In the United States Court of Federal Claims

No. 03-2190V
(Filed Under Seal December 8, 2005)[1]
(Reissued: December 30, 2005)

ERIKA PAULMINO, by Her Father and Next Friend, ALAN PAULMINO,	*	**National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-1 et seq.; Causation in Fact; Burden of Proof; Prima Facie Case; Medical Evidence; Remand.**
Petitioner,	*	
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald Craig Homer and Kevin P. Conway, Conway, Homer & Chin-Caplan, P.C., Boston, MA, for Plaintiff.

Althea Walker Davis, U.S. Department of Justice, Torts Branch, Civil Division, Washington, D.C., for Defendant.

OPINION AND ORDER

Petitioner, Alan Paulmino, acting on behalf of his daughter, seeks review of the Special Master's denial of compensation under the National Childhood Vaccine Injury Act for an injury allegedly resulting from a diptheria-tetanus-acellular pertussis (DTaP) vaccine. Petitioner claims that his daughter, Erika, suffered a 20-minute seizure and respiratory arrest on September 23, 2000, at the age of six months, as the result of receiving a DTaP, and that this initial seizure caused a

[1] This opinion was issued under seal on December 8, 2005. The Court invited the parties to submit proposed redactions by December 23, 2005. No redactions having been received, the Court publishes this opinion in toto.

permanent neurological disorder, including intractable seizures and profound developmental delay.[2]

The Special Master found that Petitioner had failed to establish that the vaccine caused Erika's injury because Petitioner did not eliminate a possible alternative cause. Specifically, the Special Master concluded that Erika had an upper respiratory infection (URI) 24 to 48 hours prior to her initial seizure and that the URI could have been an independent cause of her seizure. However, neither the factual record nor any expert opinion supports the Special Master's sua sponte finding that the URI was a "possible alternative cause" of Erika's seizure. Further, the Special Master erroneously concluded that Petitioner had not met his burden of proving the elimination of an alternative cause of injury and never shifted the burden to demonstrate alternative causation to the Government, as required under the Vaccine Act. 42 U.S.C. § 300aa-13(a).

The Special Master also determined that even if the DTaP had caused Erika's initial seizure, Petitioner had not demonstrated by a preponderance of the evidence that her permanent developmental disorder was a sequella to that initial seizure. Although Petitioner's expert opined that the DTaP vaccine caused the permanent condition, the Special Master found the supporting medical literature insufficient to establish causation as to the sequella. However, the United States Court of Appeals for the Federal Circuit in Althen v. United States, 418 F.3d 1274 (Fed. Cir. 2005) has since clarified that the Vaccine Act does not require a petitioner to provide confirmation of medical plausibility from the medical community and literature, or to demonstrate that the specific injury is recognized by medical documentation of plausibility.[3]

Because the Special Master erred in finding the URI to be an alternative cause of Erika's injury, failed to allocate the burden of proof in the manner set forth in the Vaccine Act, and applied a more stringent standard for medical evidence than adopted in Althen, the decision denying compensation is set aside and remanded for further proceedings consistent with this opinion.

Factual Background

Erika's Medical History

Erika was born on March 14, 2000. Pet. Ex. 3. On September 22, 2000, Erika had a "wellness" appointment with her pediatrician, during which she received her third DTaP and Hemophilus Influenzae Type B vaccinations and her first Prevnar vaccination. Pet. Ex. 3 at 7 and

[2] The parties agree that this is not a Table injury within 42 U.S.C. § 300aa-14(a).

[3] The Federal Circuit in Althen expressly struck down two of the five prongs required for proving causation-in-fact articulated by the Special Master in Stevens v. Sec'y of HHS, 2000 WL 387418, the "confirmation of medical plausibility from the medical community and literature" and "an injury recognized by the medical plausibility evidence and literature." Althen, 418 F.3d at 1279-81. The Court found that both of these requirements contravened the plain language of the Vaccine Act.

4 at 6-7. Prior to this appointment, Erika's medical history was uneventful. Pet. Ex. 4.

On September 23, 2000, within some 24 hours after receiving these vaccines, Erika felt warm to her mother's touch. Pet. Ex. 20 at 2. Her father took her temperature, and she had a fever of 100.5 degrees. Id. Shortly thereafter, Erika's left eye and then her left hand started to twitch. Id. Erika suffered a twenty-minute seizure and respiratory arrest and was taken by ambulance to St. Mary's Hospital in Hoboken, New Jersey. Pet. Ex. 3. Upon arrival, the triage nurse noted that Erika had a blank stare, was floppy and had no response to painful stimuli. Pet. Ex. 3 at 36. In addition, severe substernal retractions were observed, and her heart rhythm was a tachycardia with a rate of 180-200. Id. at 37. Minutes later, her oxygenation level was noted to be 81%. She was in respiratory distress. Id. Three hours later, she was intubated by an anesthesiologist. At that time, her temperature was recorded rectally as 101.2 degrees. Id. at 36-37. She was noted to have vomiting, twitching of her upper extremities, and rolling of the eyeballs, and she was found to be unresponsive and staring with slowly reactive pupils. Her diagnosis included respiratory failure, respiratory acidosis, and seizures. Id.

Later that day, Erika was transferred to the Jersey City Medical Center, where she was hospitalized for three days. Pet. Ex. 3 at 32. On September 24, 2000, the treating physician there noted that Erika had a fever prior to her seizure and referenced an upper respiratory infection.[4] Pet. Ex. 6 at 12, 14; Tr. at 9-11.[5] On September 26, 2000, Erika was released from the hospital with a diagnosis of atypical febrile seizures and macrocephaly. Pet. Ex. 6 at 17.

On November 28, 2000, Erika was taken for examination to a pediatric neurologist. Pet. Ex. 5. The doctor noted that Erika had suffered seizures after her 6-month vaccinations, decided not to give Erika her fourth DTaP, and gave her only the DT. Pet. Ex. 5.

On December 5, 2000, Erika suffered another prolonged seizure, lasting approximately 30 minutes. Pet. Ex. 11 at 34. She was taken by ambulance to the Bon Secours Venice Hospital. Pet. Ex. 11. According to the Emergency Medical Services (EMS) report, at the time of this seizure, Erika had a fever of 100.5 degrees. Id. The next day, December 6, 2000, Erika suffered another seizure and was again taken by ambulance to the Bon Secours. Id. At the hospital it was determined that she had a fever of 99.7 degrees. Id. She was transferred that day to the All Children's Hospital in Saint Petersburg, Florida and placed in the pediatric intensive care unit. Pet. Ex. 8 at 65. At All Children's, she was given an EEG which was "abnormal," diagnosed with "complex febrile seizures" and prescribed Ativan and, later, Phenobarbital. Pet. Ex. 8 at 1-2, 17, 19.

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[4] The parties dispute how this medical record ought to be interpreted with respect to when Erika had the URI. The Special Master construed the treating physician's note to mean that Erika had a URI at the time she received her DTaP. This Court has been unable to find support for this finding in this medical record or elsewhere in the record. The Special Master did not conduct an evidentiary hearing and did not obtain clarification of this record.

[5] References to the transcript are to the September 29, 2005 oral argument.

Over the next nine months, beginning on Jan. 30, 2001, Erika had multiple seizures and was repeatedly taken to All Children's Hospital where she was treated by Dr. Lisa Brunton, a neurologist. Pet. Ex. 8. She suffered seizures in February which were not accompanied by fever. Id. at 17-19. On May 7, 2001, Dr. Brunton noted that:

> [Erika's] most recent seizure occurred yesterday. She averages approximately two per month since February . . . IMPRESSION: Seizures, which occur with illness or fever.

Pet. Ex. 8 at 67-68.

On August 21, 2001, Erika suffered from a seizure which lasted 30 minutes, and on August 24, 2001, after another neurological examination, Dr. Brunton reported:

> She continues to have seizures that are afebrile, despite being on Phenobarbital 10 cc. BID . . . developmentally, she is making progress. . . . IMPRESSION: Mixed seizure disorder, including absence, complex and focal seizures.

Pet. Ex. 8, at 95-96. On September 20, 2001, Dr. Brunton noted that Erika had a history of seizures "both febrile and afebrile." Pet. Ex. 8 at 129.

On November 20, 2001, after suffering from multiple seizures, Erika was admitted to the hospital. Her diagnosis was an "acute exacerbation of seizure disorder, most likely secondary to intercurrent illness." Pet. Ex. 8 at 167. On December 4, 2001, Erika was examined at St. Petersburg Pediatrics and was determined to be suffering from "developmental delay." Pet. Ex. 7 at 13. At a follow-up examination on December 11, 2001, Erika was determined to be in a state of "developmental regression." Id. at 11. On January 31, 2002, Erika was examined by an early intervention team at All Children's Hospital. Pet. Ex. 9. The examination revealed that Erika had delayed receptive and expressive language skills, cognitive skills and motor skills. Pet. Ex. 9 at 28-29. On May 8, 2002, she was diagnosed with "[i]ntractable epilepsy." Pet. Ex. 9 at 19.

In an October 23, 2002, evaluation by Dr. Elaine Wyllie, a neurologist, Erika's history was described as follows:

> Seizures began at five months of age . . . [t]he first seizure occurred one day after immunizations, in the setting of fever. This was a generalized tonic-clonic [seizure] . . . [a]t 8 months of age she had her first afebrile seizure. Seizures have been refractory to medication since then. . . . IMPRESSION:
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> > Erika has medically refractory seizures and delayed cognitive development.

Pet. Ex. 12 at 1-3. Dr. Wyllie found the underlying etiology of the epilepsy and developmental delay to be not entirely clear. Id.

On May 18, 2004, Erika was described as: A four-year old female with intractable epilepsy, PDD [persuasive developmental delay] . . . ." Pet. Ex. 30 at 12. As of the filing of this action, Erika continues to suffer from a developmental and speech-and-language disorder and requires therapy. Pet. Ex. 15-19.

Petitioner's Expert

Petitioner filed two expert reports of J. Ben Renfroe, M.D., the President and Founder of the Child Neurology Center of Northwest Florida. Pet. Ex. 23, 23A and 24. Dr. Renfroe is a board-certified pediatric neurologist. In his first expert report, Dr. Renfroe stated that in his opinion, the administration of the DTaP vaccination on Sept. 22, 2000 "was a substantial contributing factor in the onset of [Erika's] seizure disorder and subsequent developmental delay." Pet. Ex. 23 at 2. Dr. Renfroe explained:

> Pertussis is a known neurotoxin and is acknowledged to cause seizures. With the advent of acellular Pertussis, the number of seizures associated with the immunization have decreased significantly. However, seizures continue to occur albeit at a much lower rate.

Id.

The report was accompanied by a six-year study of the Canadian Pediatric Society by Nicole Le Saux, MD, et al., Decrease in Hospital Admissions for Febrile Seizures and Reports of Hypotonic-Hyporesponsive Episodes Presenting to Hospital Emergency Departments Since Switching to Acellular Pertussis Vaccine in Canada: A Report from IMPACT.[6] 112(5) Pediatrics, (Nov. 2003) (IMPACT). Pet. Ex. 23A. This study noted a seventy-nine percent reduction in febrile seizures from pertussis vaccination since the introduction of acellular pertussis or DTaP vaccinations as opposed to whole-cell pertussis vaccinations. Id. The IMPACT Study stated:

> There were 218 reports of seizures that met the case definitions for inclusion

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[6] IMPACT is the Immunization Monitoring Program -- Active of the Canadian Pediatric Society, a Canadian surveillance program that actively documents severe vaccine-associated adverse events in children who are admitted to pediatric tertiary care hospitals. Pet. Ex. 23A at e349. In 1995, participating hospitals represented nearly 90% of the nation's pediatric tertiary care beds. Targets of surveillance included postimmunization. Id. From 1995 to 1996, all Canadian provinces used the same whole-cell pertussis-based combination vaccine (Penta, Aventis Pasteur, Toronto, Ontario, Canada). During 1997, all switched to the same acellular pertussis-based combination vaccine (Pentacel, Aventis Pasteur). Id.

> in this report . . . .[7] There were 50 reports of hospitalization for febrile seizures after a pertussis-containing vaccine. Of these, 27 (54%) children were <12 months, 21 (42%) were 12 to 24 months, and 2 (4%) were 4 to 6 years of age. Forty-three (86%) children had onset of seizure within 24 hours, 3 (6%) between 24 and 48 hours, and 4 (8%) between 48 and 72 hours after immunization. Within this group, 4 children had concurrently received pertussis and MMR vaccine, but because seizures occurred within 72 hours, they are included in this analysis. Echovirus 7 meningitis was documented in 1 case, and 1 child had influenza A.
>
> The average number of reports per month of febrile seizures after a pertussis-containing vaccine decreased from 1.21 for 1995-1996 to 0.25 for 1998-2001 (P = .0000084), a 79% decrease between periods (Fig. 1).

Pet. Ex. 23A at e349-50.

In response to an Order of the Special Master,[8] on May 10, 2004, Petitioner submitted Dr. Renfroe's supplemental opinion, in which he stated:

> You have asked me to supplement my letter to you of December 23, 2003. Specifically, you have asked me whether, in my opinion, Erika suffered an on-Table encephalopathy or, in the alternative, whether her illness was in fact caused by her DTaP vaccine . . .
>
> [A]fter Erika's acute episode, manifested by her seizures of September 23 and September 24, 2000, she did outwardly return to "a normal neurologic state." Therefore, she does not fit the strict definition of "Chronic Encephalopathy' in the Vaccine Table's Qualifications and Aids to Interpretation. However, it remains my opinion that Erika's present chronic intractable seizures and global developmental delay were in fact caused by her DTaP vaccine of September 22, 2000. My opinion is based upon several factors. First, there is a strong temporal relationship between the DTaP vaccine and the onset of Erika's seizures, which occurred within 24 hours of receipt of the vaccine. Next, pertussis is a known neurotoxin and is acknowledged to cause seizures. Although the acellular DTaP vaccine is

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[7] Active surveillance was performed between 1995 and 2001 by IMPACT monitors at 12 hospitals using standard case definitions. Seizures had to occur within 72 hours after immunization with a pertussis-containing vaccine. Pet. Ex. 23A.

[8] On April 6, 2004, the Special Master ordered petitioner to "amend his expert's report to provide a mechanism and a scientific or medical explanation for the onset of Erika's injuries or the significant aggravation of a preexisting condition, if such is the case." April 6, 2004 Order.

> safer than the whole cell DPT vaccine, seizures do rarely occur. *See*, Jackson, LA, Carste, BA, Malais D, Froeschle J, Retrospective population-based assessment of medically attended injection site reactions, seizures, allergic responses and febrile episodes after acellular pertussis vaccine combined with diphtheria and tetanus toxoids. Pediatr Infect. Dis. J. 2002 Aug: 21(8): 781-6. (Jackson Study).

Pet. Ex. 25.

The Jackson Study referenced by Dr. Renfroe was conducted between January 1997 and December 2000. Pet. Ex. 25A. That study tracked 76,133 doses of the DTaP vaccine administered to children at Group Health Cooperative, a health maintenance organization in the state of Washington. While the study concluded that the febrile seizures following administration of the acellular pertussis were substantially less frequent than febrile seizures which accompanied whole cell pertussis, there were some episodes, but none involved sequella. Specifically, the Jackson Study reported:

> Seven children with seizures within 7 days of DTaP vaccination were identified. All were younger than two years of age, and none had a prior history of seizures. Six had febrile seizures, three occurred within 2 days of vaccination and one of those required hospitalization. The rate of febrile seizures within 2 days of DTaP vaccination among children <2 years of age was 1 per 19,496 vaccinations. On follow-up none of those 6 children had neurologic abnormalities or subsequent afebrile seizures documented. 2 had recurrent febrile seizures that were not associated with the DTaP vaccine.

Pet. Ex. 25 at 784.[9] The study concluded that the DTaP was exponentially safer that the whole-cell vaccine. One child in 19,496 suffered a seizure within two days of DTaP vaccination whereas one child in 2,835 suffered a seizure within two days of the whole cellular vaccination.

On July 13, 2004, Petitioner filed three additional medical articles in support of his claim: (1) R. Alderslad, et al., The National Childhood and Encephalopathy: Whooping Cough, Reports from the Committee on Safety of Medicines and the Joint Committee on Vaccination and Immunization, (NCES I) (1981), Pet. Ex. 26; (2) Nicola Madge, et al., The National Childhood Encephalopathy Study: A 10-Year Follow-up. A Report on the Medical, Social, Behavioral and Educational Outcomes After Serious, Acute, Neurological Illness in Early Childhood (July 1993) (NCES II), Pet. Ex. 27; and (3) David Miller, et al., Pertussis Immunization and Serious Acute

[9] On April 14, 2005, the Special Master issued an order requesting further briefing from the parties on the issue of whether Erika's seizure event on the day after her DTaP fit the parameters of the Le Saux and Jackson studies submitted by Petitioner's expert witness. See April 14, 2005, Order. The parties submitted their briefs on May 2, 2005.

Neurological Illnesses in Children (1993). Pet. Ex. 28.[10]

These studies all dealt with whole cell pertussis and the neurological risks associated with whole cell pertussis vaccination. NCES I reported on the United Kingdom's National Childhood Encephalopathy Study which was set up in 1976 because of widespread public and professional concern over the safety of pertussis immunization. The article was published in 1981, 16 years before DTaP was introduced and only addressed the whole cellular vaccine. This study concluded that administering a pertussis vaccine in combination with diphtheria and tetanus immunizations, elevates the risk of neurological complications when compared to simply administering diphtheria and tetanus immunizations by themselves. Specifically, the NCES I study stated: "On the balance of available evidence, DPT vaccine probably can cause acute neurological reactions. However, these are very rare events, and few children appear to have suffered permanent damage as a result." Id. at 141.

The second and third articles on which Petitioner relies report on the ten-year follow-up studies to the NCES. Pet. Ex. 27 and 28. The follow-up studies confirmed the findings of the original NCES, specifically, that DTP vaccine can cause acute neurological reactions. Id. However, these studies did not address the DTaP vaccine, which was not introduced until 1997. The third study further concluded that the DPT "may on rare occasions be associated with the development of severe acute neurological illnesses that can have serious sequella." Pet. Ex. 28 at 1171.

Respondent's Expert

Respondent's expert, Russell D. Snyder, M.D., a board-certified pediatric neurologist and Professor of Neurology and Pediatrics at the University of New Mexico, submitted two reports. In his first report of March 14, 2004, Dr. Snyder characterized the DTaP as "a form of pertussis immunization associated with a very low rate of seizures." Resp. Ex. A. Dr. Snyder concluded that "a Table injury did not occur," in that the criteria for acute and chronic encephalopathy were not met. Resp. Ex. A. In his second report of May 2, 2005, Dr. Snyder concluded:

> DTaP does not directly cause seizures. The immunization can occasionally produce a febrile seizure secondary to a temperature elevation. It was the fever which triggered the seizure in this individual who was subsequently shown to be predisposed to seizures and presumably had a decreased seizure threshold at the time of her immunization.

Resp. to Apr. 14, 2005 Order, Ex. E. Dr. Snyder suggested an alternative etiology for Erika's condition, i.e., benign external hydrocephalus, but the Special Master rejected this. Resp. Ex. A.

[10] On August 12, 2004, the Special Master ordered the petitioner to file a brief explaining his reliance on the additional exhibits. See August 12, 2004, Order. On August 17, 2004, Petitioner filed the brief, and on September 13, 2004, Respondent filed its response to Petitioner's brief.

The Special Master's Decision

The Special Master found that "it certainly appears that Erika's initial seizure on 23 September 2000 fits the classic scenario of a febrile seizure which may have been induced by a pertussis vaccination." Dec. at 4. Nevertheless, he concluded that the medical records identified a "possible alternative cause," an upper respiratory infection, citing handwritten notes of the treating emergency room physician on the day after Erika's initial seizure. These notes stated: "six-month [status post] DPT [injection] (3rd shot) one day prior to onset of seizures + URI + low grade fever prior to seizure." Pet. Ex. 6 at 14. The plus signs in the notes were circled. Id. The Special Master interpreted these notes to mean that Erika "presented with an upper respiratory infection 24-48 hours antecedent to her first seizure event." Dec. at 4.[11] The Special Master cited three subsequent seizures which were preceded by illness and fever, either an upper respiratory infection or a cough, and concluded: "Each of Erika's initial seizures are associated with antecedent illness and fever. This pattern is the same in the first seizure as it is nearly every subsequent seizure." Id.

The Special Master concluded that while "Petitioner has proffered both a scientific temporal relationship and a credible medical theory that sets out a logical sequence of cause and effect between the vaccination and Erika's seizure event," the Petitioner "has not successfully eliminated all reasonable alternative causes as identified in the medical records." Dec. at 4. Rather, the Special Master determined it was "possible" that Erika's fever on September 23, 2000, was related either to the upper respiratory infection or the vaccination or to some combination. No expert testimony tied the URI to Erika's fever or to the DTaP vaccination.

The Special Master rejected Respondent's expert's opinion, suggesting benign external hydrocephalus as an alternate etiology for Erika's condition, noting that hydrocephalus is typically seen in children with large or rapidly growing heads and usually resolves itself by the time a child is two years old. Further, the Special Master reasoned: "[M]oreover, neither Erika's treating physician nor her neurologist attributed her condition to external hydrocephalus." Dec. at 8, n.4. The Special Master also concluded that Dr. Renfroe's report and documentation militated against this cause, and noted that even though Erika saw numerous doctors, external hydrocephalus "never made the differential diagnosis list." Id.

Because of his conclusion that the URI had possibly caused Erika's initial seizure event and that three of her subsequent seizures were preceded by illness and fever, the Special Master concluded that the Petitioner had not proven by a preponderance of the evidence that the seizure would have occurred but for the vaccination.

The Special Master did not end his analysis there, stating that even if he had found to the contrary, "it does not immediately follow that the initial seizure event [was] responsible for Erika's

[11] Erika had received the DTaP within 24 hours before her seizure. By construing the note to mean Erika had the URI 24-48 hours prior to the seizure, the Special Master found that Erika had the URI at the time she received the DTaP.

subsequent seizures and resultant developmental delay." Dec. at 4. Although acknowledging that Petitioner's expert had opined that the DTaP vaccine was a substantial and contributing factor to Erika's present chronic intractable seizures and global developmental delay, the Special Master stated that it was not "entirely clear how that opinion [was] derived." Id. at 5. The Special Master determined that Petitioner had not met his burden of proving a causal link between the initial seizure and alleged sequella by a preponderance of the evidence. In so concluding, the Special Master found that Petitioner's expert opinion was purely subjective and insufficiently supported by the proffered medical literature. Id. The Special Master noted that the Jackson Study on which Petitioner's expert relied, "support[ed] the proposition that DTaP may rarely be associated with a febrile seizure," but "in no way demonstrates that DTaP is associated with permanent brain damage." Dec. at 5; Pet. Ex. 25A. The Special Master found the NCES studies did nothing to prove that Erika's injuries were caused by pertussis vaccination because they focused on recipients of the whole-cell pertussis vaccine.

Discussion

Jurisdiction and Standards of Review

Jurisdiction lies in this Court pursuant to 42 U.S.C. § 300aa-12(e). Upon review of a vaccine compensation decision rendered by the Special Master, this Court is empowered by Congress to (1) uphold the findings of fact and conclusions of law sustaining the decision of the Special Master; (2) set aside the Special Master's finding of fact or conclusion of law "found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;" or (3) "remand the petition to the Special Master for further action in accordance with the court's direction." 42 U.S.C. § 300aa-12(e)(2)(A)-(C); Althen v. Sec'y of HHS, 418 F.3d 1274, 1277 (Fed. Cir. 2005); Saunders v. Sec'y of HHS, 25 F.3d 1031, 1033 (Fed. Cir. 1994). Findings of fact of the Special Master are reviewed under the arbitrary and capricious standard, and legal questions, under the "not-in-accordance-with-law" standard. Saunders, 25 F.3d at 1033 (quoting Munn v. Sec'y of HHS, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)). The Court of Federal Claims must uphold a special master's findings unless the court concludes that those findings are arbitrary or capricious. See 42 U.S.C. § 300aa-12(e)(2)(B); see also Munn, 970 F.2d at 870 & n.10 (noting that the arbitrary and capricious standard is "well understood to be the most deferential possible"). Reversible error is "extremely difficult to demonstrate" if the special master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision." Hines v. Sec'y of HHS, 940 F.2d 1518, 1527 (Fed. Cir. 1991). As the Federal Circuit recognized, "it is not . . . the role of [a] court [reviewing a special master decision] to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence." Lampe v. Sec'y of HHS, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (citing Munn, 970 F.2d at 871). Nor should this Court "examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder." Id.

A decision is arbitrary and capricious if it relied on factors which Congress has not intended, entirely failed to consider an important aspect of the problem, offered an explanation for its decision

that runs counter to the evidence, or is so implausible that it could not be ascribed to a difference in view or the product of the special master's expertise. Motor Vehicle Mfrs. Assn. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); Hines, 940 F.2d at 1527.

Elements and Burden of Proof

Recovery under the Vaccine Act may be established in one of two ways. Causation of injury due to a vaccine is presumed if petitioner supports, with medical records or expert testimony, a claim of an injury listed on the Vaccine Injury Table (Table), 42 U.S.C. § 300aa-14(a), and shows by a preponderance of the evidence that the injury occurred within the time period described by the Table. 42 U.S.C. § 300aa-13(a)(1)(A).

A second method of recovery is to show actual causation. This method requires a petitioner to prove by a preponderance of evidence that a vaccine caused the alleged injury. Compensation for non-Table injuries is authorized under 42 U.S.C. § 300aa-11(c)(1), and includes any "illness, disability, injury, or condition" not listed on the Table, or not meeting the Table's requirements. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I)-(II).

Causation in fact is established under a traditional tort analysis. See Althen v. Sec'y of HHS, 58 Fed. Cl. 270, 280 (2003) aff'd, 418 F.3d 1274 (Fed. Cir. 2005). To prevail, a petitioner must prove by a preponderance of the evidence that the vaccination caused her malady. Petitioner may recover if he shows "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Althen, 418 F.3d at 1278, quoting Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999). To recover, scientific certainty that a vaccination caused an injury is not required. Bunting v. Sec'y of HHS, 931 F.2d 867, 873 (Fed. Cir. 1991).

As the Federal Circuit recently articulated in Althen:

> Concisely stated, [petitioner's] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury. If [petitioner] satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine."

418 F.3d at 1278, 1282; accord Shyface, 165 F.3d at 1353; see generally, 42 U.S.C. § 300aa-13(a).

The Evidence Does Not Support the Special Master's Finding of An Alternative Cause for Erika's Initial Seizure

Because the Special Master's decision in this case preceded the Federal Circuit's decision in Althen, the Special Master necessarily employed a different analytical framework than Althen's three-pronged test. In particular, the Special Master separated the causation-in-fact analysis into two inquiries: (1) can the vaccine cause the injury alleged, and (2) did it do so in this particular instance? Dec. at 2. The Special Master, noting that both Petitioner's and Respondent's experts opined that DTaP can produce a febrile seizure secondary to a temperature elevation, found that his first inquiry was met, i.e., that DTaP can cause a seizure. Id. at 3. With respect to whether the vaccine did cause the injury here, the Special Master, concluded "it certainly appears that Erika's initial seizure on 23 September 2000 fits the classic scenario of a febrile seizure which may have been induced by a pertussis vaccination." Id. at 3. The Special Master continued: "According to the literature presented and the Vaccine Table itself, the temporal proximity of a seizure within 72 hours of receiving a pertussis vaccine is what a medical professional might expect." Id. at 3-4.

Up to that point, the Special Master's decision was fully supported by the evidence of record and substantively, if not literally, comported with the three-pronged test later articulated in Althen. The Special Master's decision, however, ran counter to the evidence when he further determined: "[T]he medical records identify a possible alternative cause. Erika presented with an upper respiratory infection 24-48 hours antecedent to her first seizure event." Id. at 4; Pet. Ex. 6 at 14. Placing the URI 24-48 hours prior to the seizure was significant because it meant that Erika had the URI at the time she received the DTaP vaccine. In reaching this determination, the Special Master relied on one page of hand-written shorthand notes, taken by a treating physician in the emergency room on September 24, 2000, twenty-four hours after Erika's initial seizure. This record states in pertinent part:

> A:[12] SP [status post] resp[iratory] failure SP [status post] extubation, complex febrile seizures: 6-month SP [status post] DPT in[jection] (3rd shot) 1 day prior to onset of seizures + [13] URI +[14] low grade fever prior to seizure which started as [illegible] generalization as per the description of seizures by parents [illegible] febrile seizures.

Pet. Ex. 6 at 14.[15]

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[12] This "A" means assessment. Tr. at 29.

[13] This "+" is circled in the notes. Pet. Ex. 6 at 14.

[14] This "+" is also circled in the notes. Pet. Ex. 6 at 14.

[15] These have been described as the physician's progress notes of the emergency room physician in the Jersey City Medical Center. Tr. at 28.

Petitioner interprets the circled plus sign to mean "positive," i.e., that Erika was evidencing the upper respiratory infection at the time of her examination by the emergency room physician on September 24, two days after the vaccine and one day after the seizure, but not at the time of her vaccine.[16] Tr. at 11-12. Petitioner's interpretation of these notes would square with the other evidence of record. Erika received the DTaP during a "wellness visit," and there is no mention in any other record that Erika had either a fever or a URI at the time the DTaP was administered. Petitioner asserts that the Special Master mischaracterized the evidence, arguing:

> PETITIONER'S COUNSEL: And then there was the explanation by the Special Master, the explanation that he had decided defeated Erika's claim. And that is to be found that URI was the actual cause of the fever that caused the seizure, the initial seizure rather than the DPT shot. . . . [W]e take great dispute with that finding by the Special Master. It is really the heart of our appeal. There was no evidence in the record that she had a URI on the day she received the vaccine, or on the day that she had her seizure.
>
> THE COURT: Well, how did he figure that out, then?
>
> PETITIONER'S COUNSEL: I can only speculate; you'd have to ask the Special Master. But we have looked at it long and hard, and we believe that there was a plus sign in the record, which [he] interpreted as meaning plus, that she had a fever plus a URI plus a seizure. But plus circled in the medical sense does not mean plus; it means positive. They found positive symptoms of a URI, but two days after the vaccine, the day after the seizure.

Tr. at 9. The Special Master did not conduct an evidentiary hearing or obtain clarification of this medical record.[17]

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[16] According to counsel for Petitioner, "plus circled" in the medical sense does not mean plus; it means positive. Tr. at 9.

[17] In response to a question by this Court, Petitioner's counsel explained why he chose to present his case on the written record without an evidentiary hearing.

> THE COURT: Why did you make that election in this case?

According to Petitioner's counsel, Erika was perfectly well at the time she received the DTaP or she would not have been given the vaccine. Tr. at 11. Petitioner's counsel continued:

> You're talking about a URI competing with a known neurotoxin, pertussis. You're talking about a Special Master who made this finding, and he's the only one who did. None of the treating doctors made this finding, neither of the experts made this finding. . . . In the literature, the NCES that we submitted, it shows that URIs frequently accompany seizures after a pertussis vaccine. It's expected, just when it happened. But to implicate it as the culprit, to make it the cause of the seizure, is just wrong, regardless of when it occurred. But the evidence in this case is that it occurred after the seizure, not before.

Tr. at 12.

In contrast, Defendant's counsel contends that the Special Master's reading of the record was plausible. Specifically, Respondent contends "it's not implausible that the [September 24] record is indicating a positive URI, positive low grade fever prior to the seizure." Tr. at 32. However, in a colloquy with the Court, counsel for Respondent admitted that the medical record of Erika's "wellness visit" when she received the DTaP made no mention of a URI:

> The Court: So what about on the date of September 22 itself? What does that record, which is the contemporaneous record, tell us?
>
> [Government Counsel]: That contemporaneous record does not indicate that the child had an upper respiratory infection at that time.

> MR. CONWAY: Because we believed that we had all the elements we needed to make a prima facie case, because there was no alternate cause.
>
> We had the medical records with the statements from the doctors attributing the vaccines to the seizures. We had the expert filed opinion of Dr. Renfroe, even though he didn't testify. We had all the literature. We had good case law.
>
> . . . we felt that we had shifted the burden, and that the Respondent would not be able to meet its burden of showing a likely alternate cause. The vaccine program is supposed to be expeditious. We have a child here in desperate need of services that the vaccine program should be providing for her. We didn't see any reason to wait any longer when our case was so strong.

Tr. at 20.

Tr. at 29-30.

There is no contemporaneous evidence that Erika was suffering from either a fever or an upper respiratory infection at the time the DTaP was administered, or 24-48 hours prior to her seizure as the Special Master concluded. The Special Master's reading of the September 24 Emergency Room record to mean that Erika had a URI 24-48 hours in advance of the seizure is factually erroneous. The Special Master's resultant theory that the URI itself may have caused the seizure is unsupported by the evidence and expert testimony.

The Special Master Misapplied the Burden of Proof

In concluding that Petitioner failed to prove that he eliminated the URI as a possible cause of Erika's injury as part of his prima facie case, the Special Master misapplied the burden of proof set out in the Vaccine Act. The Vaccine Act provides that for the Special Master to determine entitlement to compensation, he must find that, based on the record as a whole:

> (A) . . . the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition . . . ,
>
> (B) there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

42 U.S.C. § 300aa-13(a)(1).

Judge Bruggink explained the burden shifting and interplay between parts A and B of Section 300aa-13(a)(1) in Wagner v. Sec'y of HHS, 37 Fed. Cl. 134, 138-39 (1997):

> The fact of a single inquiry "on the record as a whole" by the Special Master does not mean that the burden is on the petitioner to prove both part (A) and part (B) of section 300aa-13(a)(1). Once the petitioner puts on a prima facie case of causation, the burden shifts to the Government to put on evidence, under part (B), of an "unrelated factor." Part (B) thus acts essentially as a defense for the Government in these cases. See O'Connor v. Secretary of Dep't of Health and Human Servs., 24 Cl. Ct. 428, 429-30 n.2 (1991), aff'd, 975 F.2d 868 (Fed. Cir. 1992) (respondent has the burden under 42 U.S.C. § 300aa-13(a)(1)(B) to show "an actual alternative cause."); McClendon v. Secretary of Dep't of Health and Human Servs., 24 Cl. Ct. 329, 333 (1991), aff'd, 41 F.3d 1521 (1994) (the Vaccine Act "implicitly places the onus of proving the existence of an alleged alternative cause squarely on the shoulders of the respondent") (citing Matthews v. Secretary of Dep't of Health and Human Servs., 18 Cl. Ct. 514, 518-19 (1989). Placing that burden on the petitioner would require the petitioner to affirmatively prove that an

> infinite number of potential causes were not at work causing the injuries suffered. There is no foreseeable end to the burden that would be placed on the petitioners under such a statutory interpretation. The statutory language and the purpose of the Vaccine Act do not anticipate or support such a construction.

This does not mean that a petitioner can establish a prima facie case that an injury was caused by a vaccine without addressing another potential cause of the injury evident in the record. If a potential alternative cause is identified in the medical record, petitioner must demonstrate that the vaccine was likely a substantial cause of the injury. As Judge Block explained in Pafford v. Sec'y of HHS, 64 Fed. Cl. 19 (2005), appeal filed, Fed. Cir. 05-5106 (Apr. 13, 2005):

> the overwhelming weight of authority in this Circuit is consistent with traditional notions of tort law that place an initial burden of proof regarding alternative causation on the petitioner--not as part of the § 300aa-13(a)(1)(B) "factor unrelated" test, but rather as part of establishing a prima facie case of causation-in-fact. Consistent with the Federal Circuit's instructions, . . . that an actual-causation vaccine petitioner "must prove by a preponderance of the evidence that the vaccine, and not some other agent, was the actual cause of the injury," Munn, 970 F.2d at 865 (emphasis added), the attendant burden of proof in an actual causation case subsumes the obligation to successfully eliminate potential alternative causes of the alleged injury that have been identified in the record. This is so because, in proving that the vaccine is the actual cause of the alleged harm, the petitioner bears the burden of proving that the vaccine was both the "but for" cause as well as a "substantial factor" of the harm.

Pafford, 64 Fed. Cl. at 35 (emphasis added in part). Here, however, there was no plausible alternative potential cause of injury identified in the record or suggested by any party or expert.[18] The URI that the Special Master sua sponte characterized as an alternative cause was not supported by the medical records or expert opinion.

In Althen, the Federal Circuit reiterated that if a petitioner provides "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury and (3) a showing of a proximate temporal relationship between vaccination and injury," he is "entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." 418 F.3d at 1278. Here, as the Special Master recognized, Petitioner showed that the DTaP vaccine can cause seizures and that there was a proximate temporal relationship -- just 24

[18] The Special Master found a pattern in Erika's subsequent seizures consistent with his characterization of her first seizure, i.e., that they were accompanied by fever and illness, but the record shows that Erika also suffered from subsequent afebrile seizures. Pet. Ex. 12 at 1-3.

hours -- between the vaccine and Erika's initial seizure. Further, Petitioner demonstrated a logical sequence of cause and effect showing that the vaccine caused that seizure because Erika was a well baby when she received the vaccine, and the medical records could not plausibly be interpreted to identify an alternative cause.

Analysis of the prima facie showing of causation here does not end with the initial seizure but must address the sequella -- the continuing seizures and Erika's permanent neurological disorder and profound developmental delay. The Special Master determined that even if he were to find that the DTaP vaccination was responsible for Erika's initial febrile seizure and hospitalization, Petitioner's expert report and supporting medical articles were insufficient to establish by a preponderance of the evidence that Erika's subsequent seizure disorder and developmental delay were the "residual effect or complication of the first seizure." Dec. at 8. The Federal Circuit's recent analysis of medical literature in Althen bears on this determination as well.

In Althen, the Federal Circuit affirmed the Court of Federal Claims' reversal of a Special Master's decision for impermissibly requiring peer-reviewed medical literature linking the vaccine to petitioner's injuries. The Court in Althen expressly addressed a petitioner's burden with respect to medical literature, and struck down two of the requirements for causation in fact a Special Master had established in Stevens v. Sec'y of HHS, 99-594v, 2001 WL387418 (Fed. Cl. 2001). 418 F.3d at 1280. First, the Federal Circuit declared the Stevens requirement that "confirmation of medical plausibility from the medical community in literature" was contrary to law and contravened the plain language of the statute. The Federal Circuit explained:

> by requiring medical literature, [Prong 2 of Stevens] it contravenes section 300aa-13-(a)(1)'s allowance that a medical opinion is proof. This 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 injured claimants.

418 F.3d at 1280.

The Althen Court also vacated the third prong of the Stevens test, requiring an injury to be "recognized by the medical plausibility evidence and literature," stating:

> If the Vaccine Act does not require Althen to prove medical documentation of plausibility, then it cannot require her to demonstrate that her specific injury is recognized by said medical documentation of plausibility.

418 F.3d at 1281.

The Althen Court further noted: "While this case involves the possible link between TT vaccination and central nervous system injury, a sequence hitherto unproven in medicine, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field

bereft of complete and direct proof of how vaccines affect the human body." Id. at 1280. (emphasis added). In light of the recency of substituting acellular pertussis in the DTaP vaccine for the whole cellular pertussis in the DTP vaccine, and the dearth of medical literature on how this safer neurotoxin affects the human body, the Special Master on remand, should consider the explicit instructions of the Federal Circuit that neither medical literature nor medical documentation of plausibility of the specific injury is required to show causation.

In the event that the Special Master determines on remand that Petitioner has established a prima facie case of causation as to Erika's permanent neurological disorder -- the initial seizure and the sequella, the burden of proving that a factor unrelated to the vaccine was "principally responsible" for the injury must be shifted to the government.

The Vaccine Act expressly defines "factors unrelated to the administration of the vaccine" as:

> **(A)** [do] not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and
>
> **(B)** may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition or death.

42 U.S.C. § 300aa-13(a)(2). Thus, under the statute, not only must the Government prove that a factor unrelated to the administration of the vaccine caused the injury by a preponderance of the evidence, it must prove that the factor unrelated to the vaccine is shown to have been the agent or agents "principally responsible" for causing the petitioner's injury. See Shyface, 165 F.3d at 1352-53 (If petitioner shows that the vaccine was a "substantial factor" in causing the injury, the burden shifts to the Secretary to prove "that factors unrelated to the vaccine were principally responsible for [the injury]"); Pafford, 64 Fed. Cl. at 36 (once petitioner proves that the vaccine and not other factors evidenced in the record caused injury, the burden shifts to the Government to prove factors unrelated to the vaccine caused the injury). As the Federal Circuit recognized in Shyface:

> The legislative history of 300aa-13, the provision relating to the Secretary's rebuttal of a prima facie case . . . reaffirms the burden on the Secretary. In its determination that the injury was not caused by factors unrelated to the vaccine, the Court may rely on evidence of other infections, traumas, or conditions but is not to include speculative or hypothetical matters or explanations. If the injury is not demonstrated to have been caused by other, defined illnesses or factors and the injury is demonstrated to have met the other requirements of Section 2111 [codified at 300aa-11] and the Table, the injury is to be deemed to be vaccine related. The Committee recognizes that

> there is a public debate over the incidence of illnesses that coincidently occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related.

165 F.3d at 1351 (emphasis in original) (citation omitted).

Conclusion

It is **ORDERED** that:

1. The Special Master's June 9, 2005 decision denying Petitioner's entitlement to compensation is set aside.

2. The matter is hereby remanded to the Special Master pursuant to 42 U.S.C. § 300aa-12(e)(2)(C). On remand, the Special Master is instructed to reevaluate the medical record of September 24, 2000, in light of the other evidence of record, consider the expert testimony and supporting medical literature proffered by the parties in light of the standards set forth in Althen, 418 F.3d 1274, and apply the burden of proof set out in 42 U.S.C. § 300aa-13.

3. The Special Master shall issue his decision on remand within 90 days. 42 U.S.C. § 300aa-12(e)(2).

4. The Clerk shall not disclose this decision publicly for 14 days. RCFC, Appendix B, Rule 18(b)(2).

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MARY ELLEN COSTER WILLIAMS
Judge