In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: July 30, 2010

No. 06-0730V

MATTHEW and CARRIE NANCE, as the Legal Representatives of their minor daughter, KATHERINE NANCE	)	
Petitioners,	)	Diphtheria-Tetanus-acellular Pertussis (DTaP) and Prevnar Vaccines; Afebrile Seizures; VAERS data; Petitioner's Expert Concedes Theory is Speculative
v.	)	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

Curtis Webb, Twin Falls, ID, for petitioners.

Althea Davis, Washington, DC, for respondent.

DECISION[1]

Campbell-Smith, Special Master

On October 25, 2006, petitioners, Matthew and Carrie Nance, filed a petition on behalf of their minor daughter Katherine Nance (Katie or vaccinee), seeking compensation under the National Vaccine Injury Compensation Program (the Vaccine

[1] Vaccine Rule 18(b) states that all of the decisions of the special masters will be made available to the public unless the decisions contain trade secrets or commercial or financial information that is privileged or confidential, or the decisions contain medical or similar information the disclosure of which clearly would constitute an unwarranted invasion of privacy. Within 14 days of the filing of a decision or substantive order with the Clerk of the Court, a party may identify and move for the redaction of privileged or confidential information before the document's public disclosure.

Program or the Act).[2] In the petition, petitioners allege that the diphtheria, tetanus, and acellular pertussis (DTaP) vaccination that Katie received on November 12, 2003 is a cause in fact of her seizure disorder. Petition (Pet.) at ¶10.

Petitioners rely on a theory of causation in fact. In support of their vaccine claim, petitioners submitted an affidavit from Katie's mother, Mrs. Nance, see Petitioners' Exhibit (Ps' Ex.) at 1, and a number of medical records, see Ps' Ex. 2, 3A (Mrs. Nance's prenatal records and Katie's birth records), Ps' Ex. 3B-H, 4-11 (Katie's pediatric and hospital records). Petitioners also filed an expert report from Thomas Schweller, M.D., who is board-certified in neurology, pediatrics, and electroencephalography. Dr. Schweller maintains a private practice in California and performs independent medical examinations for the Social Security Administration. Ps' Ex. 13. Accompanying Dr. Schweller's report were several medical articles. See Ps' Ex. 14, 15.

Challenging petitioners' theory of causation, respondent filed an expert opinion from John MacDonald, M.D. Dr. MacDonald is board certified in psychiatry and neurology, with a special competence in child neurology. R's Ex. B at 1. He maintains a private practice, and he serves as a member of the faculty at University of Minnesota teaching pediatric neurology. Tr. at 132. Filed with Dr. MacDonald's report were a number of supporting medical articles. See R's Ex. B Attachments 1-4.

On March 5, 2009, the undersigned conducted an entitlement hearing. The undersigned heard the testimony of Mrs. Nance and the parties' experts. Petitioners' expert acknowledged during the hearing that the mechanism of biological harm that he proposed was speculative and lacked both medical evidence and supporting data. See Tr. at 115-116, 129.

Following the hearing, the parties were afforded an opportunity to review the transcript. During a status conference held on May 12, 2009, the parties declined the opportunity to submit post-hearing briefs and asked the undersigned to rule on entitlement based on the submitted medical records, the filed expert opinions and medical literature, and the testimony of the witnesses. The case is now ripe for decision.[3]

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[2] The National Vaccine Injury Compensation Program is set forth in 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-§ 300aa-34 (2006) (Vaccine Act or the Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

[3] The undersigned is mindful of the delay in the issuance of this decision. The matter became ripe for decision while the undersigned completed her decision in Mead v. Secretary of Health and Human Services, No. 03-215, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010), one of the autism test cases in the Omnibus Autism Proceeding. Upon issuance of the

I. The Factual Record

The parties agree on the pertinent facts in this case.

Katie was born on July 3, 2003, weighing slightly more than 8.5 pounds. Ps' Ex. 3A at 3. Two days after Katie's birth, Katie's parents took her to the emergency room with concerns about her excessive sleeping and feeding difficulties. Ps' Ex. 3B at 2-3. The emergency room physicians examined Katie and discharged her in stable condition with the instruction that Katie's parents consult Katie's pediatrician within a couple of days. Id.

On July 7, 2003, two days after the emergency room visit, Katie presented to her pediatrician. He noted that Katie had lost weight. Ps' Ex. 4E at 7. In a subsequent visit on July 17, 2003, the doctor observed that Katie's feedings had improved after Mrs. Nance consulted a lactation specialist, and that Katie was gaining weight. Id. at 8. By her July 23, 2003 office visit, Katie had surpassed her birth weight, and her pediatrician noted that she was doing well. Id. at 9.

On September 3, 2003, Katie presented for her two-month physical examination. Id. at 11. The pediatrician noted that she was doing well, though she suffered from chronic nasal congestion. Id. During this visit, she received several childhood vaccines: DTaP, Hepatitis B, Prevnar, IPV, HIB, and pneumococcal conjugate. Ps' Ex. 4D at 5-6. Katie's mother testified that after Katie received that particular complement of vaccines, she cried during the entirety of the 35 minute trip from the pediatrician's office back home. Transcript of March 5, 2009 Hearing (Tr.) at 13. No other reaction to the administered vaccines was reported.

At Katie's four-month physical examination on November 12, 2003, her pediatrician indicated that she was developing normally. Ps' Ex. 4D at 12. She received additional vaccines at that visit, specifically: DTaP, Hepatitis B, IPV, HIB and Prevnar. Ps' Ex. 4E at 12.; see also Ps' Ex. 4D at 5-6. The pediatrician noted that Katie did not have any problem with her vaccinations. Ps' Ex. 4E at 12.

The description of Katie's condition after receiving this complement of vaccines provided by Katie's mother during the hearing affected the opinions of the parties' experts on the issue of the duration of Katie's initial seizure.

Mrs. Nance testified that Katie slept during the ride home from the pediatrician's office. Tr. at 15. Katie also "slept a lot" over the two days following her four-month vaccinations. Id. at 14. When she did awaken, she was fussy and "hardly" took any

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decision on March 12, 2010, the undersigned has turned to pending non-autism matters awaiting decision. The undersigned regrets the delay in the issuance of this decision.

breastmilk. Id. Katie also appeared "very pale." Id. at 15. Concerned primarily about Katie's poor feeding pattern, Mrs. Nance telephoned her lactation consultant on November 13, 2003, the day after Katie received her four-month vaccinations. Id. at 16. She did not telephone the pediatrician. Id.

On the night of November 14, 2003, Mrs. Nance put Katie in her crib for bed between 8:00 and 9:00 p.m. Id. at 16. Sometime shortly after the Nances had retired to bed–"probably" around 10:00, Mrs. Nance heard over the baby monitor Katie making a "whimpering" sound or "a little cry." Id. After listening to Katie cry for ten minutes or so, Mrs. Nance went to Katie's room to check on her. Id. at 18. When Mrs. Nance entered Katie's room, she heard a cry that was different from Katie's "normal sound." Id. The cry sounded "stuck, like it kept repeating itself." Id. at 19.

Alarmed by Katie's cry, Mrs. Nance approached Katie's crib and found her lying with her arms "straight out at the sides." Id. Mrs. Nance then reached into the crib to pick Katie up and found her "stiff." Id. With Katie in her arms, Mrs. Nance turned on the bedroom light and found Katie's eyes "open," bulging," and "kind of staring up at the ceiling" without "focusing on anything." Id. Unaware that Katie was having a seizure, Mrs. Nance called to her husband for assistance. Id. at 20. Mr. Nance dialed 911. Id. at 21.

While Mr. Nance called for emergency help, Mrs. Nance laid Katie down in the Nances' bedroom. Id. Katie was very pale, and her lips were blue. Id. She had "bubbles coming out of her mouth," and her teeth were clenched. Id. at 21-22. Mrs. Nance then moved Katie to the kitchen. See id. at 22.

Within ten to twelve minutes after Mr. Nance called 911, emergency medical services (EMS) personnel arrived from a neighboring community to transport Katie to the hospital. See id. at 23-24. When the EMS technicians arrived, Katie seemed sleepy and unresponsive; her eyelids were partially closed. See id. at 25-26. The EMS personnel gave Katie oxygen, and Katie "seemed to come out" of the state in which she had been about midway through the 30 minute ride to the hospital. Id.

The hospital emergency room records indicate that Katie presented for a "[p]ossible seizure" and "[a]bnormal movements." Ps' Ex. 3C at l. At the hospital, Katie's parents reported that they heard a gasping over the baby monitor, Ps' Ex. 3D at 10, and found Katie "with outstretched arms, stiffened, eyes fixed in [a] gaze and jaw clenched." Ps' Ex. 3C at 2. They believed the episode lasted approximately ten to fifteen minutes. Ps' Ex. 3C at 2, 4.

The examining physicians at the hospital noted that Katie was afebrile and had no recent infections and, although she was sluggish upon arrival, she quickly returned to

normal. Id. at 4. Katie's lab results and computed tomography ("CT") scan[4] were normal. Nonetheless, she was admitted to the hospital for further evaluation and observation. Id. at 2-3. During her evaluation at the hospital, Katie also underwent electroencephalogram ("EEG") testing,[5] which yielded normal results. Ps' Ex. 3D at 6; see also Ps' Ex. 3D at 13. Katie was evaluated by two physicians, who documented that she was "[a]wake, alert and oriented" with "[n]o focal deficits," Ps' Ex 3D at 4[6], and that she was "in her usual state of health." Id. at 5. She was noted to be "back to normal, smiling, and cooing." Id.

One of the evaluating physicians concluded that Katie had suffered from a single seizure–without fever before or after her seizure. Id. at 6. Katie was discharged home on the same day of her hospital admission with a diagnosis of generalized tonic seizures that were possibly provoked by the DTaP vaccination she received sixty hours before her seizure. Id. at 14. The hospital physicians noted that her pediatrician should "prob[ably]" avoid administering any further pertussis vaccinations in the absence of another explanation for Katie's seizures. Id.

Four days after Katie's hospital admission, Katie presented to her pediatrician for a post-hospitalization evaluation. Ps' Ex. 4E at 13. Dr. Handwork noted that Katie had no additional seizure activity following her hospital visit, and was "her usual self." Id. He concluded that Katie suffered a "[g]eneralized tonic seizure," and noted that "[b]ecause the seizure was [temporally] associated with receiving her D[T]aP, [Katie should] probably avoid pertussis vaccine in the future" if the cause of her seizures remains unknown. Id. at 14. Dr. Handwork also noted that he would make a final determination on the vaccination issue after Katie received additional medical evaluations. Id.

On November 20, 2003, seven days after Katie's first seizure event, Katie suffered a second seizure that was accompanied by a staring episode and lasted approximately five minutes. Ps' Ex. 3E at 2. Her temperature upon arrival at the emergency room was recorded as 97 degrees Fahrenheit. Id. at 3. The evaluating physician's impression was "[s]eizure disorder, new onset." Id. at 2. On the recommendation of Katie's treating neurologist, Katie was started on Tegretol to control her seizure activity. Id.; see also Pet.

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[4] A CT scan yields an image of the brain that is useful for evaluating the brain tissue at successive layers and identifying abnormalities. Mosby's, Manual of Diagnostic and Laboratory Tests at 1095-1096 (3d ed. 2006). This test is indicated when central nervous system disease is suspected. Id. at 1095.

[5] This test involves a graphic recording of the electrical activity of the brain and is used to detect and to study seizure activity. Mosby's at 566-567.

[6] In the medical records, Ps' Ex. 3D is assembled incorrectly. Pages 3 and 4 are found between pages 7 and 8.

Ex. 6A at 1. Nearly three weeks later, Katie underwent a CT scan and an MRI, and the results were normal. Pet. Ex. 3F at 2; see also Pet. Ex. 6C at 6.

Katie suffered a third seizure, which lasted about two minutes, on January 14, 2004 (almost two months after her second seizure). Ps' Ex. 3G at 2. Again, she presented to the emergency room, where the physicians noted that Katie did not have a fever or chills, "nausea, vomiting, diarrhea, ... [or] abnormal behavior" and was observed to be a "[h]appy, active, alert and playful child." Id. Her parents reported that they accidentally had skipped Katie's dose of Tegretol. Id.

About six weeks later, Katie suffered "possibly two seizures," with "some tonic/clonic activity" that lasted approximately fifteen minutes. Ps' Ex. 4E at 18. The Nances reported that during the seizure episodes, Katie's eyes were "rolling back in [her] head," and there was stiffening and shaking of her upper and lower extremities. Ps' Ex. 10A2 at 15. The Nances took Katie to Akron Children's Hospital for evaluation and a second opinion on her condition. Ps' Ex. 4E at 18.

On May 17, 2004, Katie's pediatrician completed a Vaccine Adverse Event Reporting System ("VAERS") form, relating that on November 14, 2003–sixty hours after Katie received Pediarix (DTaP, IPV, Hepatitis B), HIB, and Prevnar vaccines on November 12, 2003–she had a generalized tonic seizure without fever. Ps' Ex. Ex. 4A at 1. Dr. Handwork noted on the VAERS form that "[t]o date no definite etiology for [Katie's] seizures has been determined." Id.

In June 2004, Katie presented twice to the emergency room after episodes of short-lived seizure activity. The examining doctor noted that the series of three to four seizures was "slightly more than her normal one to two seizures," Ps' Ex. 11A at 3, and it was the impression of the evaluating physician that Katie suffered from status epilepticus. Ps' Ex. 11B at 10.

When Katie subsequently presented to her pediatrician for her two-year physical exam on July 29, 2005, Dr. Handwork noted that Katie's speech development was reasonably normal and that she "runs, climbs," knows her colors, numbers, and some body parts. Ps' Ex. 4E at 29. During her February 14, 2006 examination, Dr. Handwork noted that Katie had experienced twenty to forty seizure episodes, usually with a "few in a row," following her first "non-febrile" seizure at four months old. Id. at 32.

Since that time, Katie's seizure activity has continued. Throughout the development of her seizure disorder, Katie has remained on Tegretol. She continues to be monitored by her pediatrician and a treating neurologist.

III. Discussion

A. Legal Standards

Among the vaccines that Katie received at her four-month pediatric visit was DTaP. After receipt of that vaccine, Katie developed a seizure condition. The issue for determination is whether Katie's seizure condition is vaccine-related.

1. A Table Injury

The Vaccine Injury Table (the Table) lists particular injuries and conditions which, if found to have occurred within a prescribed time period, create a rebuttable presumption that an administered vaccine caused the injury or condition. 42 U.S.C. § 300aa-14(a). Of the vaccines that Katie received during her four-month pediatric visit, only the DTaP vaccine has an associated Table injury. The other vaccines that Katie received–specifically, the varicella, HIB and pneumococcal conjugate vaccines–do not have associated injuries that are listed on the Vaccine Injury Table.

Listed on the Table as a "covered" injury that is afforded a presumption of vaccine-related causation is an "encephalopathy" that occurs within seventy-two hours after receipt of a DTaP vaccine. 42 C.F.R. § 100.3(a)(II)(B). The Table defines an encephalopathy in a vaccinee who is less than eighteen months of age as "a significantly decreased level of consciousness persist[ing] beyond 24 hours that cannot be attributed to a postictal state (seizure) or medication." 42 C.F.R. § 100.3(b)(2)(i)(A). The Table also addresses how seizures should be viewed when evaluating whether an encephalopathy has occurred. The Table states:

> Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

42 C.F.R. § 100.3(b)(2)(i)(E).

In this case, Katie was four months of age when she experienced her first seizure episode. But, petitioners do not allege that Katie suffered an encephalopathy, the Table injury afforded a presumption of causation based on the timing between Katie's receipt of the DTaP vaccine and the first symptoms of her seizure condition. Nor does the testimony of Mrs. Nance, the testimony of the parties' expert witnesses, or Katie's medical records support a finding that Katie suffered an encephalopathy as defined by the

Vaccine Injury Table. Accordingly, petitioners must prove that Katie's first seizure and subsequent seizure disorder was caused-in-fact by her November 12, 2003 vaccinations.

2. An Off-Table Injury

A claim for which causation is not presumed under the Act, such as petitioners' claim in this case, is known as an "off-Table" case. To demonstrate entitlement to compensation in an off-Table case, petitioners must demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii)(I) and (II). Petitioners satisfy their burden by demonstrating: "(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 the vaccination and injury." Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

A persuasive medical theory offers "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Hines v. Sec'y of Health and Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991) (citations omitted); Knudsen v. Sec'y of Health and Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994) (same); Grant v. Sec'y of Health and Human Servs., 956 F.2d 1144, 1148 (same). A logical sequence of cause and effect may be supported by "[a] reputable medical or scientific explanation" that petitioner may offer "in the form of scientific studies or expert medical testimony." Grant, 956 F.2d at 1148. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1988 U.S.C.C.A.N. 6344, 6356.

While the support of reputable and reliable evidence is needed to prevail on a vaccine claim, the Federal Rules of Evidence do not apply in Program proceedings. See 42 U.S.C. § 300aa-12(d)(2)(B) (stating that the Vaccine Rules "shall . . . include flexible and informal standards of admissibility of evidence"); Vaccine Rule 8(b), Rules of the Court of Federal Claims, Appendix B ("In receiving evidence, the special master will not be bound by common law or statutory rules of evidence."). Hines v. Sec'y of Health and Human Servs., 940 F.2d 1518, 1525-6 (Fed. Cir. 1991). The United States Court of Federal Claims has stated, however, that in vaccine cases, the Supreme Court's decision in "Daubert[v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993)] is useful in providing a framework for evaluating the reliability of scientific evidence." Terran v. Sec'y of Health and Human Servs., 41 Fed. Cl. 330, 336 (1998), aff'd, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). In Daubert, the Supreme Court noted that scientific knowledge "connotes more than subjective belief or unsupported speculation." Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate an expert's opinion. Id. An expert's "testimony must be supported by appropriate validation . . . based on what is

known." Id. More recently, the Federal Circuit observed that "[a]lthough a Vaccine Act claimant is not required to present proof of causation to the level of scientific certainty, the special master is entitled to require some indicia of reliability to support the assertion of the expert witness." Moberly v. Sec'y of Health and Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010) (internal citations omitted).

Petitioners need not show that the vaccine was the sole or even the predominant cause of the injury. See Shyface v. Sec'y of Health and Human Servs., 165 F.3d 1344, 1353 (Fed. Cir. 1999). But petitioners bear the burden of establishing "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Id. at 1352; see also Pafford v. Sec'y of Health and Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006) (reiterating that petitioner must prove by preponderant evidence both that the received vaccination was a substantial factor in causing her injury and that the harm would not have occurred in the absence of the vaccination). Petitioners do not satisfy their burden by the mere showing of a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating "inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation")).

The Federal Circuit has stated that there is no requirement in the Vaccine Act's preponderant evidence standard that petitioners submit particular types of evidence as "objective confirmation" to support their theory of causation. Althen, 418 F.3d at 1279. The Court of Appeals for the Federal Circuit has explained that requiring particular types of evidence "prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of the injured claimants." Id. at 1280 (citing Knudsen, 35 F.3d at 549); see also Capizzano v. Secretary of Health and Human Services, 440 F.3d 1317, 1325 (Fed. Cir. 2006) (denouncing the requirement of "either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect"). The expressed "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." Id. at 1324.

Importantly, the decisions of the Federal Circuit do not preclude special masters from considering presented medical literature when evaluating expert testimony. Rather, the Federal Circuit has reiterated recently that Vaccine Rule 8, like the Vaccine Act, "directs [a] special master to consider all relevant and reliable evidence," including "all . . . relevant medical and scientific evidence." Hazlehurst v. Sec'y of Health and Human Servs., --F.3d --, 2010 WL 1904914 (Fed. Cir. May 13, 2010) (quoting 42 U.S.C. §

300aa-13(b)(1) and Vaccine R. 8(b)(1) (2009)). Such evidence is not to be evaluated "through the lens of the laboratorian" seeking scientific certainty, but in accordance with the Vaccine Act's preponderant evidence standard. See Andreu v. Sec'y of Health and Human Servs., 569 F.3d 1367, 1380 (Fed. Cir. 2009). "Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and . . . special masters have that responsibility in Vaccine Act cases. Moberly, 592 F.3d at 1325 (internal citations omitted).

B. The Opinions of Causation Offered by the Parties' Experts

1. The Opinion of Petitioners' Expert

As briefly described earlier, petitioners offered the expert opinion of Thomas Schweller, M.D. a neurologist. See Ps' Ex. 13. Board-certified in pediatrics, neurology, and electroencephalography,[7] Dr. Schweller maintains a private practice in San Diego, California. See Tr. at 51, 67. During the course of a week, he sees approximately three to five pediatric patients. Id. at 68. He estimates that approximately ten percent of his time is spent in a consultative capacity seeing children with previously diagnosed neurological disorders. Id. at 52. The balance of Dr. Schweller's time is spent examining patients with work-related injuries and performing evaluations for Social Security determinations. Id. The undersigned found Dr. Schweller to be a qualified witness and candidly responsive to the questions asked of him.

Dr. Schweller filed two expert reports in this case. In his initial expert opinion, Dr. Schweller focused on Katie's DTaP vaccination. Ps' Ex. 12 at 2. He opined that if the pertussis component of the DTaP vaccine were able to penetrate Katie's blood-brain barrier, then the pertussis toxin could damage the brain, by binding to neuro-transmitting proteins in the brain and causing interference with the cellular-signaling process. Ps' Ex. 12 at 2. The consequence of this sequence of events would be the creation of a seizure focus that could lead to the development of epilepsy. Id. According to Dr. Schweller, Katie's first seizure occurred within an appropriate time frame after vaccination to suggest that the DTaP vaccine "played a role" in the onset of Katie's seizure disorder. Id. Dr. Schweller opined that Katie's DTaP vaccination was, more likely than not, the cause of her current seizure disorder. Id.

Upon review of Dr. Schweller's expert opinion, the undersigned conducted a status conference with counsel. See Order of October 4, 2007. The undersigned inquired how petitioners' claim that an administered DTaP vaccine caused an ongoing seizure condition in the absence of a fever could be distinguished from the numerous cases in which

[7] Encephalography is a film record of the fluid-containing intracranial spaces after removal of cerebrospinal fluid and introduction of air or other gas. Dorland's at 609.

compensation has been denied for claims involving claim similar to the one advanced here–specifically, that an administered DTaP vaccine caused afebrile seizures. See, e.g., Karapetian v. Sec'y of Health and Human Servs., No. 06-783V, 2009 WL 1490586 (Fed. Cl. Spec. Mstr. May 8, 2009) (denying compensation where petitioner alleged DTaP alone or in combination with IPV and Comvax caused encephalopathy, subsequent seizures, hearing impairment, and speech and language disabilities); Christian v. Sec'y of Health and Human Servs., No. 03-1169V, 2004 WL 2059491, *9 (Fed. Cl. Spec. Mstr. Aug. 31, 2004) (in which the special master denied compensation for a claim that a DTaP vaccine led to afebrile seizures, and the special master observed that she had "held repeatedly in other cases that DPT (much less DPaT) does not cause afebrile seizures, based on the National Childhood Encephalopathy Study, the Institute of Medicine (IOM), and other literature"); Nanez v. Sec'y of Health and Human Servs., No. 02-1261V, 2003 WL 22434113 (Fed. Cl. Spec. Mstr. Sept. 23, 2003) (dismissing petition where petitioner alleged that DTaP caused afebrile seizures. In contradistinction to the facts presented in the instant case, cases involving the occurrence of febrile seizures within a period of time after the administration of the DTaP vaccine have been compensated. See Sucher v. Sec'y of Health and Human Servs., No. 07-0058V, 2010 WL 1370627 (Fed. Cl. Spec. Mstr. Mar. 15, 2010) (compensating where genetic predisposition did not supersede DTaP vaccine as cause of a febrile seizure and a subsequent seizure disorder); Teller v. Sec'y of Health and Human Servs., No. 06-840V, 2009 WL 255622 (Fed. Cl. Spec. Mstr. Jan. 13, 2009) (compensating where DTaP vaccine caused a febrile seizure and seizure disorder); Bell v. Sec'y of Health and Human Servs., No. 04-1038V, 2008 WL 2345947 (Fed. Cl. Spec. Mstr. May 20, 2008) (finding entitlement where DTaP vaccine claimed to have caused a febrile seizure and seizure disorder); Deribeaux v. Sec'y of Health and Human Servs., No. 05-306V, 2007 WL 4623461 (Fed. Cl. Spec. Mstr. Dec. 17, 2007) (finding entitlement where DTaP and HIB vaccines triggered a febrile seizure, and in turn, a subsequent seizure disorder and developmental delay); Mersburgh v. Sec'y of Health and Human Servs., No. 04-997V, 2007 WL 5160384 (Fed. Cl. Spec. Mstr. July 9, 2007) (awarding compensation where a DTaP vaccine led to febrile seizures, subsequent seizure disorder, and developmental delay); Simon v. Sec'y of Health and Human Servs., No. 05-941V, 2007 WL 1772062 (Fed. Cl. Spec. Mstr. June 1, 2007) (compensating a Program claim that a DTaP vaccine caused a febrile seizure, subsequent epilepsy, and death); Armstrong v. Sec'y of Health and Human Servs., No. 04-242V, 2005 WL 6117664 (Fed. Cl. Spec. Mstr. May 13, 2005) (finding entitlement for a claim that a DTaP vaccine caused a febrile seizure and a subsequent seizure disorder). But see Stone v. Sec'y of Health and Human Servs., No. 04-1041V, 2010 WL 1848220 (Fed. Cl. Spec. Mstr. Apr. 15, 2010), appeal docketed, No. 04-1041V (Ct. Fed. Cl. May 17, 2010) (denying compensation and finding febrile seizures and severe myoclonic epilepsy following DTaP vaccination were caused by a SCN1A genetic mutation). While the undersigned noted that the opinions of other special masters are not binding authority, the undersigned observed that she has found persuasive those opinions denying Program compensation for vaccine claims alleging that afebrile seizures occurred after receipt of a DTaP vaccine. See

Hanlon v. Sec'y of Health and Human Servs., 40 Fed. Cl. 625, 630 (1998) (stating that decisions issued by special masters and the judges of the Court of Federal Claims may constitute persuasive, but not binding authority).

After the conduct of that status conference, petitioners' expert filed a supplemental opinion of causation and a number of medical articles. See Ps' Ex. 17-22, Ps' Ex. 24. In his supplemental expert report, he posited that of the "multiple" vaccinations that Katie received on November 12, 2003, the Prevnar and DTaP vaccinations, in particular, were likely to have had a role in causing Katie's seizure disorder. Ps' Ex. 17 at 2. At hearing, however, he testified that he had changed his earlier position and that he "just [did not] know" whether the administered DTaP vaccine played any role in the onset of Katie's first seizure event which was noted to have been an afebrile one. See Tr. at 99-100. Dr. Schweller then offered a revised theory of Prevnar-related causation based on the findings contained in and the views expressed in the articles filed by petitioners.

Dr. Schweller's opinion that the administered Prevnar vaccine likely cause Katie's initial seizure event was based, in part, on the reports of both febrile and afebrile seizures–among other adverse events reported to the Vaccine Adverse Event Reporting System (VAERS)–that were detailed in the 2004 Wise study of postlicensure safety surveillance for 7-valent pneumococcal conjugate vaccine which was filed as Ps' Ex. 18 in this case.[8] Prevnar is a trade name for 7-valent pneumococcal conjugate vaccine, P's Ex. 18 at 1702 (using internal pagination), and VAERS is a database that has been operated jointly by the Food and Drug Administration and the Centers for Disease Control and Prevention since 1990. Ps' Ex. 18 at 1703. VAERS is a passive surveillance system that accepts "voluntarily submitted reports of events from manufacturers, health care workers and patients." Id. Typically, the experiences reported to VAERS are unsolicited and reflect a "concern or suspicion of a possible relationship to 1 or more vaccine products." Id. When questioned about his reliance on reported VAERS data in forming his opinion, Dr. Schweller admitted that the reports merely reflect "potential adverse reaction[s]," and he acknowledged that no requirement for medical verification attaches to events reported to VAERS. See Tr. at 105-106.

In addition to noting that VAERS reporting did not require any medical verification, Dr. Schweller acknowledged at hearing that a child could present with seizures without being encephalopathic. Tr. at 91-92, 97. Prior to hearing, Dr. Schweller stated in his supplemental expert report that Katie's first seizure was "not an atypical benign seizure" because, in his view, her seizure lasted between ten and thirty minutes–a time period that is longer than the typical febrile seizure. Ps' Ex. 17 at 3. Dr. Schweller

[8] See R. Wise et al., Postlicensure safety surveillance for 7-valent pneumococcal conjugate vaccine, JAMA Vol. 292, No. 14, pp. 1702-1710 (2004).

further stated that he was persuaded that Katie's pallor, increased period of sleep, and poor appetite as well as her second seizure on November 20, 2003 were consistent with an "encephalopathic process . . . triggered by the combination of immunizations." Id. He added that in circumstances–similar to the instant one–in which an encephalopathic process results from changes in the immune system, a patient need not demonstrate a fever. Id.

At hearing, however, Dr. Schweller conceded that in assessing the length of Katie's seizure, he included in his calculus both the ictal state and post-ictal state, that is, the states that respectively precede and follow a frank seizure event. See Tr. at 87. Dr. Schweller also conceded that Katie's particular presentation on arrival at the hospital after her first seizure episode–which was noted to have included an alert and oriented state accompanied by cooing and smiling–was not consistent with an encephalopathic condition, whether defined broadly or in the context of the Vaccine Injury Table. Tr. at 91-92, 97.

Dr. Schweller addressed further at hearing the other bases for his opinion of vaccine-related causation. Among the matters informing Dr. Schweller's opinion of vaccine-related causation in this case were the results of a retrospective study of children with seizure disorders in Singapore. As detailed in the 2004 Lee and Ong article,[9] filed as Ps' Ex. 21, researchers compared three types of children with seizure disorders, specifically: (1) children who had experienced "febrile" seizures (that is, seizures associated with an illness causing a fever); (2) children who had experienced "provoked" seizures (that is, seizures occurring without a fever but in association with an infection); and (3) children who had experienced "unprovoked" seizures (that is, seizures occurring in the absence of either a fever or an infectious illness). Ps' Ex. 21 at 157-158. Finding that all of the patients "with provoked seizures manifested symptoms and signs of infection such as cough, coryza[–a symptom more commonly known as a runny nose], vomiting, diarrhea, or fever," id. at 159, the researchers noted the possibility of an association between infection and the presentation of an afebrile seizure. Id. at 162.

In another article filed by petitioners, other researchers confirmed the results of 2004 Lee and Ong study through a retrospective study of children diagnosed with seizures at a pediatric hospital in Seattle, Washington. See Ps' Ex. 19 at 952-953 (D. Zerr et al., Nonfebrile illness seizures: a unique seizure category?, Epilepsia, Vol. 26, No. 6:952-955 (June 2005)). The researchers reported in the 2005 Zerr article that the evaluated data "demonstrate[d] an association between diarrheal illness and nonfebrile illness seizures." Id. at 954. Although Dr. Schweller relied on these two articles–specifically, the 2004 Lee and Ong article and the 2005 Zerr article–in developing his opinion, he conceded that

[9] W. Lee & H. Ong, Afebrile seizures associated with minor infections: comparison with febrile seizures and unprovoked seizures, Pediatr. Neurol., Vol. 31, No. 3, pp. 157-164 (Sept. 2004).

there was no evidence that Katie had an infection prior to her initial seizure event.[10] See Tr. at 97-98.

Dr. Schweller also derived support for his opinion of vaccine-related causation from a letter to the editor, filed as Ps' Ex. 20,[11] addressing the 2004 Lee and Ong article on which Dr. Schweller relied. As stated in the letter to the editor, a group of Iranian researchers led by Dr. Mohammad Mohebbi expressed interest in the findings of the 2004 Lee and Ong study, but noted that "the delineation between febrile seizures and provoked afebrile seizures with illnesses appear[ed] elusive, inexact, and somewhat arbitrary." Ps' Ex. 20 at 291. Noting that the fever associated with an infection is a consequence of a change in the levels of the cytokine interleukin-1 beta, the Mohebbi group of researchers queried "whether the fever, the cytokines, the infectious agent, or another substance" might be among the causal factors provoking seizures–that occur with or without a measurable fever–in mildly ill children. Id.

Based on his reading of the filed articles and the 2005 Mohebbi editorial, Dr. Schweller posited that "the release of [the] cytokine interleukin-1 beta in the course of the immune response" to a minor infectious agent (as manifested by such symptoms as a runny nose, cough, vomiting or diarrhea) could, in turn, trigger a cluster of afebrile convulsions or seizures. See Ps' Ex. 17 at 2. Dr. Schweller speculated that the DTaP and Prevnar vaccines administered to Katie similarly could lead to the release of those same cytokines that were part of the immune response to the minor infections (noted in the literature to bear an association with afebrile seizure events) and similarly could provoke an afebrile seizure event. Tr. at 129; see also Ps' Ex. 17 at 2 (Dr. Schweller stating that "the implication of the[] [referenced] studies is that [an] immune response triggered by the cluster of immunizations, whether it be the DTaP or the Prevnar vaccinations, both of which could trigger the release of interleukin-1 beta, should also be able to trigger seizures without fever"). In Dr. Schweller's opinion, any of the vaccines that were administered to Katie on November 12, 2003 was capable of triggering an immune response, specifically the release of the particular cytokine interleukin-1 beta, and in turn may have caused Katie

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[10] Additional support for the proposition that afebrile seizures have been observed to occur in the context of diarrheal illnesses, in particular, was provided by the 2004 Narchi article filed as Ps' Ex. 22. The full citation for the article is H. Narchi, Benign afebrile cluster convulsions with gastroenteritis: an observational study, BMC Pediatr. Vol. 4 (2005). As the researchers reported in the 2004 Narchi article, a three-year study of 14 British children showed an association between gastroenteritis and afebrile seizures, a finding noted by the researchers to be consistent with findings reported in other studies of afebrile seizures occurring in the context of mild infectious illnesses. Ps' Ex. 22 at 2, 4.

[11] See M. Mohebbi & K. Holden, Febrile and afebrile or provoked and unprovoked seizures?, Pediatr. Neurol., Vol. 32, No. 4, p. 291 (April 2005).

to suffer an afebrile seizure within 48 hours after she received her four-month vaccinations. Tr. at 122; see also Ps' Ex. 19; Ps' Ex. 21.

2. Respondent's Expert's Opinion

In refutation of petitioners' theory, respondent offered the expert opinion of John MacDonald, M.D., a pediatric neurologist. See Tr. at 131. Board-certified in neurology, Dr. MacDonald is a faculty member teaching pediatric neurology three days a week at the University of Minnesota. Id. at 132, 133. Two days a week, he sees patients in his private practice. Id. And one week a month, Dr. MacDonald performs rounds at inpatient services at the University of Minnesota's Medical Center. Id. Engaged in a full-time pediatric neurology practice, Dr. MacDonald has experience diagnosing and treating children with seizure disorders, including children–who like Katie–have had seizures events when less than one year of age. Id. at 134-135. He also has experience diagnosing and treating children who have suffered an encephalopathy. Id. at 136. Dr. MacDonald was a forthright and qualified witness.

Dr. MacDonald opined that Katie suffered from genetically-based, "generalized epilepsy." R's Ex. A at 3. He stated that the standard definition of epilepsy is the occurrence of "two unprovoked seizures over a period of time," Tr. at 135, and he explained that seizures in young children under one year of age "are typically either very brief– . . . [only] one or two minute seizures–or the more prolonged ones, which are 10 or 15 minutes." Id. at 139. Because there was no evidence that Katie had an infectious illness, because there were no significant findings on the brain studies and EEG performed after Katie's first seizure, and because the hospital records upon Katie's admission show no evidence of weight loss due to vomiting or dehydration, but rather make note of Katie's state of alertness, Dr. MacDonald concluded that Katie's first seizure event ended "quickly" and that she did not experience an acute encephalopathy as a result of her vaccinations. R's Ex. A at 3; Tr. at 141.

In response to the supplemental expert report filed by petitioners' expert, Dr. MacDonald reiterated his view that the emergency room physicians' notations gave no indication that Katie condition after her initial seizure event was encephalopathic. R's Ex. C at 1. He opined that Katie most likely suffered an uncomplicated, benign seizure after she had received her four-month vaccinations. Id.

Dr. MacDonald was not persuaded that the literature filed by petitioners supported Dr. Schweller's theory that a vaccine-related release of cytokines led to an immune system response that triggered Katie's seizure. Id. at 2-3. Dr. MacDonald pointed out that the 2005 Zerr article–on which Dr. Schweller relied as support for his offered cytokine-release theory–did not involve the study of cytokines. Id. at 2. Dr. MacDonald also pointed to the researchers' acknowledgment in the 2005 Zerr article that the occurrence of an afebrile

seizure in the context of an intercurrent illness may reflect a coincidental occurrence rather than a seizure event that was "provoked" in some manner by the illness. Id.

Dr. MacDonald further noted that in response to the 2005 Mohebbi editorial–on which Dr. Schweller placed significant reliance because the Mohebbi researchers openly speculated about the role that both cytokines and infectious agents play in causing afebrile seizures–the authors of the 2004 Lee & Ong article that first caught the attention of the Mohebbi researchers also sent a letter to the editor. The 2005 Lee and Ong editorial response appeared in the same publication as did the 2004 Mohebbi editorial and appeared immediately following the 2004 Mohebbi editorial. In their responsive letter to the editor, Drs. Lee and Ong explained that in their "original" submission, they too had "speculated" that cytokines played a role in provoked seizures (afebrile seizures occurring in the context of an intercurrent illness) and possibly played a role in febrile seizures as well. Ps' Ex. 20 at 292. But Drs. Lee and Ong deleted their comments regarding a possible association from their submitted article based on the recommendation of a reviewer who thought the comments regarding a possible association were "too speculative and [were] well beyond the data in the paper." R's Ex. C at 2.

While acknowledging that "vaccinations can cause a high fever" that in turn, could "cause a seizure," Tr. at 156, Dr. MacDonald asserted that associating Katie's received vaccine with her afebrile seizure "would be pure speculation." Id. at 147.

C. Evaluating the Presented Evidence

Having reviewed the experts' respective reports and having heard the testimony of the experts at hearing, the undersigned turns now to evaluate the presented evidence under the standard set forth in Althen v. Secretary of Health and Human Services, 418 F.3d 1274 (Fed. Cir. 2005). In accordance with the Federal Circuit's guidance in Althen, the undersigned must consider whether petitioners have demonstrated: "(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 the vaccination and injury." Id. at 1278.

It is the view of the undersigned that in this case, the first Althen prong is dispositive. Petitioners have presented, by their expert's own admission, a speculative medical theory linking Katie's received vaccines to her afebrile seizure event. After revising his initial opinion of causation, Dr. Schweller offered an opinion that the received Prevnar vaccine as well as the other vaccines that Katie received were the responsible triggers for the cytokine release that ultimately led to her seizure disorder. Tr. at 58. In forming this opinion, Dr. Schweller analogized the effect of having a mild infection to the effect of receiving vaccines. He then hypothesized that the triggered immune response from both sources–whether an infectious agent or an administered vaccine–could stimulate

the release of interleukin 1-beta cytokines that, in turn, could cause afebrile seizures. The difficulty, however, with Dr. Schweller's theory is the underlying series of admittedly speculative premises on which he based his theory.

As a threshold matter, Dr. Schweller relied on reports submitted to the passive surveillance system VAERS as support for the proposition that both febrile and afebrile seizures are causally associated with the receipt of the Prevnar vaccine. Dr. Schweller readily acknowledged, however, that such reports could be submitted without any medical verification and thus, at best, reflected the mere suspicion of an association. Analla v. Sec'y of Dept. of Health and Human Servs., 70 Fed. Cl. 552, 558 (2006) (citing cases and indicating "concerns about the reliability of VAERS data").

As further support for the theory petitioners offered, Dr. Schweller relied on a few articles that considered only whether a causal link might exist between a mild intercurrent illness and an afebrile seizure event. Dr. Schweller sought to bolster this opinion of vaccine-related causation by also relying on a letter to the editor that questioned whether the change in cytokine levels that occurs during a mild infection might trigger the onset of seizures, both febrile and afebrile. Dr. Schweller then posited that similar to mild infections, administered vaccines could cause changes in cytokine levels that trigger seizures as well.

Each of the respective premises of Dr. Schweller's opinion as well as the sum of the premises is speculative and falls short of the more likely than not evidentiary standard that petitioners must meet.

As required in Vaccine cases, Dr. Schweller has advanced what appears to be a biologically plausible medical theory, and the sum of the sources on which Dr. Schweller relied–if construed as Dr. Schweller urges–appear to be supportive of his theory. But petitioners have failed to show that the support offered for Dr. Schweller's theory is reliable. The principal support for Dr. Schweller's opinion is his own interpretation of editorial letters and a summary of VAERS reports, an interpretation that generated the theory of causation that he ultimately set forth on petitioners' behalf. Dr. Schweller acknowledged over the course of the proceedings a change in his position. He first attributed the development of Katie's seizures to the DTaP vaccine. He then attributed her condition to her receipt of the Prevnar vaccine, and finally he implicated all of the vaccines that Katie received at four months of age as possible factors causing Katie's disorder. He explained at hearing that this change in position resulted from his changing his mind. See Tr. at 99-100. The changes in Dr. Schweller's opinion of causation–without more explanation than he simply had a change of mind–diminishes considerably the evidentiary weight that the undersigned can accord Dr. Schweller's opinion.

Although the hearing in this case was conducted prior to the Federal Circuit's issuance of its decision in Moberly v. Secretary of Health and Human Services, 592 F.3d 1315 (Fed. Cir. 2010), the Federal Circuit's guidance in Moberly underscores the shortcomings of petitioners' presented claim in this case. In Moberly, petitioners asserted that an administered DTaP vaccine caused afebrile seizures. As in this case, the special master in Moberly found the opinion of petitioners' expert wanting. On appeal, the Federal Circuit stated in Moberly that a special master is entitled "to require some indicia of reliability to support the assertion of the expert witness." Moberly, 592 F.3d at 1324.

The conduct of the hearing in this case also preceded the issuance of the Federal Circuit's decision in Andreu, another case involving a claim that an administered DTaP vaccine caused a seizure disorder. This case is distinguishable, however, from the Andreu case. In this case, petitioners' expert conceded the speculative nature of the opinion that he offered, and he acknowledged that his opinion was based on his own extrapolation from the filed articles. The Supreme Court observed in General Electric Company v. Joiner, 522 U.S. 136, 147 (1997) that while "[t]rained experts commonly extrapolate from existing data," a court properly may conclude that the analytical gap between the data and the opinion proffered is "simply too great" in a circumstance in which the offered "opinion evidence . . . is connected to existing data only by the ipse dixit of the expert." In such circumstance in which the reliability of the offered opinion is called into question, the trier of fact may exclude such evidence under the Federal Rules of Evidence. See id. at 146-147. In vaccine cases, however, the Federal Rules of Evidence do not apply, see Vaccine Rule 8(b)(1), and rather than exclude unreliable evidence, special masters accord little, if any, weight to offered evidence that is unreliable.

In this case, Dr. Schweller admitted at hearing that he relied on his own speculative interpretation of the filed materials as the chief support for his offered theory of causation. Moreover, Dr. Schweller forthrightly acknowledged that he interpreted the materials filed by petitioner to propose merely a possible or theoretical–rather than a more likely than not–causal association between the vaccines administered to Katie and her seizure disorder. See Tr. at 115-116. Having conceded the limitations of his own testimony, the undersigned cannot accord greater weight to Dr. Schweller's offered opinion than did he.

Petitioners have not shown either that Dr. Schweller's theory is a reliable one or that his offered theory satisfies the applicable preponderant evidence standard that requires a showing that the vaccine "more likely than not" can cause the alleged injury. See Althen, 418 F.3d at 1278; see also Moberly, 592 F.3d at 1322, 1324 (noting that a question existed regarding whether the theory advanced by petitioners' expert was reliable and finding no error in the dismissal of petitioners' claim based on the concession of petitioners' expert that no evidence existed in that case that the proposed mechanism was at work). Petitioners here have failed to carry their burden under Prong 1 of the Althen standard, and this failure is dispositive. Petitioners's vaccine claim must fail.

C. Conclusion

Petitioners have failed to prove that they are entitled to compensation under the Vaccine Program. The petition for compensation **SHALL BE DISMISSED** and the Clerk of the Court shall enter judgment consistent with this decision.[12]

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
Patricia E. Campbell-Smith
Special Master

[12] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of notice renouncing the right to seek review.