Acute encephalopathy is defined as "one that is sufficiently severe to require hospitalization (whether or not hospitalization occurred)." 42 C.F.R. § 100.3(b)(2)(i). For Sebastian, a child less than 18 months old who did not suffer a seizure, "an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours." 42 C.F.R. § 100.3(b)(2)(i)(A). If Sebastian had suffered a seizure, his decreased level of consciousness would have to extend beyond 24 hours and not be attributed "to a postictal state (seizure) or medication." *Id.* At least one of three clinical signs must be present for the required time period. 42 C.F.R. § 100.3(b)(2)(i)(D). Chronic encephalopathy is defined as

a change in mental or neurologic status, first manifested during the applicable time period, persist[ing] for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy.

42 C.F.R. § 100.3(b)(2)(ii).

his 1998 vaccinations and that on April 15, 1998, a “treating pediatrician wrote in the records a concern whether Sebastian was exhibiting a reaction to his DTAP vaccination” but noted that the real issue was whether the reaction constituted an acute encephalopathy as defined in the QAI section of the Vaccine Injury Table. Tr. at 99. Pointing to Dr. Trescher’s inability to opine that Sebastian suffered an acute encephalopathy, as defined in the Vaccine Act, or to provide evidence of a chronic encephalopathy, Special Master Edwards concluded that petitioner had not shown Sebastian suffered a Table encephalopathy and thus, petitioner was not entitled to a presumption of vaccine causation. Tr. at 100. Special Master Edwards indicated he would not be writing a decision but would enter an order adopting his bench ruling. Tr. at 100-101; see *also* Order, issued Jan. 26, 2004. It is clear from his ruling that he rejected petitioner’s accounts of symptoms of an encephalopathy or autism arising quickly after Sebastian’s April 14, 1998 vaccination and subsequent illness.

## 2. Off-Table Injury.

In order to prove vaccine causation, petitioner must satisfy the *Althen* test. Thus, I will further analysis the record in this case<sup>44</sup> to determine if petitioner has satisfied each *Althen* prong.

### a. A Reliable Medical Theory.

To satisfy the first prong of the *Althen* test, petitioner must provide “a medical theory casually connecting the vaccination and the injury.” *Althen*, 418 F.3d at 1278 (quoting *Grant v. Sec’y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The medical theory must be a reliable one. *Knudsen*, 35 F.3d at 548 (“This ‘logical sequence of cause and effect’ must be supported by a sound and reliable medical or scientific explanation.”). Petitioner must prove the existence of this medical theory by a preponderance of the evidence. *Broekelschen v. Sec’y, HHS*, 618 F.3d 1339, 1350 (Fed. Cir. 2010). In other words, petitioner must show that it is more likely than not that the received vaccine **can** cause the alleged injury. *Pafford*, 451 F.3d at 1355-56 (emphasis added).

Ms. Vig has failed to proffer any theory explaining how a DTaP vaccination can cause an encephalopathy manifesting as autism. Her claims as set forth in her amended petition are inadequate to establish causation. Moreover, one of the physicians whose opinion she relies upon stated that “**no** studies have shown a cause or link between immunization and autism.” Pet. Ex. 5, p. 22 (emphasis added).

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<sup>44</sup> Although I will examine the record as a whole, I note that the only evidence filed by petitioner after the January 23, 2004 hearing was the letter and exhibits she filed on June 23, 2011. I discussed this evidence in detail in Section III.B. As I noted earlier, many of these documents were filed as expert reports or medical records prior to the January 23, 2004 hearing. The only documents not previously filed are the second note from Dr. Caruso, the June 8, 2000 letter from Dr. Buckley, and the report from Dr. Parker. Although petitioner claimed the second letter from Dr. Trescher was “newly filed” when updating her exhibit list on September 9, 2011, it was filed as an expert report prior to the January 23, 2004 hearing.

Petitioner's assertion that Sebastian "sustained a [sic] autism as a direct and proximate result of the vaccines administered as set forth in the medical submissions" (Second Amended Petition, filed Oct. 21, 2002, at 3), is not evidence of causation.

Although the Federal Circuit has held that "identification and proof of specific biological mechanisms" is not necessary to establish causation, *Knudsen*, 35 F.3d at 549, petitioner has not offered a complete theory. At best, petitioner has asserted a good faith belief that either the DTaP vaccine or the fever Sebastian experienced as a result of this vaccination damaged his brain, causing encephalopathy severe enough to result in autism-like symptoms. However, that claim does not account for apparently normal development for many months after the vaccination, followed by the onset of autism symptoms sometime between 14-18 months of age. If the DTaP vaccine caused brain damage, it is likely that the damage would have been apparent shortly after vaccination rather than months later.

Petitioner has not satisfied the first *Althen* prong because she has failed to produce any reliable evidence that a DTaP vaccination can cause autism or an encephalopathy manifesting as autism.

b. Second Prong.

Even if petitioner had provided a theory which satisfied the first prong, to satisfy the second prong of the *Althen* test, petitioner must establish a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. In other words, petitioner must show that the received vaccine actually caused the alleged injury. *Pafford*, 451 F.3d at 1356. The sequence of cause and effect need only be "logical and legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548-49; *accord. Capizzano v. Sec'y, HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). Testimony from a treating physician may assist petitioner in meeting her burden of proof under the second *Althen* prong. *Capizzano*, 440 F.3d at 1326.

Petitioner contends statements from Sebastian's treating physicians support her claim and, when viewed in isolation, some appear to do so. See, e.g., Pet. Ex. 27, p. 3 (Doctor Trescher's statement that Sebastian's "mental status [was] consistent with an encephalopathic process"). However, when viewed in context, and in light of Special Master Edwards's ruling that Sebastian did not display a persisting encephalopathy in the months after his April 1998 illness, these statements do not rise to the level of preponderant evidence of a logical connection between vaccination and Sebastian's autism. Many of these statements indicate only the possibility of a connection between vaccine and injury. Other statements show only that Sebastian suffered a fever following his third DTaP vaccination and may have an allergy to the pertussis component of the vaccine. These statements do not constitute proof of a logical connection between the DTaP vaccination and Sebastian's autism. At best, they show that the treating physicians were concerned that the febrile illness Sebastian experienced was caused by the DTaP vaccine, or that a possible connection between

this illness and his subsequent ASD diagnosis should be considered. They do not constitute preponderant evidence of the vaccine as a substantial factor or but-for cause of Sebastian's condition.

In Dr. McCarton's statement, she merely indicated that a connection should be considered. When writing to Ms. Vig's insurance company, Dr. Buckley opined that the DTaP vaccine "**may** be a contributing factor." Pet. Ex. 25 at 1 (emphasis added). However, in his assessment of Sebastian, Dr. Buckley clearly indicated he does not believe the DTaP vaccine caused Sebastian's injuries.

All three letters from Dr. Trescher were prepared prior to the January 23, 2004 hearing and addressed petitioner's Table claim. At hearing, he negated any statements he previously made regarding a Table encephalopathy, admitting he could not opine that Sebastian suffered an acute or chronic encephalopathy as defined by the Vaccine Injury Table. In the letters, Dr. Trescher only mentions causation when he indicates there "**may** be an association between acute encephalopathy after the vaccination and [Sebastian's] current condition." Pet. Ex. E, p. 14 (emphasis added). Like the statements of Drs. McCarton and Buckley, Dr. Trescher's observation does not prove it is more likely than not that Sebastian's vaccination caused his injuries.

Likewise, the fact that Sebastian was administered only the DT vaccine a year later at his 18 month well child visit does not demonstrate vaccine causation. As other special masters have noted, whether an inference can be drawn that a treating physician believes there is a logical link between vaccination and injury because she withholds future vaccinations depends on the "content and context" of the physician's decision. *Rickard v. Sec'y, HHS*, No. 09-729V, 2011 WL 1979601, at \*12 (Fed. Cl. Spec. Mstr. Apr. 11, 2011) (holding the treating doctor's recommendation was not evidence of causation because he clearly indicated "his recommendation . . . was based on a 'standard practice' concerning children with severe epilepsy"). In this case, Sebastian experienced a fever (a common side effect of vaccination) following his third DTaP vaccination. The elimination of the pertussis component in his last dose, given a year later, appears to be simply an effort to avoid a similar fever or potential complication. At the time of that DT vaccination, no autism diagnosis had been made and speech delay and some oppositional behavior were the only autism-like symptoms recorded. The physician did not think those symptoms were severe enough to refer Sebastian to a specialist at that time. Thus, use of a pertussis-free vaccine cannot be considered as evidence that the treating doctor thought pertussis played any role in encephalopathy or autism.

Petitioner also relies upon VAERS reports as proof of her claim. However, these reports indicate only that the individual or agency filing the report believed there may be a causal connection between the vaccines received and injuries reported. Further details are not provided and many of these reports are unverified, incomplete, or involve multiple vaccinations. As I noted in another case, relying on VAERS reports is like "fishing for data in a stocked pond, and then extrapolating from the resulting catch to opine on the fish population of a nearby lake." *Tompkins v. Sec'y, HHS*, No. 10-261V,

2013 WL 3498652, at \*16 (Fed. Cl. Spec. Mstr. June 21, 2013). VAERS is a “stocked pond,” containing only reports of adverse events after vaccinations but no data about the number of vaccines administered or the occurrence of the same adverse event in individuals who have not been vaccinated. Thus, the information in the VAERS report is meaningless without this additional data. Taken individually or as a group, these reports do not constitute proof of a logical connection between Sebastian’s DTaP vaccination and his autism.

I thus conclude that petitioner has not provided a logical sequence of cause and effect showing that the DTaP vaccine Sebastian received caused his autism or an encephalopathy.

c. Third Prong.

When proving that a vaccine was the cause of an injury, petitioner must also show “a proximate temporal relationship between vaccination and injury.” *Althen*, 418 F.3d at 1278. Petitioner must prove “that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medical acceptable to infer causation-in-fact.” *de Bazan v. Sec’y, HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Failure to provide a proximate temporal relationship will result in a denial of compensation. *Id.* at 1353. Ms. Vig has produced no evidence regarding what constitutes a proximate temporal relationship between a DTaP vaccination and onset of autism symptoms.

Additionally, petitioner’s later assertions describe an earlier onset of autism symptoms than those reflected in Sebastian’s medical records. *See supra* Section III.B.1. These discrepancies are not surprising as conflicts between contemporaneous medical records and subsequent statements, testimony, and medical histories are common in Vaccine Act cases.

Two general legal principles guide the resolution of conflicts between contemporaneous records and later-adduced evidence. The first is that the absence of a reference to specific symptoms in a medical record does not conclusively establish the absence of symptoms during that time frame. *See, e.g., Murphy v. Sec’y, HHS*, 23 Cl. Ct. 726, 733 (1991), *aff’d*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied*, 506 U.S. 974 (1992) (“[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.”)

The second principle addresses the degree of reliance commonly accorded to contemporaneous records. Special masters frequently accord more weight to contemporaneously recorded medical symptoms than those recounted in later medical histories, affidavits, or trial testimony. “It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.” *Murphy*, 23 Cl. Ct. at 733; *see also Cucuras v. Sec’y, HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Memories are generally better the closer in time to the

occurrence reported and when the motivation for accurate explication of symptoms is more immediate. *Reusser v. Sec'y, HHS*, 28 Fed. Cl. 516, 523 (1993). Inconsistencies between testimony and contemporaneous records may be overcome by “clear, cogent, and consistent testimony” explaining the discrepancies. *Stevens v. Sec'y, HHS*, No. 90-221V, 1990 WL 608693, at \*3 (Fed. Cl. Spec. Mstr. Dec. 21, 1990); see also *Burns v. Sec'y, HHS*, 3 F.3d 415, 417 (Fed. Cir. 1993) (decision to credit contemporaneous medical records over oral testimony “uniquely within the purview of the special master”). The following medical history and the conclusions drawn therefrom are presented with these legal principles in mind.

Despite petitioner’s current assertions, the medical records show Sebastian did not exhibit developmental and behavioral issues until at least a year after receiving his April 14, 1998 DTaP vaccination. Sebastian was not diagnosed with autism until more than two years after vaccination on June 1, 2000. Petitioner’s assertions are not supported by the medical records.

Petitioner cannot show a proximate temporal relationship because she has failed to show any relationship between Sebastian’s DTaP vaccination and his autism.

#### **IV. Conclusion.**

The medical records and medical opinions submitted do not constitute preponderant evidence that the DTaP vaccine Sebastian received on April 14, 1998 caused his injuries. The evidence presented is not sufficient to satisfy any of the three *Althen* factors. I have given petitioner every opportunity to provide a reliable medical opinion on vaccine causation, first ordering petitioner to file any additional expert reports more than two years ago. See Order, issued June 8, 2011, at 2. In spite of the assistance of four attorneys and her own efforts, petitioner has failed to find a physician willing to opine in her case.

Petitioner has failed to demonstrate either that Sebastian suffered a Table injury or that Sebastian’s injuries were actually caused by a vaccination. Thus, petitioner has failed to demonstrate entitlement to compensation. **This case is dismissed for insufficient proof and for failure to prosecute. The clerk shall enter judgment accordingly.**

**IT IS SO ORDERED.**

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**Denise K. Vowell**  
Chief Special Master